State of Kuwait
Series of Publications of
Islamic Organization For Medical Sciences
Islam and Recent Medical Problems

The International Islamic Code for Medical and Health Ethics

December 11 - 14, 2004
29 Shawwal - 2 zu alkaida
Cairo, Egypt

Supervised by
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In The Name of God,
The Most Compassionate,
The Most Merciful

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Dr. Abdul Rahman A. Al-Awadi

President,
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FOREWORD

Dr. Abdul Rahman Al-Awadi
President,
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Progress in science, especially medicine, has been tremendous. The medical profession has come to be held in high esteem; indeed higher than any other human profession, as physicians are looked upon as God's way of showing mercy to those afflicted, either physically or mentally by a visitation of ill health. Such people are in dire need of whatever alleviates their pain and enhances their hopes of recovery. They also need words that strengthen their faith in God; words that remind them that their affliction, like any thing else in this universe, is preordained.

On the other hand, medical sciences have successfully done away with many epidemics that used to wreak havoc on whole nations. Now such diseases are a thing of the past; thanks to vaccines, inoculation, and antibiotics that are produced in huge quantities to cover the needs of an increasing world population. Medicine has also achieved impressive results in innovating treatments for several types of hard-to-cure diseases. The use of several state-of-the-art medical instruments and equipments has led to finding out a lot more about pathogens and ways of overcoming the resulting disorders. The twenty first century will witness more and more applications of the theories that were developed by medical scientists during the twentieth century.

But the question is: have all these feats of success brought happiness to mankind? Unfortunately, the twentieth century saw certain behaviors by some workers in the medical field that fly in the face of morality. Such misdeeds constitute a deviation from the lofty principles of the medical profession.

Although deviation is a recognized human trait best known for its major role in the conflict between good and evil; and despite the fact that it is not confined to any particular race, nation, generation, or profession, the twentieth century witnessed such a remarkable rise in deviant thoughts and attitudes that moralists worldwide have banded together to stand up to any such conduct and to lay down a legal and ethical frame of reference that spells out in the clearest terms the normal and acceptable ways of administering medical services. Any departure from that clear line of ethical behaviour should be considered punishable deviation. This matter requires immediate attention as a patient receiving health services has now to deal not only with his physician but also with a large number of people with varied duties in the domain of medical care. Some of these workers have confused ideas about duties and rights and carry out their tasks with irresponsible negligence and/or dishonest designs, thus tarnishing one of the noblest professions on earth.

Misconduct is not confined to delivery of health services. It has also affected the area of scientific research where man's crave for knowledge is most dominant if left unbridled. Medical scientists have been so enraptured by a chain of discoveries which go beyond their wildest dreams that they have overlooked the sanctity of man who, of all God's creatures has been honoured by responsibility of life on earth. Islam calls upon Muslims to conduct research on whatever universal phenomena they may observe and urges them to look intently into everything surrounding them on earth or in heaven as well as into themselves as long as their findings are employed for the benefit of mankind. Unfortunately, scientific research has lately been heading for areas that could turn out to be disastrous to mankind. It has become essential, therefore, to map out the framework within which researchers may work freely without fear of transcending man's safety and sacred rights. In short, research procedures should be considered from an ethical perspective. This is particularly important in view of certain recent scientific findings and their actual application

to people. The proposed ethical framework for research should lay down general rules for what may or may not be a subject of research and application.

With all the efforts exerted by moralists from all religions and tenets to condemn and curb faulty trends, commercial considerations have become the leading principle in the persistence of such trends. The media are awash with news stories about people being used as guinea pigs for scientific and commercial purposes as well, thus degrading man both physically and psychologically.

Before the ship sinks with all aboard when such serious deviations turn into a phenomenon; before humanity loses its dearest accomplishments to a handful of unscrupulous people who are satanically bent on making money regardless of any human values, the Islamic Organization of Medical Sciences (IOMS) has stood up to that phenomenon since its inception. In 1981, IOMS issued its first document containing recommendations about the rights and duties in the doctor-patient relationship. At the time, the document was considered an important and unique event. The IOMS received a letter form the Vatican expressing Papal blessing for the document. But the IOMS did not stop at that. It has also been watching closely a number of medical innovations submitting each to thorough scrutiny based on Islamic jurisprudence. In a series of meetings that brought together medical scientists and scholars of Islamic jurisprudence each new finding was the subject of a full-scale academic discussion marked by transparency and freedom of speech. The IOMS fight against aberrant trends and behaviours has been enormously enriched by such meetings. The ultimate goal of the IOMS is to revive the Islamic values of commitment to ethical conduct in the field of medical services. These values were tenaciously upheld by doctor, patient, and the whole society when Islamic medicine was predominant in the whole world.

We have compiled the views and analyses reached by the above-mentioned joint meetings. The result is this issue entitled "The Islamic Code for Medical and Health Ethics". We have seen fit to present the workers in the medical domain with these jurisprudent conclusions based on Islamic *Shari'a* concerning medical innovations during the

past two decades. The purpose is to pinpoint the rules that should be followed in order to preserve the dignity of mankind and protect humanity against any abuse of man's body or soul.

The contents of this Code have been carefully arranged into logical sections by a select group of highly qualified researchers so that reference and cross reference is made easy.

The Code has an introduction which delves deeply and comprehensively in Islamic morals and jurisprudent rules that constitute the point of departure in the Code.

Putting the outcome of our efforts safely in your hands, dear reader, we pray that these efforts have been rewarded with modest success. We sincerely hope that you will be critical enough to write to us proposing any remarks, modifications, or even opposing views which will all be taken into account in future editions.

It is my pleasure to acknowledge with appreciation to our brothers in EMRO, ISESCO, CIOMS and Ajman University of Science and Technology Network for their cooperation and partnership of that meeting.

I deeply appreciate the contributions made to this work and pray that each effort put into it, no matter how little, will be rewarded by Allah.

INTRODUCTION

Dr. Ahmed Rajai El-Gendy

Secretary General Assistant,
Islamic Organization for Medical Sciences,
Kuwait

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Dr. Ahmed Rajai El-Gendy
Secretary General Assistant
Islamic Organization for Medical Sciences,
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Issuing the Islamic Code of Medical Ethics is a watershed in the history of the IOMS which has accentuated its prominence not only in the Arab and Islamic world but at the international level as well. The Code is considered a unique document comprising three parts. The first part deals with the behavior prescribed for the medical professionals in addition to their rights and duties. The second part focusses on medical research: its requirements; the areas specified as off limit; and the rights of researchers, patients and the whole society. The third part is about medical innovations.

The Code draws heavily on the Islamic Sharia and keeps in line with its purposes and the interests it serves. It represents a historic development in medical thought. In 1980 when IOMS issued " The Islamic Constitution for Medical Professions" it was a unique event at that time although it confined itself to matters that were of interest then both to IOMS and to world organizations as well. On the international arena the medical researchers did not have then the same status and renown they have now. The only medical accomplishment up to that time was the test-tube baby.

Today, news of major scientific achievements surprise us almost on the hour: organ transplantation, the Human Genome, genetic engineering, and cloning, among others. Some of these achievements are not less exciting than science fiction. Day after day we read about the results of their application to real problems on the ground.

The use of the computer and many other high-tech apparatuses has created a situation where several health care providers participate

in treating a patient. Handling health problems has also grown so sophisticated that they are approached from various angles. The inevitable corollary of all this is that a patient's confidential information circulate now in more than one medical quarter. Therefore, the principle of strict confidentiality of a patient's information vigilantly kept by his/her doctor seems to have become outdated and needs to be reviewed and regulated in light of the new developments in the field of health care. That is exactly what the Islamic Code of Medical Ethics is meant to do. The Code is the end result of very serious and deep discussions by specialized committees in a symposium which required a whole year of preparations. These committees were membered by scholars of Islamic jurisprudence, health care professionals and academic Ethicists. A committee was set up for each of the above mentioned axes of the Code. The first committee responsible for the proper behavior of medical professionals in addition to the rights and duties of physicians was formed of the following members. They worked on a draft paper prepared for the committee by Dr. Ahmed Rajai El-Gendy, the IOMS Secretary General Assistant.

Counselor Abdalla Al Eissa
Dr. Tawfeek Bin Ahmed Khoga
Dr. Osama Raslan
Dr. Mahmoud Al Manawi
Dr. Salah Al Aateqi
Dr. Ali Yousef Al Saif
Dr. Ahmed R. El Gendy
Dr. Yousef Al Nesef
Dr. Fayez Al Kendari
Dr. Fayez Al Zefeery
Dr. Mohamed Al Mesh'aan
Dr. Abdallah Sa'eed Hattab
Dr. Abdallah Al Ghuneim
Dr. Khaled Al Mazkoor
Dr. Mohamed Haytham Al-Khayyat
Dr. Basel Abdul Gabbar
Dr. Gamal Al Garallah
Dr. Ma'moon AL Hajj
Dr. Saleh Rachid Al Ma'mari
Dr. Hamdi Abdellah
Dr. Abdallah Bin Ibrahim Al-Shereef
Dr. Abdallah Al Kendari

After a comprehensive discussion of the draft paper, the committee members eventually agreed on a semi-final form that was to be presented to the symposium.

Concerning the second part of the Code which deals with scientific research, the relevant committee has decided to work on the international document entitled "The World Ethical Guidelines for Biomedical Research Related to Humans: an Islamic Perspective" issued by CIOMS.

The document was translated into Arabic and sent to the Islamic jurisprudent Dr. Nazeeh Hamaad who contributed with writing down the Islamic point of view. It was then referred to Sheikh Mohamed Al Mokhtar Al Salami, Dr. Abdelsattar Abu Ghudda, Dr. Mohamed Maher Hammamy, Dr. Fayez Al Zefeery, Dr. Sa'eed Hattab, Dr. John Briant and Dr. Hossam Fadl for perusal and later on for comments when the symposium was in session.

Professor Saad Eddeen Helal was assigned the task of looking into the third part related to medical innovations and putting it in the accomplished from that was to be presented. It was then sent to His Eminence Dr. Ali Gom'aa, the Grand Mufti of Egypt, Dr. Gamal Abul Suroor, Dr. Gamal Al Garallah, Dr. Sayyid Rachid Hussien and Dr. Mostafa Al-Musawi for opinions and remarks preliminary to debate in the symposium.

The symposium was held in Cairo from Shawal 28 to Zul Ke'da 2, 1425 H. (Dec 11 -14, 2004). Three subcommittees were set up to finalize the formulation of the Code's three parts. The Committee on behavior and the physicians rights and duties was formed of:

Dr. Haytham Mohamed Al Khayyat
Dr. Ahmed R. El-Gendy
Dr. Mohamed Ali Al Barr
Dr. Farahat Mo'azzam
Dr. Tawfeek Bin Ahmed Khoga
Dr. Ajeel Al Nashmi
Dr. Osama Raslan
Dr. Fayez Al Kendari
Dr. Mahmoud Al Manawi

Dr. Mohamed Haytham Al Khayyat undertook the task of revising the whole part, then he put it in the form it assumes now.

The second committee on "The World Ethical Guidelines for Biomedical Research: an Islamic Perspective" was formed from:

Sheikh Mohamed Al Moktar Al Salami
Dr. Nazeeeh Hammaad
Dr. Abdel Sattar Abu Ghuda
Dr. Mohamed Maher Hammami
Dr. Fayez Al Zufeery
Dr. Abdallah Sa'eed Hattab
Dr. Hussam Fadl
Dr. John Briant

The third committee on "Medical Innovations and Related Islamic Juridical Rules" was formed of:

Dr. Ali Gom'aa
Professor Saad Eddeen Helal
Professor Gamal Abu El Surrur
Professor Gamal Al Garallah
Dr. Mostaffa Al Musawi
Dr. Mahmoud Fathallah
Dr. Abdallah Bin Ibrahim Al Shereef

The results reached by all these committees were finally submitted to the Recommendations Committee formed of:

Counselor Abdallah Al Eissa Chairman
Dr. Khaled Al Mazkoor
Dr. Salah Al Ateeki
Dr. Abdelsattar Abu Ghudda
Dr. Mohamed Haytham Al Kayyat
Dr. Saad Eddeen Helal (Rapporteur)
Dr. Abdullah Al Ghuneim
Dr. Ali Yousef Al Saif
Dr. Nazeeh Hammaad
Dr. Hassan Hathut
Dr. Ahmed R. El-Gendy

One of the committee recommendations was to assign the task of writing an introduction to the Code to one of the colleagues. Dr. Ahmed R. El-Gendy undertook the job and submitted the draft introduction to Dr. Abdul Rahman Abdallah Al Awadi, counselor Abdallah Al Eissa and Dr. Abdallah Al Ghuneim for revision.

The IOMS General Secretariat revised the final version of the Code which will hopefully fill up a gap and serve as a frame of reference in this field.

The IOMS Board of Trustees has issued a resolution making it necessary that the contents of the Code should be revisited every two years so that new events or researches anywhere in the world can be appended.

We humbly hope that we have done our job as appropriately as expected and pray God to grant us His gracious acceptance.

We would also like to express our deepest appreciation and gratitude to all those who have contributed to this work hoping it will live up to the purposes it was meant to serve.

INTRODUCTION

The International Islamic Code for Medical and Health Ethics

INTRODUCTION

The International Islamic Code for Medical and Health Ethics

Within the past fifty years, humanity has come a long way in the fields of science and medicine. A lot of far advanced scientific discoveries have been made thanks to which people are enjoying better health as many diseases have either disappeared or become easily curable. The progress has been achieved in both areas of pharmaceuticals and medical equipment. Naturally, people are now happy to live in a world where ferocious attacks of epidemics have been successfully warded off, and where new sophisticated approaches to curing physical ailments have been applied. This has not only saved many lives, but also increased people's lifespan in most developed and many developing countries. Furthermore, the spectacular developments in the field of genetic engineering have raised hopes for unprecedented treatments of what were considered incurable diseases before.

Now, if all this is the bright side of the matter, there has to be a dark side in the form of certain negative aspects when such discoveries are marred by abuse. One is prepared to live with a reasonable proportion of negativeness if it is scientifically inevitable as a natural concomitant and morally acceptable as a necessary price. But negative aspects are totally objectionable when they constitute a serious threat to man's very existence and an obvious deviation from proper scientific methods, especially if the deviation takes place in the application of scientific theories for the purpose of gaining undeserved fame or making unlawful money. Such immoral practices are on the rise now and threaten to reduce people to lab rats without any appropriate rules to govern scientific experimentation. In certain cases, man has come to be looked upon as a storehouse of human spare parts: kidneys, livers, hearts, etc. Deviant application of genetic

engineering theories has even gone so far as to attempt to clone man and toy with human life itself. The world is utterly dismayed to see science, which should be a source of power and happiness, turn into a nightmarish source of grief and misery.

Medicine is one of few sciences that arouse much interest from a moral point of view: people always question the morality of every medical practice and every application of medical discoveries. This may be ascribed to the fact that medicine is closely related to the well-being of man, God's most honoured creatures on earth. Thus interest in the morality of medical practice has been significantly apparent in all civilizations including the Mesopotamian, the Ancient Egyptian, the Greek, and the Islamic.

The most tragic incidence of callous medical practice was in the first half of the twentieth century during World Wars I & II when some German physicians conducted cruel experiments on POWs and detainees. This was revealed in the Nuremberg tribunal in 1946. The interrogations proved that the victims were never informed about any surgical procedures and their approval was never sought. In some of those experiments, poisonous gases were tried on the victims to see how different organs of the body would react to them.

The world woke up to the dreary reality: something had to be done about those atrocities. "The Nuremberg Document" was issued in 1947 specifying a code of ethics that had to be adhered to when conducting research on man.

This was followed by "The Helsinki Declaration" issued by the International Medical Union in 1964. It was revised several times in 1975, 1983, 1989, 1996, and 2000.

Then there was the "Islamic Constitution of Medical Ethics" issued by the Islamic Organization for Medical Sciences (IOMS) in 1982.

There were also the International Guidelines concerning the ethics of bio-medical research including studies on human cases (IOMS/ WHO) 1995 - 2000.

In almost every issue of scientific and medical magazines now there are reports of such immoral practices especially those relating to trying

some new pharmaceutical products on the citizens of poor countries before they are officially approved for human consumption in developed countries.

In view of the blatant violation of human rights in the developing countries mostly populated by Muslims, the IOMS has decided to issue the "Islamic Code of Medical and Health Ethics".

The Code comprises following parts:

1 - Acceptable conduct in delivering medical services; the rights and duties of the doctor.

2 - World guidelines of the ethics of conducting bio-medical research, involving human elements, from an Islamic perspective.

3 - Medical innovations as viewed by Islamic Jurisprudence.

The Code aims to do the following:

Point out the disorder in the moral system and its physical and spiritual criteria. This is particularly important as many theories and principles have emerged, some of which are the product of individual judgment, while others draw on some religions. But the vacuum is still there, especially in the Islamic countries which are privileged by the Quran and the Prophet's Sunnah in addition to the writings of Islamic scholars and thinkers. Thus, an Islamic contribution to the subject of establishing moral rules for scientific research and applications will greatly enrich and enhance this matter on a world scale. The Islamic nation is quite qualified to make this contribution as the subject is in line with the Islamic nature, beliefs, customs, and traditions.

Therefore, it was essential that we bring up the subject, which has been a major point of interest at IOMS since its inception. The organization keeps a close watch of the developments on the scientific arena worldwide with special emphasis on faults or unethical practices that may undermine useful scientific accomplishments. The organization's ultimate goal in this area is to set down a Code based on Islamic Sharia that can light the way for workers in the field of health care.

The Code deals with the following topics:

First: the Code's importance

a - The need to demonstrate the Islamic viewpoint concerning the moral practice of medical service in an attempt to provide guidance to medical conduct at a time when some medical practitioners have drifted away from moral values.

b - The importance of setting up a crystal clear system of values that can be used to evaluate medical conduct and purify it from any disorders.

c - Finding an alternative to the profiteering model that dominates the medical arena.

d - Proposing a mechanism of empowerment that can be resorted to whenever it proves difficult or impossible to access studies relating to incidents and crises in the medical domain.

e - The need for a Muslim doctor to have values that drive him to do his very best in delivering medical service; thus taking his job to higher levels of performance and effectiveness.

f - Pointing up the comprehensive Islamic view of man when dealing with him. This can be done through showing the positive effects this view has in providing medical care.

g - A Code of professional ethics will do away with the negative effects of faulty practices in the medical profession and its relevant activities.

Secondly, the Code's Function:

1 - Underscoring full dedication to the human soul, preserving its dignity and abstaining form any offensive action against it for any reason; then showing how all this is related to man's function in life, which is borne out in the following verse where Allah (SWT) says:

> "Whoso slays a soul not to retaliate for a soul slain, nor for corruption done in
> the land, shall be as if he had slain mankind all together;

and whoso gives life
to a soul shall be as if he had given life to mankind all together."

(*Al* Ma'eda [The Table]: 32)

2 - A doctor treating patients should make a point of emphasizing that it is Allah who is the Healer; for Allah holds the reins of power over heaven and earth and wills everything in the universe. Allah (SWT) says:

"Blessed be He in Whose hand is the Kingdome -He is powerful over
everything-Who created death and life, that He might try you which of you is
fairest in works; and He is the All- Mighty, the All-Forgiving."

(*Al Mulk* [The Kingdome]: 1& 2)

3 - Pointing up the high rank of performance when the practicing doctor keeps in line with the Islamic ways in dealing with his patients.

4 - Drawing attention to the fact that practicing medical treatment is only one of man's activities which is bound, like all others, by the meaning of slavery to Allah. This should constitute a guarantee against any wanton or arrogant behaviour by a doctor.

5 - Explaining the middle course that Islamic legal judgment strikes between ethics and Jurisprudence. Islamic Jurisprudents and fundamentalists have always endeavored to base jurisprudence on ethics and guide ethics through Jurisprudence.

6 - The point should be made clear that, with regard to Jurisprudence, ethics is the law that governs its applications and daily usage. Moral science is not merely an abstract philosophical view of things without a chance of practical use in real situations. It represents the criteria by which human behavior is evaluated and judged.

7 - The gaps in the general laws should be filled by combining legal obligation with moral commitment.

8 - Putting the noble design of Sharia into effect by replacing the materialistic principles and rules that currently govern our life by Islamic legal laws.

9 - Upgrading the Muslim doctor's efficiency by supplying him with an ethical and spiritual set of principles and rules to help him do his utmost in discharging his duties.

The content of the Code pivots on high moral standards that should be elucidated from an Islamic perspective.

The Arabic word for "manners" is *akhlaaq*, the singular of which is *khuluq* or *khulq*. Ibn-Manthour's definition of the word in "Lesan Al-Arab" is "The temper or the natural disposition". It has to do with the inner image of man, i.e. his soul. This is different from *khalq* (creation) which is a description of the outer image of man for which he is not responsible for he has nothing to do with it.

Ibn-Manthour's definition of the Arabic word for "manners" emphasizes that man is rewarded or punished for his deeds which are determined by his inner will because this will is under the control of his mind with which he is distinguished from all other creatures of God.

"Manners", then, are a description of actually occurring deeds or behaviour. They are principles and rules based by each individual on the faith he embraces or the philosophy he adopts in his life. They thus become the criteria he applies to judge things and deeds issuing from him or from others. The basis of judgment lies in the dichotomy of virtue and vice or good and evil. It may be objected that good and evil are relative in different communities and with different people. This can not be more wrong; for good is the desire to elevate values, whereas evil is the opposite act of lowering and impairing them. In a strict sense, then, moral values are man's ascension to the high ideals to sharpen the soul and help it rise above evil drives. Allah (SWT) says:

> "Prosperous is He Who purifies it [the soul] and failed has he who seduces it"
>
> (*Al Shams* [The Sun]: 9&10)

The lofty position occupied by morals in Islam and in human communities is best expressed in the Quran when referring to Prophet Muhammed (PBUH) it says:

"We have not sent thee save as a mercy unto all beings."

(*Al Anbia*' [The Prophets]: 107)

Look also at how Allah describes and praises His Messenger:

"surely thou art upon mighty morality."

(*Al Qalam* [The Pen]: 4)

Lady Aisha also described the manners of the Prophet (PBUH) by saying: "His manners were [a true reflection of] the Quran."

The Prophet himself said about the essence of his message: "I was only sent to bring the moral standards to their completion."

Good manners based on proper criteria represent a decisive factor in the advancement and prosperity of communities and nations, whereas bad manners can lead to deterioration and devastation. Historical evidence shows that morality has always been the main variable in the rise and fall of civilizations. So, moral science has occupied a central position in the history of nations, and a focal point of interest for thinkers and theorists. Each of these has approached the subject in accordance with what he holds to be his true faith. The main task of each of the three major religions is to guide its followers to high moral standards.

At this juncture, we should remember that Islam pays special attention to the individual as he is the nucleus of the family, which in turn is the nucleus of the whole society. This is meant to motivate the individual to do good and to effectively interact with the community in ways that give precedence to altruism over selfishness and collective considerations over narrow individualistic interests. The Quran here says about the true believers:

"And preferring others above themselves even though poverty be their portion"

(*Al Hashr* [The Mustering]: 9)

Allah (SWT) also says:

> "They [the pious] give food, for the love of him, to the needy, the orphan, the captive: we feed only for the face of God; we desire no recompense from you, no thankfulness"
>
> (*Al Insan* [Man]: 8 & 9)

The prophet (PBUH) says: "Your money can not suffice to make people happy, but your good manners can." He also says: " Nothing weighs more in the balance than noble manners." When a man asked the prophet (PBUH) what good manners really meant, he recited from the Quran:

> "Opt for the forgiveness, and bid to what is honorable and turn away from the ignorant."
>
> (*Al A'raaf* [The Heights]: 199)

Noble manners, then, mean that you maintain relations with someone even if he severs them, and give to someone even if he deprives you, and forgive whoever wrongs you. When a man asked the prophet (PBUH): "What's religion?" The answer was "noble manners". And when one of the companions asked the prophet (PBUH) for advice, here is what he heard: "Fear Allah wherever you are; do a good deed in the wake of a bad one so it can be erased; and treat people with nobility and good manners."

Once the prophet (PBUH) was told that a certain woman always fasted by day light and prayed all night yet she was ill-tempered and offended her neighbors. His comment was: "She cannot be counted among the good, and she is destined to Hell".

When the prophet (PBUH) was asked which of the believers was considered the best. He said: "The best-mannered," He also said: "The best-mannered among you are my favourites. They will sit closest to me on the day of final judgment.

Anas reported that the prophet (PBUH) said: "A person may reach the highest rank in the Hereafter thanks to his good manners even though he is mediocre in worship."

The prophet (PBUH) is also reported as saying: "Generosity is the essence of good manners"

Ibn Abbas was once asked: "What is noble-mindedness?". He said: "The answer lies in what Allah (SWT) has clarified in the Quran:

> "To Allah the most noble-minded is he who is most God-fearing"

The query then was: "What is noble descent?" Ibn Abbas replied: "The best-mannered among you are of the noblest descent." He also said: "Every building rises above a solid foundation; and the solid foundation of Islam is a high moral standard."

What constitute a high moral standard?

Ali Ibn Abi Taleb, may God be pleased with him, defined high morals as consisting of three traits: staying away from prohibitions, seeking the permissible, and being generous in supporting one's family.

Imam Ghazali says: "A person may be said to have good *khalq* and *khulq"* (good looking and well-mannered), meaning that he is good both outwardly and inwardly. The outer as well as the inner image may be either ugly or beautiful. The inner soul which perceives through insight is better than the body, which perceives through sight. On this point, Allah (SWT) says:

> "(Remember) as your Lord said to the Angels, "Surely I am creating a mortal of a clay. So when I have molded him and breathed into him of My Spirit, then fall down to him prostrating!"
>
> *(Sad: 71,72)*

This verse draws attention to the fact that the body is linked to earth, but the soul originates in God. In this context, soul and self mean the same thing. A high moral standard, then, is a well-established configuration in the self which is the source of all activities.

The inner self, or soul, consists of four forces: knowledge, wrath, lust and justice. All four must be characterised by goodness for one's manners to be noble.

The force of knowledge, if judged to be good by mental and legal criteria, will breed wisdom which comes at the top of good manners. About wisdom, Allah (SWT) says:

> "He brings (the) Wisdom to whomever He decides; and whoever is brought (the) Wisdom, then he has been brought much charity (i.e., benefit); and in no way does anyone constantly remember except the ones endowed with intellects.
>
> (*Al Baqara* [The Cow]: 269)

As for the forces of wrath and lust, they are good to the extent that their liberty and restraint are under the full control of wisdom, mind and legality. Full liberty or full restraint are the two objectionable extremes; a middle course is preferable.

The force of justice is the main factor in determining the amount of control required of wisdom. Justice has no extremes; it only has an antithesis: one is either just or unjust.

In short, good manners can be identified with faith: bad manners with hypocrisy. The Quran is full of verses that illustrate morality. Likewise, Traditions of the prophet (PBUH) on the subject are too many to mention in this limited space. Some Islamic thinkers summed up the characteristics of a well-mannered person as follows:

He tends more towards bashfulness and humility and less towards hostility, he is righteous and pious. When he talks he tells only the truth; he is short on words but long on action; he seldom slips into error or pries into people's affairs; he is reverent and devoted, friendly and communicative, dignified and patient; he is grateful and content, mild-tempered and tolerant, tender and chaste, compassionate and affectionate. He does not swear, insult, gossip or slander; he is not impatient, rancorous, parsimonious or envious; he displays a friendly mien and wears a cheerful smile. In loving, approving or getting exasperated, he only seeks God's pleasure.

Fundamental Components of Morality in Islam

Imam Ghazali says: "The main constituent factors of morality are: 1) wisdom, 2) courage, 3) chastity, 4) justice. Any other factors are only ramifications of these.

About the objectives of the prophet's mission on earth, Allah (SWT) says:

> "We have not sent thee save as a mercy unto to all beings."
>
> (*Al Anbya'a* [The prophets]: 107)

And:

> Your mercy and Your knowledge embrace all things"
>
> (*Al Ghafer* [The forgiving one]: 6)

The mission, then, aims to bring about mercy and equity to all people: no one outranks another except through piety. "You all are traced back to Adam who is made up of a lump of earth. An Arab outranks a non-Arab only if he is more pious and has a record of more good deeds." All Muslims are brethrens: no one should wrong the other or oppress him. A Muslim desires for his brethrens what he desires for himself. He can never accept to sleep with full stomach while his neighbor is famished. Islam even calls upon a Muslim to be merciful to himself and advises against overcharging oneself with unbearable tasks. Allah says:

> "Allah does not charge a soul with more than it can bear. It shall be requited for whatever good and whatever evil it has done."
>
> (*Al Baqara* [The Cow]: 285)

In Islam, mercy is not confined to man; it extends to shade animals as well. The prophet (PBUH) is reported as saying: "A woman was destined to Hell because of a cat that she had locked up until it died: she neither fed it nor released it to feed itself on whatever vermin it might have come by."

The prophet (PBUH) instructed us to have mercy on cattle when he said: "When you slaughter, do it properly."

A Muslim should also be willing to forgive and waive a right to which he is entitled dropping any claims when deemed morally necessary to do so. Allah (SWT) says:

> "Opt for forgiveness, and bid to what is honourable, and turn away from the ignorant."
>
> (*Al-A'raaf* [The Heights]:199)

And says:

> "Yet that you should remit is nearer to God-fearing."
>
> (*Al-Baqara* [The Cow]: 237)

Man is motivated to forge brotherly relations with others by the idea that he is not alone in this world. He has to live in his community as an element of good, with joint responsibility for the interests of the whole society.

Brotherhood in Islam is a kind of relationship that seeks nothing but God's pleasure. It is not based on self-interest or ambitions. In one of the Prophet's Traditions we read: "Seven categories of people will be shaded by God on the Day of Resurrection when nothing protects save God's shade....among these are two men who only sought the face of God in forging their brotherly relationship."

About virtue, which is one of the main pillars on which Islamic morals are founded, Ibn-Maskaweh says it occupies a middle positions between two contradictory things both of which are vices. Hence, Islamic concept of the right conduct cautions against extremism and calls upon Muslims to be moderate. Ibn-Maskaweh goes on to say that sages have unanimously agreed that virtue fundamentally consists of: wisdom, chastity, courage and justice; whereas the four basic constituents of vice are: ignorance, evil, cowardice and injustice.

Ibn-Hazim says that man wrestles with urges and instincts which he has in common with all other creatures in the animal kingdom. He either completely succumbs to them, bringing about his own downfall, or gets the upper hand by responding to them with the moderation expected of a higher being endowed with perception and reason.

Moderation comes to man's rescue and paves the way for adherence to the ideals derived from Islamic Sharia. This is borne out by what Allah (SWT) says:

> "But as for him who feared the station of his Lord and forbade the soul its caprice, surely Paradise shall be the refuge."
>
> (*Al-Nazi'aat* [The Pluckers]:39-40)

Ibn-Hazm referred, likewise, to some types of vice and their corresponding types of virtue. He started with greed that leads to self-humiliation and drives a person to use every possible means in pursuit of what he covets even if that costs him his human dignity and esteem.

Greed, therefore, is at the root of man's humiliation and distress. The antithesis of greed is integrity which is a compound trait comprising readiness to help in an emergency or crisis, hospitality and understanding. Greed is at the root of humiliation because it leaves the door wide open for pursuing sensual desires, turning man into an insatiable sensuous animal, which seriously blemishes his image as a rational human-being. Every type of depravity and viciousness is the result of greed and coveteousness. A person who covets money so much may attempt to lay his hands on it through such illegal and unhonourable means as stealing, swindling, monopolizing or exploiting others. That is why uprightness and integrity come at the top of all virtues.

As for love, it is said to be the road to happiness. But genuine happiness, according to Imam Ghazali, is that attained in the 'Here-after' by those who love God and love for God. With this kind of sublime love, one can do without anything else. Moreover, this kind of love is closely linked to all moral values. Allah (SWT) says:

> "Surely the pious shall be in bliss, and the libertines shall be in a fiery furnace."
>
> (*Al-Inftaar* [The Splitting]: 13-14)

And:

> "Yet there be men who take to themselves compeers apart from God, loving them as God is loved; but those that believe love God more ardently."
>
> (*Al-Baqara* [The Cow]: 165)

About this divine love, Galaluddin Al-Rumi says: "Love is the medicine for treating our maladies of pride and conceit. It is the doctor required for all sorts of our weakness. The one whose heart is brimful of this divine love tends to love all people because they are God's creation. So this exalted love becomes the source of all virtuous acts. The prophet (PBUH) says: "Allah the Supreme says on the Day of Judgment: Where are those who are joined by the bond of love for My Sublimity. Today I protect them with My shade, for this is the Day when there is no other shade but Mine"

The prophet (PBUH) says: "By God, you shall not enter Paradise until you believe, and you do not believe until you love each other. Shall I show you something that can make you love one another? Spread peace among yourselves."

Justice is a grand virtue. It is one of the 99 attributes of God. Linguistically, it is defined as economy in doing things, i.e. it is a middle course between the two extremes of excess on the one hand and complete laxity on the other. Justice is a human necessity that leads to moral virtues. It is akin to good deeds, piety and charity. Allah (SWT) says:

> "Surely, God bids to justice and good-doing and giving to kinsmen; and he forbids indecency, dishonour and insolence, admonishing you so that haply you would remember."
>
> (*Al Nahl* [The Bee] : 90)

God Almighty has associated justice with trustworthiness in performance. This could mean that the believer is entrusted with administering justice and preserving it. On this point, the Quran says:

> "God commands you to deliver trust back to their owners, and when you judge between the people, that you judge with justice."
>
> (*Al Nissa'* [Women]: 58)

In a Hadith Qudsi, Allah (SWT): "Oh mankind I have ordained that injustice be prohibited unto Me. I have made it prohibited amongst you."

Al Ghazali defines justice as a condition whereby the three forces (wisdom, courage and chastity) are arranged into the required proportionate structure of superiority and submission. Therefore, justice is not a portion of virtues, it is the grand total of all the virtues. In contradistinction to justice there are not two vices but only one injustice; for there is not a middle course between arrangement and disarrangement of the three forces constituting justice.

It was mentioned above that justice is a combination of all virtues. By the same token it can be said that injustice is a combination of all vices. Justice is a religious duty a Muslim has to fulfill, even if others do not. This is confirmed by the Quran where it says:

> "Let not detestation for the people move you not to be equitable; be equitable - that's nearer to God-fearing."
>
> (*Al Ma'eda* [The Table]: 8)

God has promised to punish and destroy the unjust:

> "Then did their Lord reveal unto them: We will surely destroy the evildoers."
>
> (*Ibrahim*: 13)

And

> "And then a herald shall proclaim between them: God's curse is on the evil-doers."
>
> (*Al A'raf* [The Heights]: 44)

Performance of good deeds is a high Islamic value associated by God with justice and with giving due rights to kinsmen, the orphans, the meek and wayfarer. We are enjoined not only to establish justice among them but also to do good deeds for them. Allah (SWT) says:

> "Surely, God bids to justice and good-doing and giving to kinsmen; and he forbids indecency, dishonour and insolence, admonishing you so that haply you would remember."
>
> (*Al Nahl* [The Bee] : 90)

The prophet (PBUH) says: "Allah has ordered that every deed should be performed well. So if you slay, do it right; and if you slaughter, do it right: one should sharpen the knife to spare the slaughtered cattle as much pain as possible."

He also says: "Kindness beautifies, but cruelty uglifies."

Allah (SWT) says:

> "Opt for forgiveness, and bid to what is honourable, and turn away from the ignorant."
>
> (Al-A'raaf [The Heights]:199)

The prophet (PBUH) says: "Shall I tell you who will be rendered immune against [the punishment of] fire: the one who is easy to communicate and deal with."

The prophet (PBUH) was once asked about good-doing. He said: "Worship Allah as if you could see Him; for if you can't see Him, He can see you." A close reading of the Hadith will reveal that it is expressed in the imperative. This requires of every Muslim to observe God in whatever deed he is performing, no matter how small.

This was a brief account of the fundamentals of Islamic morals or "the grand principals of morals" as Al Ghazali called them. The limited space of this introduction does not allow detailed description of many other attributes such as patience, generosity, chivalry, fidelity, etc.

Quotations in this account come from the Quran, Hadith and writings by Islamic eminent scholars, if only to prove that Islam has a lot to say about ethical rules which, combined, can be considered an Islamic constitution capable of leading mankind from darkness to light; from injustice to justice and from depravity to chastity.

Moral sources guiding IOMS:

Undoubtedly, philosophers and scholars who are interested in ethics have set down many rules that broadly agreed with Islamic morals. But details show some differences. To them, morals are based on one aspect such as pleasure, happiness or moderation. Other aspects have been neglected rendering their rules incomplete. When IOMS set about drafting this Code, two options were considered: either to adopt the morals set down by a long line of thinkers and moralists, or to follow the rulings put forward by Islam, which is a divine religion revealed by Allah. The choice for IOMS was obvious: Islam and Islamic Sharia as a source of moral rules. The reason was no less obvious: Islamic Sharia was able to build up a civilization that traded POWs in for books and paid for a translated book with its weight in gold. Opting for Islamic Sharia was not decided on for bias or extremism but for objective reasons, some of which are:

1 - The three divine religions: Judaism, Christianity and Islam have in common the main objective of rectifying wrong conduct and propagating a high standard of morals.

2 - God is the Originator of this universe and the Creator of man. For all the whispered temptations man is prone to hearken to, he has been honored by God in more than one way. He has been entrusted with responsibility on earth; the angels were ordered by God to prostrate for him, he has been taught the names of all things.

Now, if we believe in all this we have to admit that the Creator is most knowing of the secrets of his creations. The inevitable corollary is that God's commandments coincide with all human aspects and tendencies known only by Him.

3 - Islam treasures human life. An attempt on the life of an individual amounts to an attempt on the life of mankind. Likewise, an effort to save the life of an individual is of equal importance to saving the whole of mankind. Although Islam holds the individual in such high esteem, it does not allow him

full reins in freedom. According to Islamic directions, my freedom ends where yours begins. This restriction is quite useful for the good of the whole society.

4 - On the other hand, the moral standards postulated by philosophers and theorists remain limited because they are relative: each thinker has his own convictions, inclinations, interests, philosophy and environment. These factors are reflected on his conceptions, decisions and writings. What one may consider necessary another may not.

These various visions and the confusion in determining criteria could be attributed to failure in tracing philosophy back to its real origin; viz, religion, which combines humanitarian, spiritual and transcendental elements that are not believed in by those who do not believe in divine religions.

5 - Western philosophy is based on sanctifying the individual who, accordingly, is entitled to fully-fledged freedom in leading the kind of life he deems fit. So, whereas there could be a person with extreme views on religion there is another who has no faith whatsoever.

It is beyond the scope of this introduction to cite examples about Western concepts; for these contradict one another. The philosopher of the market economy has his own moral attitude that may diametrically oppose that of the philosopher of socialism or communism. And, whereas religious rules urge belief in the one God, Paradise and Hell, resurrection, final judgment and divine revelation, the atheists have their different views. In other words, the point of departure are so different that seeing eye to eye is almost impossible.

6 - Islam is characterized by its series of prescriptions and proscriptions i.e. permissibles and prohibitions. These do not represent optional ways of behavior. They are obligatory to the Muslim. If he does not stick to them, he will have a sinful heart for violating the rules of his religion. Islamic morals are equally obligatory to those who adopt them. Violation of such morals is at the risk of

severe punishment both in this world and the Hereafter. Posited morals, however, are not obligatory as they do not constitute a part of any law or legislation.

7 - If we seek to set down well-established and viable rules that are sensitive to the depths of the human soul and are not biased to social conditions, personal likes or social and economic trends, the only resort must be to an infallible divine source, i.e. the straight forward religion of Islam.

8 - The English equivalent for the Arabic word *akhlaq* has two synonyms: ethics and morals. Western philosophers disagree about the semantic differences between them. Some use the word "morality" arguing that it includes the meaning of "ethics". Others argue for the other way around because they do not basically agree on the same points of departure.

9 - "Applied ethics" is a new term that has recently floated on the surface of Western Ethics. This suggests the existence of Theoretical Ethics. Islam, however, relies on concepts and principles derived from one source: Islamic Sharia. There is no difference, therefore, between theoretical and applied ethics since they all come from the same source.

10 - The ethical philosophy of most philosophers involve the theory that the end justifies the means. This licenses the trend of committing sinful acts in some positivistic theories to attain an aim considered noble by those holding such a theory.

11 - Belief in the Creator and the Hereafter produces a refined Muslim with high morals who accepts ungrudgingly all prohibitions because they come from his God. He also believes in the Day of Reckoning, resurrection, Paradise and Hell.

On he other hand, positivism argues that man is master of his own fate. His decisions to accept or reject are based on real and tangible facts rather than on mere ideas. There is a world of difference, then, between believers and non-believers.

Reasons for Interest in the Moral Aspects of Medical and Health Sciences:

First of all, morality is a primary requirement in all walks of life, so that virtuous and moral conduct may prevail as a daily way of life for the individual as well as the family. If that is the case, the whole society will be very much like one body in which a discomfort felt by one organ is echoed by all others. Likewise, different sciences form one body of knowledge where progress and development in one is reflected in all the others. This is particularly true with medicine, the distinguishing feature of which is that it is the closest to man who has been honored and elevated above all other creatures on earth.

The first priority of science should be man's happiness through alleviating his pains and realizing his hopes and ambitions. Nevertheless, some imaginative scientists have lately been toying with ideas that could jeopardise man's dignity and infringe upon his sanctity, when newly developed medicines or methods of treatment are tried on him. Many of these innovations have gone beyond the stage of experimentation and are being adopted in medical practice.

It was imperative, therefore, to watch these developments very closely and conduct research on them to find out the extent to which they conform to the rulings of the Islamic Sharia. Research was also required to reach the most practical guidelines on these innovated medical practices with a view to protecting man's dignity; otherwise, we will wake up one day to find on our hands seriously deformed children as a result of using certain new medicines or methods of treatment.

Besides, the rights and duties of doctors and other workers in the field of health services have become a hazy area, which may lead to medical errors. That is the real worry for a lot of citizens especially at a time when the introduction of electronic equipment and health insurance have compromised the confidentiality of the patients' information.

The main objective of all these efforts is to make sure that a doctor is really God's means of bringing mercy to His servants.

Describing the medical profession, Imam Shafi'ie says: "Next to Islamic Sharia, the noblest and most distinguished science that I know of is medicine."

On the same subject, Ibn Rushd says: "The relationship between medicine and wisdom is a matter of methodology. One cannot take up the medical profession without being fully conversant with logic. A good physician is necessarily a philosopher: semantically a philosopher is a person who likes wisdom"

Islamic Juridical Rules from which the Code Derives its Articles and Guidelines:

First principle:

Respect for persons as elaborated below is an established fundamental in Islamic Sharia; for it is a token of esteem stipulated in the Quran:

"We have honoured the Children of Adam"

(*Al-Israa* [The Night Journey]:70)

a - A legally competent person (capable of independent self-determination) is entitled to respect for his independence. He should enjoy free choice in taking whatever decisions he deems suitable without the slightest suspicion of duress, deception or exploitation. The general juridical rules have confirmed this principle as they specify the following: "The right of a human-being cannot be disposed of or relinquished without his permission." And, "Man's rights cannot be nullified without his consent." "Sharia has stipulated the rights of human-beings."

b - A legally incompetent person (whose independence is undermined or impaired) is in need of protection from others who may take advantage of his weakness, and from himself as he may put himself in the way of harm due to his inability to manage his own affairs properly. So, Islamic Sharia prevents such a person from independent action and does not hold him responsible for what he says. Accordingly, general juridical rules stipulate: "Whoever is incompetent in action shall consequently be considered

incompetent in words." The rules further require that a guardian should be designated for such a person to take over the running of his affairs in ways that ascertain his interests and block any attempt by others to use him for their own ends.

Second Principle:

Achieving benefit [the moral commitment to maximize benefit, neutralize deliberate harm to others and minimize unavoidable damage] This is also one of the main rules in Islamic legislation confirmed by what the Prophet (PBUH) says:" Neither get harmed nor bring harm to bear." This pronouncement has become one of the intents and overall purposes of legislation. It gave rise to the juridical rule: "Bringing about benefit and averting loss." On this point, Al-Quraafi says: "God (SWT) has sent the Messengers (peace be upon them) to achieve benefits for mankind by induction: whatever is beneficial is most probably preferred by legislation."

Al-Qaadi Ibnil-Arabi defines "benefit" as every meaning in the Islamic laws that contributes to the realization of public utility for the people. This concept has been emphasized by the juridical rule:" Any act that brings harm to bear or stands in the way of benefit is interdicted." And, "Malicious acts must be legally and rationally banned at all times and for all persons including notables." This rule applies to acts that can be described as "utter evil".

In cases where the choice is between two courses of action both of which seem to be harmful, the only resort is to ward off the greater and settle for the lesser of the two evils. Hence, the juridical rules stipulate the following:" Thwarting the greater of two evils by opting for the lesser is a must." And,: "If two acts happen to be the only available alternatives and both are judged as reprehensible, forbidden or harmful, the choice must be the lesser of the two evils."

Another important rule specifies that if the choice is between realizing a benefit or warding off an evil, the latter outweighs the former. The basis for this is elucidated by Ibn-Taimiya where he says: "Little corruption may not be warded off by allowing much corruption, and the lesser of the two evils cannot be warded off by giving in

for the greater. Sharia rules that benefits shall be achieved or supplemented and that evil deeds shall be foiled or reduced to a possible minimum. They direct that if two benefits cannot be obtained together, priority should be for the greater one. By the same token, if two evils cannot be warded off at the same time, the greater should take precedence over the lesser."

Third Principle:

Administer justice [the moral commitment to treat every person in accordance with what is morally correct and proper; giving every person, male or female, his/her what is due to him/her; and inhibiting greed and moral depravity in transactions]. This, too, is a well-established ruling in Islamic legislation which puts the principle of administering justice into action. This principle has been founded by Islam to serve as the pivot of righteousness and success in life. It can even be claimed that the prophets, Messengers and Holy Writs have the common purpose of administering justice in the world. This is corroborated by the Quran:

> "Indeed We sent our Messengers with the clear signs, and we sent down with them the Book and the Balance so that men might uphold justice."
>
> (*Al-Hadeed* [Iron]: 25)

Ibnul-Qayyim says: "Allah (SWT) has clarified that His prescribed laws and ways of conduct have the intent of administering justice among His servants. Any course of action that leads to justice is congruous with religion."

Al-Ezz Bin Abdussalam says in his book "Al-Qwaa'id Al-Kubra" (the Greater Rules): "The most comprehensive verse in the Quran that exhorts people to do all kinds of good and abstain from all kinds of evil is:

> "Surely Gods bids to justice and good-doing"
>
> (*Al-Nahl* [The Bee]: 90)

Justice is settlement [of disputes and controversies] and equity; good-doing is attaining a benefit or averting a cause of corruption.

This has been a quick, but significant, look at the Islamic approach to moral education and the importance of sticking to the time-honoured values. The necessity and usefulness of adopting these values in daily life has been highlighted by many verses of the Quran, which is the source of high ideals, and explained by Prophetic Traditions. Inspired by this Prophetic guidance, the writings of Islamic thinkers subscribe to these values and demonstrate how closely related they are to the world we live in, especially to the domain of medicine and health sciences.

We have deemed it appropriate to include these arguments and such strong evidence in this Islamic Code hoping they will contribute to achieving success for the targeted purposes.

PART ONE

MEDICAL BEHAVIOR AND PHYSICIAN RIGHTS AND DUTIES

Contents

CHAPTER ONE

PHYSICIAN ETHICS

Chapter One
Physician Ethics

Article One:

A physician should be sincere in performing his work, enjoy high moral values, be grateful towards his teachers and trainers, and acknowledge the efforts of others. He should serve as an example in taking care of his own health and giving due attention to the requirements of his body and to his general appearance, and he should refrain from anything that may influence the esteem accorded to his profession inside and outside his place of work.

Supporting Islamic Legal Evidence:

I - In the Glorious Quran:

1 - "You have sublime manners" (*Al-Qalam* LXVIII: 4).

2 - "Show forgiveness, enjoin what is right, and turn away from the ignorant" (*Al-A'raaf* VII: 199).

3 - "If they both opt for weaning by mutual agreement and after consultation, they will be free from blame" (*Al-Baqarah* II: 233).

4 - "And they conduct their affairs by mutual consultation" (*Al-Shura* XLII: 38).

II - In the Prophet's Tradition:

1 - In an attributed tradition quoting Omar, "If you go in to check on a sick person, ask him to pray for you; his is like angels' prayers." (Cited by Ibn Maaja with a verified chain of citation.)

2 - "No person who has in his heart the equivalent of one iota of pride will be admitted into paradise." (Cited by Muslim.)

3 - Anas is quoted as saying that the Prophet, blessings and peace be upon him, used to get close to a sick person, sit near his head, and ask how he was doing, saying, "How do you find yourself?" (Cited by Al-Bukhari.)

4 - In an attributed tradition quoting Abu Sa'eed, "If you go in to check on a sick person, suggest to him that he still has long to live. That does not change a thing, and it makes the patient feel better." (Cited by Al-Tirmithi and Ibn Maaja.)

CHAPTER TWO

THE PHYSICIAN'S DUTIES TOWARDS THE PATIENT

Chapter Two
The Physician's Duties towards the Patient

Article Two:

A physician should listen carefully to the patient's complaint, sympathizing with him in his suffering, treat him well, and be gentle while examining him. He should avoid any condescending attitude in dealing with the patient or any ridicule or derision of him, regardless of the patient's educational or social level, or religious or racial background. A physician should respect his patient's opinion, particularly in matters that concern the latter personally, but that should not keep the physician from giving the appropriate instructions.

Article Three:

A physician should treat all his patients equally, without any discrimination based on their prestige, their social or moral status, the physician's own feelings towards them, their religious or racial background, their political orientation, or their gender, nationality, or color.

Article Four:

A physician should fear God when dealing with his patients; show respect for their beliefs, religions, and traditions when engaging in the process of examination, diagnosis, and treatment. He should avoid any violations of Islamic law, such as being alone with a member of the opposite sex or looking at the private parts (*'awra*) of a patient except in as much as the process of examination, diagnosis, and treatment requires; in the presence of a third party; and after obtaining permission from the patient.

Supporting Islamic Legal Evidence:

I - In the Glorious Quran:

1 - "We offered Trust to the Heavens, the Earth, and mountains, but they declined to bear it and were afraid of it, while Man undertook to bear it. He is so unjust and ignorant" (*Al-Ahzaab* XXXIII: 72).

2 - "God commands you to deliver trusts where they are due" (*Al-Nisaa* IV: 58).

II - In the Prophet's Tradition:

3 - In an attributed tradition quoting Abu Sa'eed, "Among the worst people in God's estimate on the Day of Resurrection is a man who tells private things to his wife and she to him, and then he discloses her secret." (Cited by Muslim.) Another version says, "One of the gravest cases of [betraying] trust in God's estimate on the Day of Resurrection is a man who tells private things to his wife and she to him, and then he discloses her secret." (Cited by Muslim, Abu Dawood, and Al-Tirmithi.)

4 - In an attributed tradition quoting Jaber, "The confidentiality of meetings should be observed, except in three cases: a meeting where unjustified bloodshed takes place, a meeting where a woman is illicitly violated, and a meeting where property is illegally usurped." (Cited by Muslim.)

Article Five:

A physician should ask only for the tests needed for the patient, without adding any tests not justified by the patient's case. He should base his whole diagnosis and treatment on the best available evidence and data, and refrain from using any unauthorized, unaccepted, or scientifically unrecognized methods of diagnosis or treatment. Moreover, he should ask only for the medications or surgical operations that are called for in the patient's case.

Article Six:

A physician should honestly explain to the patient or anyone representing him the type, causes, and complications of the illness, and of the usefulness of diagnostic and therapeutic procedures. The physician should also explain clearly the proper options of diagnosis and treatment in as much as the patient's physical and psychological condition allows.

Article Seven:

A physician should not hesitate to refer the patient to a doctor specialized in the type of disease the patient has or to a doctor who has more effective equipment whenever the patient's case calls for such a referral, nor to refer him to a doctor whom the patient wishes to consult. It is unacceptable for a physician to delay the referral when it is in the patient's interest. The physician should make the patient's medical record accessible when referring him to another doctor, and to give the patient, without delay, an adequate medical report of his case.

Article Eight:

A patient or a member of his family has the right to invite another efficient doctor for consultation, after the original physician's consent has been obtained. The latter, however, has the right to discontinue his services, without having to give any reason, if the patient or a member of his family insist on consulting another doctor unacceptable to him.

Article Nine:

A physician should never decline or discontinue to treat an emergency patient under any circumstances, unless the patient refuses to follow his instructions or seeks, without the consent of the physician attending him, the services of another doctor. Nor should a physician decline or discontinue to treat a patient, unless the case is not within his field of specialization.

Article Ten:

A physician should continue to give an emergency patient the proper treatment until it is no longer needed or until care for the patient is taken over by another doctor.

Supporting Islamic Legal Evidence:

I - In the Glorious Quran:

1 - "And do good deeds, so that you may succeed" (*Al-Haj* XXII: 77).

2 - "Do not pursue what you have no knowledge of. Hearing, sight, and the heart - man will be accountable for all these" (*Al-Israa* XVII: 36).

3 - "You are the best nation that has been known by Mankind. You enjoin justice and censure evil, and you believe in God" (*Aal 'Imraan* III: 110).

4 - "We offered Trust to the Heavens, the Earth, and mountains..." (*Al-Ahzaab* XXXIII: 72).

II - In the Prophet's Tradition:

1 - "Religion is sincerity" (Cited by Muslim).

2 - In an attributed tradition quoting Ibn Mas'ood, "Any person who keeps knowledge from his people will be restrained by a bridle of fire." (Cited by Ibn 'Adi).

3 - In an attributed tradition quoting Jaber, "The best people are those who give benefit to their folks." (Cited by Al-Qidhaa'i).

4 - "A chief is liable to compensation payment."

Article Eleven:

A physician should continue to extend proper care to patients with incurable, terminal, or fatal diseases, and to console them and give them hope to the last minutes of their lives.

Article Twelve:

To the best of his ability and with all the preventive and therapeutic means available to him, whether material or psychological, a physician should relieve the patient's pain and give him the feeling that the physician is eager to give him proper care and attention.

Supporting Islamic Legal Evidence:

I - In the Glorious Quran:

1 - "To you has come a messenger who is one of you. He grieves that you should perish, and he is solicitous over you. He is compassionate and merciful towards believers" (*Al-Tawbah* IX: 128).

2 - "Are you then going, if you are placed in charge, to do evil in the land and sever ties of kinship?" (*Muhammad* XLVII: 22).

3 - "Say, 'Lord, forgive and have mercy; you are the Best of the Merciful'" (*Al-Muminoon* XXIII: 118).

4 - "Say, 'Lord, have mercy on them for they have raised me up when young'" (*Al-Israa* XVII: 24).

II - In the Prophet's Tradition:

1 - In an attributed tradition quoting Al-Ni'maan Ibn Basheer, "In their mutual affection, mercy, and compassion, Muslims are similar to a single body: whenever one of its organs complains, all other organs are mobilized to support it through wakefulness and fever." (Cited by Muslim.)

2 - "Answer the person who appeals to you, visit the sick, and relieve sufferers." (Cited by Al-Bukhari and Muslim.) In another, attributed version quoted by Abu Musa: "Answer the person who appeals to you, visit the sick, and relieve sufferers." (Cited by Al-Bukhari, quoting Abu Musa.)

3 - Ibn Maaja quotes Ibn 'Abbaas as saying that the Prophet, blessings and peace be upon him, visited once a sick man. He asked him, "What would you feel like having?" The man

said, "I feel like wheat bread." The Prophet said, "If any of you has wheat bread, let him send it to his brother." He added, "If a sick person feels like eating something, let him have it." (Cited by Ibn Maaja).

4 - In an attributed tradition quoting Abu Sa'eed, "If you go in to check on a sick person, suggest to him that he still has long to live." (Cited by Al-Tirmithi and Ibn Maaja.)

Article Thirteen:

A physician should see to it that the patient is enlightened as regards his illness and his health in general, as well as to the way to maintain his health and follow proper and effective methods of disease prevention. This should be through face-to-face enlightenment or through the employ of other effective methods when available.

Supporting Islamic Legal Evidence:

I - In the Glorious Quran:

1 - "You are the best nation that has been known by Mankind. You enjoin justice and censure evil, and you believe in God" (*Aal 'Imraan* III: 110).

2 - "We only sent men before you, so ask people with learning if you do not know, with clear signs and with written rules. To you We have revealed a reminding message, so that you may explain to people what has been revealed for them, so that hopefully they would contemplate" (*Al-Nahl* XVI: 43-44).

3 - "Believers, fear God and be among the truthful" (*Al-Tawbah* IX: 119).

II - In the Prophet's Tradition:

1 - In an attributed tradition quoting Tameem Ibn Aws Al-Daari, "Religion is sincerity towards God, His Messenger, and Muslim leaders and masses." (Cited by Muslim.)

2 - In an attributed tradition quoting Ibn Mas'ood, "A person keeps telling the truth until he is labeled by God as a truthful person." (Cited by Al-Bukhari and Muslim.)

3 - "A Muslim's claim upon a fellow Muslim consists of six points, and if he seeks your advice be sincere with him." (Cited by Muslim, quoting Abu Hurrairah.)

Article Fourteen:

A patient should not be examined or treated without his consent, except in cases when emergency medical intervention is required and informed consent cannot be obtained for any particular reason, or when the disease is communicable or poses a threat to public health or to others, and in accordance with the laws in force. In the case of a patient with full legal competence, his consent can be expressed orally or implicitly. When the patient is a minor, an unconscious adult, or a person who fails to meet one or more of the competence conditions, consent should be given by someone who legally represents him. For surgical operations and for treatment and examinations that have potential side effects, consent should be informed and given in writing.

Supporting Islamic Legal Evidence:

I - In the Glorious Quran:

1 - "We have fastened the fate of every human being around his neck" (*Al-Israa* XVII: 13).

2 - "Then give warning; your task is only to warn. You have no control over them" (*Al-Ghashiyah* LXXXVIII: 21 - 22).

3 - "Do not consume your property among yourselves in vanity, unless it is a trade by your mutual agreement, and do not kill yourselves: God is Merciful to you" (IV: 29).

II - In the Prophet's Tradition:

1 - In an attributed tradition quoting 'Itbah Ibn 'Aamer, "Do not force food and drink upon your patients; God, the most

glorious and sublime, feeds them and gives them drink." (Cited by Al-Tirmithi, who says it is well-attributed, and Al-Haakem.)

2 - In an attributed tradition quoting Haneefah Al-Raqqaash, "It is only by his free consent that a Muslim's property can be touched." (Cited by Abu Dawood.)

3 - In an attributed tradition quoting Abu Bakr, "The blood, property, and honor of each of you are inviolable by the rest of you." (Cited by Al-Bukhari and Muslim.)

Article Fifteen:

A physician is entrusted to investigate the health care programs suitable for the patient's case. He should ascertain the usefulness of a course of treatment before choosing it and applying it to the patient. He should follow the patient's case until he fully recovers, if the disease is curable. When a patient asks for an ineffectual course of treatment, the physician should convince him that it is useless.

Article Sixteen:

Taking into consideration the stipulation of Article Four, a physician should make sure to observe the following while examining a patient:

a - He should make a record of the patient's condition and of personal and family medical history before beginning to diagnose and treat the case.

b - He should be careful and efficient in, and give sufficient time to, the examination and diagnosis process.

c - Prescriptions should be made in writing and should be clear, with dosages and method of administration specified. The patient or his family members, as the case requires, should be made aware of the importance of following the method of treatment prescribed by the physician and of the serious potential side effects of the medical or surgical treatment.

d - Side effects resulting from medical or surgical treatment should be monitored and treated promptly when possible.

Supporting Islamic Legal Evidence:

I - In the Glorious Quran:

1 - "To you has come a messenger who is one of you. He grieves that you should perish, and he is solicitous over you. He is compassionate and merciful towards believers" (*Al-Tawbah* IX: 128).

2 - "Are you then going, if you are placed in charge, to do evil in the land and sever ties of kinship?" (*Muhammad* XLVII: 22-24).

3 - "Say, 'Lord, forgive and have mercy; you are the Best of the Merciful'" (*Al-Muminoon* XXIII: 118).

4 - "Say, 'Lord, have mercy on them for they have raised me up when young'" (*Al-Israa* XVII: 24).

II - In the Prophet's Tradition:

1 - "In their mutual affection, mercy, and compassion, Muslims are similar to a single body: whenever one of its organs complains, all other organs are mobilized to support it through wakefulness and fever." (Cited by Muslim.)

2 - "Answer the person who appeals to you, visit the sick, and relieve sufferers." (Cited by Al-Bukhari and Muslim.) In another, attributed version quoted by Abu Musa: "Answer the person who appeals to you, visit the sick, and relieve sufferers." (Cited by Al-Bukhari, quoting Abu Musa.)

3 - Ibn Maaja quotes Ibn 'Abbaas as saying that the Prophet, blessings and peace be upon him, visited once a sick man. He asked him, "What would you feel like having?" The man said, "I feel like wheat bread." The Prophet said, "If any of you has wheat bread, let him send it to his brother." He added, "If a sick person feels like eating something, let him have it." (Cited by Ibn Maaja).

4 - In an attributed tradition quoting Abu Sa'eed, "If you go in to check on a sick person, suggest to him that he still has long to live." (Cited by Al-Tirmithi and Ibn Maaja.)

Article Seventeen:

A physician should make sure that surgical operations are performed under the following conditions:

- The physician who performs an operation should have the specialization and medical experience that qualify him to do the required type of surgery.
- The surgical operation should be performed at a therapeutic institution or health establishment which is sufficiently equipped for the performance of such a surgery.
- Proper laboratory and radiology tests should be made to confirm that surgical intervention is necessary and appropriate as a treatment for the patient and to make certain that the patient's health condition allows the surgery to be performed.
- The surgeon attending the patient has the obligation of performing the surgery himself. He may be helped by a resident at the hospital or some other surgeon, with no need for the patient's consent. The surgeon may also authorize an assistant of his to perform certain procedures of the surgery, provided that they are done under the surgeon's supervision and with his help, and that he bears the legal responsibility for them.

Supporting Islamic Legal Evidence:

I - In the Glorious Quran:

1 - "We offered Trust to the Heavens, the Earth, and mountains, but they declined to bear it and were afraid of it, while Man undertook to bear it. He is so unjust and ignorant" (*Al-Ahzaab* XXXIII: 72).

2 - "God commands you to deliver trusts where they are due" (*Al-Nisaa* IV: 58).

3 - "Let no scribe decline to write as taught by God; therefore, let him write" (*Al-Baqarah* II: 282).

II - In the Prophet's Tradition:

1 - "When a person who is unknown to have medical experience practices medicine, he is accountable."

2 - "The blood, property, and honor of each of you are inviolable by the rest of you."

3 - "Injustice leads to layers of darkness on the Day of Resurrection."

Article Eighteen:

A patient should be made aware of his heath condition and of available treatment alternatives, if he can grasp this information. A physician should not force a treatment on a patient without his consent, nor force him to sign, unwillingly, data in his medical file.

Article Nineteen:

A physician should gently, honestly, and wisely and without undue exaggeration explain to the patient the consequences of declining to follow a treatment and the resulting complications. The physician should also take the patient's admission if the latter declines to follow the treatment, and when he refuses to give it, a statement signed by the physician and a member of the nursing staff should be added to the patient's medical file, in order to clear the physician from any responsibility.

Supporting Islamic Legal Evidence:

I - In the Glorious Quran:

1 - "We have fastened the fate of every human being around his neck" (*Al-Israa* XVII: 13).

2 - "Then give warning; your task is only to warn. You have no control over them" (*Al-Ghashiyah* LXXXVIII: 21 - 22).

3 - "Do not consume your property among yourselves in vanity, unless it is a trade by your mutual agreement, and do not kill yourselves: God is Merciful to you" (IV: 29).

II - In the Prophet's Tradition:

1 - In an attributed tradition quoting 'Itbah Ibn 'Aamer, "Do not force food and drink upon your patients; God, the most glorious and sublime, feeds them and gives them drink." (Cited by Al-Tirmithi, who says it is well-attributed, and Al-Haakem.)

2 - In an attributed tradition quoting Haneefah Al-Raqqaash, "It is only by his free consent that a Muslim's property can be touched." (Cited by Abu Dawood.)

3 - In an attributed tradition quoting Abu Bakr, "The blood, property, and honor of each of you are inviolable by the rest of you." (Cited by Al-Bukhari and Muslim.)

Article Twenty:

When a patient is referred to one of the institutions in which the physician holds shares, the following should be observed:

a - The establishment should offer outstanding services that are not inferior to others in type or quality.

b - Referral to the establishment should be warranted by the incapability to deal with the patient's condition. The patient should not stay in the establishment he is referred to longer than necessary.

c - The physician should inform the patient that he, the physician, has a financial interest in the establishment to which he is referring the patient.

In all cases the patient should be given the freedom of choice.

Supporting Islamic Legal Evidence:

The rules of the Islamic Jurisprudence (Fiqh) include the following:

1 - A lesser evil is given precedence [in being tolerated] over a more general one.

2 - Prevention of harm has precedence over the acquisition of benefits.

3 - Intention is the criterion of actions.

Article Twenty-One:

A patient should be checked out of the health establishment where he is receiving treatment only if his health condition allows that or he expresses his desire to leave although he is made aware of the consequences of his departure. In the latter case, a written statement should be obtained from the patient or, when he is not fully competent, from a family member of the first, second, third, or fourth degree of kinship and should be included in the patient's medical file.

Supporting Islamic Legal Evidence:

I - In the Glorious Quran:

1 - "We offered Trust to the Heavens, the Earth, and mountains, but they declined to bear it and were afraid of it, while Man undertook to bear it. He is so unjust and ignorant" (*Al-Ahzaab* XXXIII: 72).

2 - "God commands you to deliver trusts where they are due" (*Al-Nisaa* IV: 58).

3 - "Let no scribe decline to write as taught by God; therefore, let him write" (*Al-Baqarah* II: 282).

II - In the Prophet's Tradition:

1 - "When a person who is unknown to have medical experience practices medicine, he is accountable."

2 - "The blood, property, and honor of each of you are inviolable by the rest of you."

3 - "Injustice leads to layers of darkness on the Day of Resurrection."

Article Twenty-Two:

A physician should cooperate with the other members of the medical team involved in providing care to the patient, and he should make available to them, whenever he is asked to do so, what information he has of the patient's condition and of the method of treatment he, the physician, has been using.

Article Twenty-Three:

A physician should give to his patient an advance notice of any travel or absence plans he has and should tell him how to act when the physicians is absent. Under all circumstances, a suitable physician should be available in the absence of the doctor in charge of the patient to guarantee that the latter continues to receive treatment.

Article Twenty-Four:

If invited to examine a patient being treated by a colleague, a physician should observe the following rules:

a - Even if there are no clear justifications, he should answer the invitation for consultation if it comes from the attending doctor. The consulted physician should disclose his findings to his colleague, rather than to the patient himself.

b - The consulted physician should reassure the patient, reduce his anxiety, and use his own discretion in determining what the patient should know and what should be reserved to the attending physician.

c - He should guard against any word or suggestion that implies any discredit or disparagement of the attending doctor or any under-estimation of the latter's efforts in treating the patient. This should be particularly observed when the consulted physician's point of view differs from that of the attending doctor.

d - If the patient desires to terminate the service of the original physician, the latter has to be informed of that decision.

e - The attending doctor has the right to consult another colleague in the same field of specialization after the first consulted doctor has given his opinion and made his recommendations.

Article Twenty-Five:

When a physician is commissioned to extend health care to individuals with limited freedom, he should abide by the following:

a - He should provide them with the same type and level of health care available to persons with no freedom restrictions.

b - He should not, actively or indirectly, perform anything that amounts to collaboration in torture procedures or other forms of cruel or inhuman treatment, or to complicity in, enticement of, or keeping silent about such acts.

c - He should never use his professional knowledge or skills to help in the interrogation of people with restricted freedom in a way that is hazardous to their physical or psychological condition. Nor should he participate in any restricting procedure against them.

d - If he notices that a restricted person has been or is being subjected to torture or abuse, he should report it to the proper authorities.

Article Twenty-Six:

Physicians who attend minors, should explain to these patients, each to the extent of his comprehension skill, the nature of the medical procedures or interventions applied.

Article Twenty-Seven:

When treating a child patient, a physician should defend his patient's interest if the family or relatives of the child fail to appreciate the case fully or if they fail to carry out their duty towards the child.

Article Twenty-Eight:

A physician attending a patient who takes any addictive material should deal with his patient seriously, carefully, and confidentially. He should endeavor to apply the best treatment procedures to his patient,

whether in special institutions or at his own office if treatment equipment is available. In doing so, the physicians should observe the laws in force.

Supporting Islamic Legal Evidence:

All this can be covered, as far as Islamic Law is concerned, by the above-cited rules of Islamic Jurisprudence (*Fiqh*) and legal purposes.

CHAPTER THREE

MEDICAL CONFIDENTIALITY

Chapter Three
Medical Confidentiality

Article Twenty-Nine:

A physician may not disclose a personal secret that has come to his knowledge through the performance of his profession, whether the patient confides the secret to him, or the physician comes to know it in the course of his work, except in the following situations and similar cases that are stipulated in the national laws:

a - if disclosure of a person's secret is done at his own request, which should be in writing or if disclosure of a secret is in the interest of the patient or of society;

b - if the laws in operation require disclosure of the secret, or an order to disclose it is made by a judicial authority;

c - if the purpose of disclosing the secret is to prevent a crime, in which case the disclosure should be strictly to the official authority concerned and to no other party;

d - if disclosure of a person's secret is in the interest of the patient's spouse, provided that it is made to the couple, and not to one without the other;

e - if the physician makes the disclosure in defending himself before a judiciary authority at its request and in as much as the defense requires; and

f - if the purpose of disclosing the secret is to prevent the spread of an infectious disease that would be harmful to society members, provided that the disclosure is made only to the concerned health authority.

Article Thirty:

When minor patients ask to be treated in secret, without their guardians knowing about it, the physician in charge should attempt to find out the reason behind the desire to keep the condition secret from the minor's family, should encourage the patients to get their family involved, and should correct any misconceptions the minor may have.

Article Thirty-One:

A physician may treat underage patients and may refrain from revealing any information that may cause harm to the minors in question, unless the existing laws stipulate otherwise.

Article Thirty-Two:

Before releasing any information about a patient to third parties - such as researchers, pharmaceutical companies, and data collecting institutions - a physician should obtain the patient's informed consent in writing.

Article Thirty-Three:

A patient has the right to obtain, upon request, a detailed report of his medical condition from his attending physician, based on the latter's own examination. The physician, however, should not write a medical report or give testimony on a subject not within his field of specialization, and his report or testimony should be true to the facts that he has learned through his own examination of the patient.

Article Thirty-Four:

A physician may discuss a patient's case, diagnosis, and treatment, as well as the expected development of the case, with the patient's lawyer, provided that the patient or his guardian consent to that.

Article Thirty-Five:

A physician may release information about a patient to an insurance agent, provided that the patient or a legal representative of

his should consent in writing. The information released should be only what relates to the insurance item involved. Before disclosing the information, the physician should make the patient aware of the consequences of such disclosure.

Article Thirty-Six:

Physicians and all health staff members should do their utmost to guard the confidentiality of medical reports, including those stored in computer memory. Data should be entered into computers only by authorized people. The date and timing of adding any new data entries should be scheduled, and the person adding or modifying an entry should sign his name.

Article Thirty-Seven:

A patient or a representative of his should be informed when the health institution has a computer data base before the physician sends any data related to that patient to the computer department for storage. All parties who can access the data should be specified in advance. Revealing such information to the patient is an important element in getting his informed consent. Security measures, in proportion with the extent of sensitivity of the patient's data, should be taken to prevent any information leakage or any access to the data base by unauthorized persons.

Article Thirty-Eight:

A patient or someone acting on his behalf should be informed before any report containing data that concerns the patient is distributed. Moreover, the attending doctor should be informed before any data or information relating to the patient is released to parties outside health care establishments, so that no disclosure of such data is made before the patient's consent is obtained.

Article Thirty-Nine:

Confidential information may be disclosed only to parties that keep it highly secret, in accordance with existing laws and regulations, and should be restricted to the data that meets the purpose specified

when such disclosure is requested and to the time period specified. All such parties should be told that releasing the data to them does not mean they can pass these data to other parties, apply them for purposes other than what is specified when the data are requested, or use them against the patient's interest.

Article Forty:

Computers should be equipped with backup and retrieval functions to avoid the loss of any data when some failure occurs in the programs or server used. Before a file is deleted, a printout should be submitted to the attending physician.

Article Forty-One:

As soon as the attending physician receives a copy (a printout or a copy saved on a hard, compact, or floppy disk) of stored data, they should be deleted from the data base. The computer department should inform the attending doctor in writing that the deletion is done. A patient has the right to request the deletion of some of the data that concern him, subject to the laws in operation.

Article Forty-Two:

Very strict measures should be taken to prevent free access to the data base, including the introduction of systems to discover any attempts to break into it by any unauthorized party.

Supporting Islamic Legal Evidence:

I - In the Glorious Quran:

1 - "God commands you to deliver trusts where they are due" (Al-Nisaa IV: 58).

2 - "Do not spy, and do not backbite one another. Would any of you like to eat the flesh of his dead brother? You would loathe it." (*Al-Hujuraat* XLIX: 12).

3 - "Those who would like atrocities to be common among believers will receive painful punishment" (XXIV:19).

II - In the Prophet's Tradition:

1 - "A chief is liable to compensation payment."

2 - In an attributed tradition quoting Ali, "The confidentiality of meetings is a trust." (Cited by Al-Khateeb Al-Baghdaadi.)

3 - In an attributed tradition quoting Thooban, "Do not cause harm to God's servants, nor seek to look at their private parts, for soon after a person seeks to look at the private parts of his fellow Muslim, God would cause his private parts to be exposed so that he is shamed even in his own house." (Cited by Ahmad.)

4 - In an attributed tradition quoting Abu Hurairah, "When an individual shields for another, he is shielded by God on the Day of Resurrection." (Cited by Muslim, quoting Abu Hurairah.)

5 - "Beware of backbiting. If the things you say about a person [in his absence] are true, you are taking him unaware. If they are not, you are slandering him."

CHAPTER FOUR

PHYSICIAN DUTIES TOWARDS SOCIETY

Chapter Four
Physician Duties towards Society

Article Forty-Three:

A physician should be an active member of society, interacting with it, influencing it, and taking interest in its affairs. His actions should also aim at satisfying God, and he should never get involved in any practices or behaviors that are unethical or harmful to society.

Article Forty-Four:

A physician should help society in dealing with elements of health enhancement, disease prevention, and protection of the natural and social environment. He should live up to his responsibility of promoting health awareness and education. He should take advantage of patient visits to offer advice on the proper styles of healthy life and to discourage all health-damaging life styles.

Article Forty-Five:

A physician should use his skill, knowledge, and experience to improve the quality of health services offered to the community.

Article Forty-Six:

A physician should endeavor to conserve health resources and use them in the best possible way and make optimal utilization of these resources, setting an example by his own behavior.

Article Forty-Seven:

A physician, particularly when holding an official position, should take an active part in setting regulations, drawing health policies, and solving health problems, thus serving the interests of the community.

Article Forty-Eight:

In the case of communicable diseases, a physician should follow relevant regulations, report cases of the disease to the proper authorities, and take all necessary measures.

Supporting Islamic Legal Evidence:

I - In the Glorious Quran:

1 - "That this nation of yours is one nation, and I am your Lord, so worship Me" (*Al-Anbiyaa* XXI: 90).

2 - "Whoever contends with the Messenger after guidance has become evident to him and follows a course other than that of believers - We will let him follow what he has chosen and We will place him in Hell, which is a miserable fate" (*Al-Nisaa* IV: 115).

II - In the Prophet's Tradition:

1 - "A person who cares not for the affairs of Muslims is not one of them."

2 - "Stick to the group; a wolf only devours stray sheep."

CHAPTER FIVE

SOCIAL ISSUES

Chapter Five
Social Issues

Utilization of Health Resources

Article Forty-Nine:

Physicians bear the moral responsibility of employing all the professional experience they have to contribute to the decision-making process relevant to the distribution or rational utilization of limited medical resources in a way that protects patient interests and observes the principle of equity and equality.

Article Fifty:

The decision-making process concerning the distribution of limited medical resources should be based on the medical, scientific, and moral criteria applicable to the patient's health condition. These criteria include the extent of the patient's need for these limited resources, the duration of treatment, the likelihood of the patient's death, and, in certain cases, the amount of materials needed for the treatment to succeed.

Article Fifty-One:

A physician should not abandon his role as a patron of the patient entrusted with the task of guarding the patient's interest, particularly what concerns his treatment needs.

Article Fifty-Two:

Patients who are denied certain medical resources have the right to know the reason for that. The policies practiced by some institutions

of controlling scarce medical resources should be made known to the public. Moreover, these policies should be subject to the occasional revision of supervisory medical authorities.

Supporting Islamic Legal Evidence:

The rules of the Islamic Jurisprudence (Fiqh) include the following:

1 - A lesser evil is given precedence [in being tolerated] over a more common one.

2 - Prevention of harm has precedence over the acquisition of benefits.

3 - Intention is the criterion of actions.

Article Fifty-Three:

A physician should not make a decision to admit a patient into a hospital, to discharge him, or to engage in any diagnosis or treatment procedure for the purpose of financial gain and without considering the actual need of the patient.

Article Fifty-Four:

Physicians should prescribe medicines and medical aids, equipment, or other approved therapeutic methods only on the basis of medical considerations and patient needs and not under any type of pressure. A physician should not accept offers from other parties.

Article Fifty-Four:

Every physician should endeavor to suggest policies aimed at equity in providing a decent standard of health care to all society members.

Article Fifty-Five:

When selecting the preventive and therapeutic procedures and approaches which guarantee a decent standard of health care, physicians should observe the following ethical considerations:

a - the extent to which a patient benefits from the course of treatment,

b - the likelihood of benefit to the patient from the treatment,

c - the duration of that benefit,

d - the cost of the treatment, and

e - the number of patients benefiting from the treatment.

Supporting Islamic Legal Evidence:

The rules of the Islamic Jurisprudence (Fiqh) include the following:

1 - A lesser evil is given precedence [in being tolerated] over a more common one.

2 - Prevention of harm has precedence over the acquisition of benefits.

3 - Intention is the criterion of actions.

Patients with AIDS or Any Other Communicable Disease

Article Fifty-Seven:

It is the right of a patient infected with AIDS or with another communicable disease to receive the treatment and health care that his condition warrants, regardless of the cause of his infection. The physician is obliged to treat such a patient, taking the necessary precautions to protect himself and others.

Article Fifty-Eight:

A patient with an AIDS or another communicable infection should be told how to prevent further deterioration of his condition and to avoid transmitting the disease to other people.

Article Fifty-Nine:

A physician who knows that he himself is HIV-positive or a carrier of some other communicable disease must not engage in any activity

that involves a clear risk of transmitting the disease to his patients, his colleagues, or others. In such a case, the physician should consult the proper authority at the health establishment where he works to determine the tasks he may perform.

Article Sixty:

Taking the stipulation of Article 28 (d) into consideration, a physician should inform the spouse of a patient with AIDS or another communicable disease of his or her spouse's infection in accordance with existing regulations and in the presence of the patient.

Supporting Islamic Legal Evidence:

The purposes of Islamic Law include

1 - self and mind preservation and protection of personal honor,

2 - relieving any strain to which the nation is exposed, and

3 - bringing benefits and preventing harm.

Euthanasia and Physician-Assisted Death

Article Sixty-One:

Human life is sacred, and it should never be wasted except in the cases specified by *shari'a* and the law. This is a question that lies completely outside the scope of the medical profession. A physician should not take an active part in terminating the life of a patient, even if it is at his or his guardian's request, and even if the reason is severe deformity; a hopeless, incurable disease; or severe, unbearable pain that cannot be alleviated by the usual pain killers. The physician should urge his patient to endure and remind him of the reward of those who tolerate their suffering. This particularly applies to the following cases of what is known as mercy killing:

a - the deliberate killing of a person who voluntarily asks for his life to be ended,

b - physician-assisted suicide, and

c - the deliberate killing of newly born infants with deformities that may or may not threaten their lives.

Article Sixty-Two:

The following cases are examples of what is not covered by the term "mercy killing":

a - the termination of a treatment when its continuation is confirmed, by the medical committee concerned, to be useless, and this includes artificial respirators, in as much as allowed by existing laws and regulations;

b - declining to begin a treatment that is confirmed to be useless; and

c - the intensified administration of a strong medication to stop a severe pain, although it is known that this medication might ultimately end the patient's life.

Supporting Islamic Legal Evidence:

The purposes of Islamic Law include

1 - self and mind preservation and protection of personal honor,

2 - relieving any strain to which the nation is exposed, and

3 - bringing benefits and preventing harm.

Abortion

Article Sixty-Three:

A physician should not cause a pregnant woman to abort, unless when medical considerations call for it, the mother's health and life being threatened. Abortion, however, is permissible before the end of the fourth month of pregnancy when it is definitely established that continued pregnancy involves a risk of a serious injury to the mother. This, however, should be confirmed by a medical committee of specialists of no less than three members, one of whom familiar with the disease for which the termination of pregnancy is recommended. The committee members should prepare a report in which they specify

the definite risk that threatens the mother's health if the pregnancy continues. When abortion is recommended, the mother and her husband or guardian should be advised of the fact and their written consent obtained. All other exceptional cases, including pregnancy resulting from rape, should be referred to the authorities of Islamic *fatwa* and legislation, and to the laws and regulations in force.

Supporting Islamic Legal Evidence:

The purposes of Islamic Law include

1 - self and mind preservation and protection of personal honor,

2 - relieving any strain to which the nation is exposed, and

3 - bringing benefits and preventing harm.

Organ Transplants

Article Sixty-Four:

The procedure of transplanting organs from a living donor or a dead body is one of the most important methods of life saving, a method in which the mutual love, sympathy, and compassion of society members is clearly manifested, provided that Islamic ethical and legal controls are exercised.

Article Sixty-Five:

When physicians declare the death of a certain patient who may have donated some of his organs, they should not get directly involved in removing these organs from his body or in the consequent implanting procedures, and should not be the physicians attending the potential recipients of these organs.

Article Sixty-Six:

Before initiating the procedures of organ transplantation in accordance with the applicable legal regulations, a physician should explain to the donor the medical consequences and hazards he may be exposed

to as a result of the procedure. He should also obtain, before the operation, the necessary statements from the donor that indicate his awareness of all such consequences.

Article Sixty-Seven:

It is not permissible to transplant an organ from the body of a living minor to another individual. An exception may be made in the case of regenerative tissues if the law of the nation allows it.

Article Sixty-Eight:

It is not permissible to subject the human body and its components to commercial transactions, and any commerce in organs, tissues, cells, or human genes is prohibited. It is forbidden to advertise the need or the availability of organs in return for a price to be paid or received. A physician should under no circumstances take part in such commercial traffic. Physicians, as well as all other health professionals, should not undertake organ transplant procedures if there is anything that suggests to them that the organs to be transplanted were subject to commercial transactions.

Article Sixty-Nine:

A physician who undertakes an organ transplant procedure should guarantee that full medical care is provided to the donor, ensuring that he would not suffer in any way as a result of that procedure.

Article Seventy:

Physicians are forbidden to transplant testicles or ovaries.

Supporting Islamic Legal Evidence:

The purposes of Islamic Law include

1 - self and mind preservation and protection of personal honor,

2 - relieving any strain to which the nation is exposed, and

3 - bringing benefits and preventing harm..

Cases of Violence

Article Seventy-One:

A physician has the right to report to the proper authorities the cases of violence he learns of in the course of his work, particularly when the victim is a juvenile, a woman, or a helpless person who cannot defend himself either because of old age or due to physical or mental illness, if the physician believes that such an action on his part protects the victim from further physical, mental or psychological violence.

Supporting Islamic Legal Evidence:

The purposes of Islamic Law include

1 - self and mind preservation and protection of personal honor,

2 - relieving any strain to which the nation is exposed, and

3 - bringing benefits and preventing harm..

CHAPTER SIX

ADVERTISEMENT AND THE MEDIA

Chapter Six
Advertisement and the Media

Article Seventy-Two:

What is meant by advertisement and the media is for the doctor to resort, directly or through an intermediary, to conventional visual, auditory, or printed advertisement media - such as newspapers, magazines, visual or auditory broadcasting, and ordinary or electronic mail, as well as other media - to transmit information that introduces the physician, his field of specialization, and his experience.

Article Seventy-Three:

An advertisement may list the physician's degrees, fields of specialization, professional history, experience, and other objective data, as long as none of them is misleading.

Article Seventy-Four:

An advertisement should not include information with the purpose of misleading the receiver, giving a false image, or hiding the side effects of an advertised treatment. Likewise, the advertisement should not be indecent, jeopardize the dignity of the profession, or offend professional colleagues.

Article Seventy-Five:

A physician should not claim for himself or his establishment to have diagnostic or therapeutic skills or services for which he is not qualified or which he is not licensed to perform.

Article Seventy-Six:

A physician should not exploit a patient's ignorance in the field of medicine to mislead him by claiming that the physician is capable of

performing certain diagnostic or therapeutic procedures that have no scientific basis, or by offering a guarantee to cure certain diseases. The content of an advertisement should include only true information, with no exaggeration, and should not include statements in any form that imply superiority to others or discredit them.

Article Seventy-Seven:

A physician should have his name, qualifications, address, and contact data in any local or national directory or in other, similar highly regarded publications. Physicians and specialists who work in the private sector may notify their colleagues and other health establishments of the services and practices they perform.

Article Seventy-Eight:

Although it is necessary to use printed, auditory, and visual media extensively for the purpose of health education and health awareness, it is also necessary to take all precautions to avoid abusing these media for the promotion of a physician in a manner contradictory to the advertisement controls listed above.

Article Seventy-Nine:

Physicians who work in private-sector health establishments or specialized clinics should avoid to advertise the services offered by these establishments in statements in the mass media, papers or articles they write, and the like.

Supporting Islamic Legal Evidence:

The purposes of Islamic Law of self preservation and protection of personal honor should be applied.

CHAPTER SEVEN

PHYSICIAN DUTIES TOWARDS THE ESTABLISHMENT HE WORKS AT

Chapter Seven
Physician Duties towards the Establishment He Works at

Article Eighty:

A physician should protect the reputation and dignity of the establishment at which he works, and should actively contribute to the organization, development, and improvement of the establishment and its performonce.

Article Eighty-One:

He should abide by the laws, bylaws, and regulations applied in that establishment.

Article Eighty-Two:

He should safeguard its property and use it most rationally.

Supporting Islamic Legal Evidence:

I - In the Glorious Quran:

1 - "God commands you to deliver trusts where they are due" (*Al-Nisaa* IV: 58).

2 - "When in his company on a congregational matter, they do not depart before they beg his leave" (*Al-Noor* XXIV: 62).

3 - "Do not withhold a testimony. Any person who withholds it, has a sinful heart. God has knowledge of what you do" (*Al-Baqarah* II: 283).

II - In the Prophet's Tradition:

1 - In an attributed tradition quoting Khawlah of the *Ansaar* (Supporters), "Some men help themselves unjustifiably to God's property; they will get Hellfire on the Day of Resurrection." (Cited by Al-Bukhari.)

2 - In an attributed tradition quoting 'Obaadah Ibn Al-Saamet, "Do not betray the trust you are given; such betrayal is fire and disgrace in this life and the Hereafter for those who practice it." (Verified by Ibn Habbaan.)

3 - In an attributed tradition quoting Anas, "Listen and obey, even if an Abyssinian slave is made a ruler over you." (Cited by Al-Bukhari and Ahmad in his attributed collection.)

CHAPTER EIGHT

RELATIONS WITH COLLEAGUES

Chapter Eight
Relations with Colleagues

Article Eighty-Three:

A physician should behave politely and decently towards his colleagues, and base his relations with them on reciprocal trust, constructive cooperation, and mutual respect. He should refrain from direct criticism of a colleague in front of patients. He should endeavor to teach physicians in his medical team and trainees working with him, and should be precise and honest in evaluating them, giving every member his due, without exaggerated praise and without giving the same evaluation to diligent and negligent staff members.

Article Eighty-Four:

If a physician finds that the intervention of one of his colleagues or superiors may undermine his proper medical performance, or if he fears that such an intervention may be hazardous to the patient, he should have an oral discussion of the matter with the colleague or superior concerned. When they fail to reach an agreement, the matter should be referred in writing to the proper authority for consideration and for making the proper decision.

Article Eighty-Five:

A physician should not charge any fees for examining or treating a colleague, or a member of the immediate family of a colleague (a spouse, a parent, or a child), unless it is a reimbursement for additional expenses paid by the examining or attending physician.

Article Eighty-Six:

A physician should never try to compete with a colleague in a dishonest manner in any professional undertaking.

Article Eighty-Seven:

A physician should settle amicably any differences he may have with a colleague. If no settlement is reached, the matter should be referred to the proper authority for a final decision.

Article Eighty-Eight:

When a physician substitutes for a colleague at the latter's office, he should never take advantage of the situation to serve his own interests. He should inform every patient, before examining him, that he is substituting temporarily for the office owner.

Article Eighty-Nine:

When a physician is asked to visit a patient being treated by another doctor who could not be contacted, the new physician should allow his colleague, as soon as he is back, to carry on with the treatment and inform him of the measures taken, unless the patient or his family want the new doctor to continue.

Article Ninety:

A physician should never demand any share of the fees from one of his colleagues or assistants, unless he has actually taken part in the examination or treatment.

Article Ninety-One:

A physician should respect his non-physician professional colleagues, appreciate their role in the treatment extended to the patient, and refrain from criticizing them in front of patients. He should base his relations with them on reciprocal trust and constructive cooperation to serve the patients' interest. He should endeavor to teach and train them, and make sure they abide by the principles of professional ethics.

Article Ninety-Two:

In dealing with members of the supporting medical staff, a physician should observe the following:

a - He should respect and honor them and make any professional observations to them in a friendly and proper manner;

b - give any instructions to them in writing and with no ambiguity, and make sure, as much as possible, that these instruction are carried out;

c - listen objectively and without any condescension to their observations, criticism, and reservations concerning his treatment instructions; and

d - help in and contribute to their scientific and career advancement and in the updating of their knowledge and skills.

Supporting Islamic Legal Evidence:

I - In the Glorious Quran:

1 - "... merciful with each other...." (*Al-Fatth* XLVIII: 29).

2 - "Cooperate in charity and piety and not in sin and aggression, and fear God; God is severe in His pun" (*Al-Maaedah* V: 2).

3 - "When in his company on a congregational matter, they do not depart before they beg his leave" (*Al-Noor* XXIV: 62).

4 - "And they conduct their affairs by mutual consultation" (*Al-Shura* XLII: 38).

II - In the Prophet's Tradition:

1 - In an attributed tradition quoting Anas, "Listen and obey, even if an Abyssinian slave is made a ruler over you." (Cited by Al-Bukhari and Ahmad in his attributed collection.)

2 - "In their mutual affection, mercy, and compassion, Muslims are similar to a single body."

3 - "Be gentle when serving under your fellows."

CHAPTER NINE

PHYSICIAN RIGHTS

Chapter Nine
Physician Rights

Article Ninety-Three:

A physician has the right to be provided by society with the means of training, acquiring scientific qualification, and drawing regulations that guarantee the high quality of health establishments and their performance, in accordance with internationally recognized standards.

Article Ninety-Four:

A physician has the right to have the opportunity of continuing education through conferences, seminars, scientific gatherings, libraries, scholarships, courses for the refinement of information and skills, and other means. He should not fail to keep up and interact with the latest professional developments in his field of specialization.

Article Ninety-Five:

A physician has the right to be treated by society with due respect and appreciation and be accorded all the human and civil rights enjoyed by other, normal people. He should not to be suspended or prevented from practicing unless this is done within the limits of the law. During any investigation or judicial procedure, his dignity must be respected, he should have legal protection, and he should enjoy the right to defend himself when he commits any violation of the law.

Article Ninety-Six:

A physician has the responsibility to extend the needed care to a patient of his but not to cure him.

Article Ninety-Seven:

When a physician is treating a patient for a fee, it is permissible for them to reach an agreement that payment is contingent on recovery.

Article Ninety-Eight:

A physician should not be influenced physically or morally, or forced to perform or refrain from performing a task related to his professional practice, unless this is done within the limits of the law. He should not be forced to testify against his conscience and should enjoy the full immunity due to him when invited to give an opinion or a technical testimony before a court of law or an investigation authority.

Article Ninety-Nine:

A physician may refer a patient to another doctor or health establishment for diagnosis or treatment, in accordance with the regulations that cover such cases, taking into consideration the following:

a - The doctor to whom the patient is referred should have specialized experience that can benefit the patient.

b - The first physician should communicate, verbally or in writing, to the doctor to whom he is referring the patient the information he believes to be necessary for continuing the treatment.

c - The referral should not be prompted by a belief that the patient's case is incurable or by financial motivation.

Article 100:

A physician has a claim on the health authority members to assist him in carrying out his instructions, to discuss things with him in order to get an explanation whenever possible, and to observe and never go beyond the limits of their profession in their fields of specialization.

Supporting Islamic Legal Evidence:

I - In the Glorious Quran:

1 - "They [i.e. women] have as many rights as they have obligations." (*Al-Baqarah* II: 228).

2 - "A group from each contingent should stay behind, instruct themselves in religion, and admonish their people when they return to them" (*Al-Tawbah* IX: 128).

3 - "The noblest among you in God's consideration are those who fear Him the most" (*Al-Hujuraat* XLIX: 13).

II - In the Prophet's Tradition:

1 - "A person who does not respect our elderly, is not merciful to our young, and does not observe what is due to scholars is not one of us." (Cited by Al-Haakem and Ahmad in his attributed collection.)

2 - In an attributed tradition quoting 'Aisha, "Concede to people their due positions." (Cited by Abu Dawood).

CHAPTER TEN

PHYSICIAN DUTIES TOWARDS HIS PROFESSION

Chapter Ten
Physician Duties towards His Profession

Article 101:

A physician should maintain the dignity and reputation of the medical profession, observe the standards of medical practice, and strive to upgrade the cognitive and scientific aspects of his profession through research, studies, articles, and continuing education and training.

Article 102:

In dealing with a patient, a physician should avoid everything that might undermine his integrity and honesty, or discredit the medical profession. He should strive not to lose the patient's confidence through resorting to deception or fraud, having an inappropriate affair with the patient or one of his/her family members, or making material gain through irregular methods. He should also refrain from seeking fame at the expense of professional ethics and principles.

Article 103:

A physician should give testimony to concerned authorities whenever he is required to do so. Moreover, he should not fail to write honest and precise medical reports according to existing regulation.

Article 104:

A physician should refer a patient to a practitioner of complementary (folk, traditional, alternative) medicine only when the latter is licensed to practice such medicine by the proper health authority.

Supporting Islamic Legal Evidence (1):

I - In the Glorious Quran:

1 - "Recite in the name of your Lord, Who created. He created man from clots of blood. Recite, and your Lord is Most Generous, Who has taught by means of the pen. He taught Man what he had not known" (*Al-'Alaq* XCVI: 1 - 5).

2 - "God will raise in position those of you who believe and are given knowledge" (*Al-Mujaadilah* LVIII: 11).

3 - "We raise whomever we will several degrees, and there is above everyone with knowledge one who is more knowing" (*Yusuf* XII: 76).

4 - "God commands you to deliver trusts where they are due" (*Al-Nisaa* IV: 58).

5 - "Do not withhold a testimony" (*Al-Baqarah* II: 283).

II - In the Prophet's Tradition:

1 - In an attributed tradition quoting Anas, "The pursuit of knowledge is an obligation for every Muslim." (Cited by Al-Baihaqi, Al-Tabaraani, and Ibn 'Odai.)

2 - "People are as equal as a comb's teeth; none have distinction over another except in their fear of God." (Cited by Al-Dailami.)

Article 105:

A physician should serve as an example in maintaining his health and in all his actions. He should take all necessary precautions to protect himself from all potential hazards while practicing his profession.

Article 106:

A physician should never

a - use intermediaries or illegitimate means, whether paid for or not, to attract patients;

b - allow his name to be used for the promotion of medicines, drugs, or any other type of treatment, or for commercial purposes in any form;

c - demand any kind of fee or compensation in return for undertaking to prescribe particular medicines or equipment to patients or for referring them to a health establishment, therapy clinic, nursing home, pharmacy, or any specific place of medical tests and examination or of trading in medical aids and equipment, or act in any way as an agent for another physician or health institution;

d - offer medical consultations for companies that offer such consultation through communication media; and

e - sell any medications, prescriptions, or medical equipment or aids in his clinic, while practicing his job, for commercial purposes.

Article 107:

A physician may engage or participate in telemedicine in as much as permitted by laws and regulations.

PART 2

INTERNATIONAL ETHICAL GUIDELINES FOR BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS

(An Islamic Perspective)

Contents

Introduction to the Research Paper Section

When the Islamic Organization of Medical Sciences contemplated issuing an Islamic code of medical and health ethics, it decided to include the research papers in health fields as an important basic element of the code. Many reasons called for that decision, including:

First: An important role is played by research in general and health research in particular in the awakening of nations.

Second: There is a need to set down ethical principles to be observed in conducting research, establish patient rights, and protect researchers from legal and ethical consequences.

Third: Although the question of research provoked much controversy at the session held to discuss this part of the code, with some participants arguing that no research of outstanding quality is conducted in Arab countries, the fact is that there are two types of research undertaken in some developing countries, including most Arab countries. These are:

A - Research conducted by international institutions on endemics of these countries that are unlikely to occur at industrial countries. This type requires a lot of carefulness and ethical commitment, which should not be influenced by the background of a person, whether he is rich or poor, since all people are equal, regardless of time and place. He should be regarded as a human being who enjoys his full rights, rather than a guinea pig to conduct experiments on.

B - Many - perhaps all - medicines are first discovered and tested in the West. When it is introduced into other countries, it is better to have their effectiveness-evaluated and their side effects monitored when used by citizens of those countries. This is called for because in most Islamic countries the environment is different and so are the habits, type, quantity, and quality of food and drink.

Daily behavior also varies from one country to another. Therefore, increased or reduced dosages may be needed, and some nations may have resistance to a certain new drug for domestic reasons that have no equivalent in the country where the drug has been invented.

Things do not stop at drug testing; research may also be for the purpose of introducing new treatment techniques, including surgeries, such as organ transplants, microinjection, genetic therapy, and cloning.

In addition to the scientific evaluation of treatment and performance, there is another dimension of importance for Islamic countries. Because in Islam things are either permissible or prohibited, before any experiment is begun, it has to be evaluated with reference to the principles of Islamic Law to determine how much of it is permissible and how much prohibited, making every Muslim reassured that all the medicines he take and treatment he receives are under Islamic supervision. It should be noted, however, that Islam has the rule that in necessity, prohibited things are rendered permissible.

Fourth: The task of selecting an international academic reference that sets down research ethics was not easy. Eventually International Ethical Guidelines for

Biomedical Research Involving Human Subjects (An Islamic Perspective)

was chosen for several reasons.

A - This work has been translated to several languages, but not to Arabic. The IOMS took care of having an Arabic translation made, in order for it to be accessible by Arab researchers who are interested in knowing what is going on in the world.

B - Many countries throughout the world have adopted the principles included in this work and observe them when undertaking any research that involves human subjects.

C - About 200 scientists and specialists - representing various disciplines, cultures, and nationalities - collaborated in writing this work, achieving an remarkable outcome and arriving at points of view that are compatible with many human cultures.

Therefore, the IOMS believed it to be the best reference work in the field, and it can be consulted to find out the ethical attitude towards many questions. The IOMS had it translated into Arabic and reviewed by a scholar of Islamic jurisprudence to write down the Islamic rationale of every guideline in it. This Islamic rationale was then referred to a group of jurisprudence scholars, physicians, and people with interest in ethics and the law, in order to check the Islamic point of view in preparation for the discussions on the subject at a conference convened to issue the "The International Islamic Code for Medical and Health Ethics."

This is the outcome that participants at the conference agreed upon after three-day discussions. We have set down that outcome after incorporating the additions, omissions, and amendments requested by the participants.

We pray that we have succeeded in doing what God favors and is satisfied with.

Dr.Ahmed Rajai El- Gendy

Background Of The International Ethical Guidelines for Biomedical Research Involving Human Subjects (CIOMS)

The Council for International Organizations of Medical Sciences (CIOMS) is an international non-governmental organization in official relations with the World Health Organization (WHO). It was founded under the auspices of WHO and the United Nations Educational, Scientific and Cultural and Organization (UNESCO) in 1949. Among the mandates of CIOMS is maintaining collaborative relations with the United Nations and its specialized agencies, particularly with UNESCO and WHO.

CIOMS, in association with WHO, undertook its work on professional ethics in relation to biomedical research in the late 1970s. At that time, newly independent WHO Member States were setting up health-care systems. WHO was not then in a position to promote ethics as an aspect of health care or research. Therefore, CIOMS has set out, in cooperation with WHO, to prepare guidelines to determine "how the ethical principles that should guide the conduct of biomedical research involving human subjects, as set forth in the Declaration of Helsinki, could be effectively applied, particularly in developing countries, given their socioeconomic circumstances, laws and regulations, and executive and administrative arrangements." The World Medical Association had issued the original Declaration of Helsinki in 1964 and an amended version in 1975. The outcome of the CIOMS/WHO undertaking was, in 1982, *Proposed International Ethical Guidelines for Biomedical Research Involving Human Subjects.*

The period that followed saw the outbreak of the HIV/AIDS epidemic and proposals to undertake large-scale experiments with vaccine and treatment drugs for the condition. These raised new ethical issues that had not been considered in the preparation of the

proposed guidelines. There were other factors also: rapid advances in medicine and biotechnology, changing research practices such as multi-national field trials, experimentation involving vulnerable population groups, and a changing view, in rich and poor countries, that research involving human subjects was largely beneficial and not threatening. The Declaration of Helsinki was revised twice in the 1980s: in 1983 and 1989. It was timely to revise and update the 1982 guidelines, and CIOMS, with the cooperation of WHO and its Global Programme on AIDS, undertook the task. The outcome was the issuing of two sets of guidelines: in 1991, *International Guidelines for Ethical Review of Epidemiological Studies*; and, in 1993, *International Ethical Guidelines for Biomedical Research Involving Human Subjects.*

After 1993, ethical issues arose for which the CIOMS Guidelines had no specific provision. They related mainly to controlled clinical trials, with external sponsors and investigators, carried out in countries with moderate resources, and to the use of comparators other than the established effective intervention techniques. The issue in question was the perceived need in those countries for low-cost, technologically appropriate, public-health solutions, and in particular, for HIV/AIDS treatment drugs or vaccines that poorer countries could afford. Some may advocate, for low-resource countries, trials of interventions that, while they might be less effective than the treatment available in better-off countries, would be less expensive. Others may believe that all research efforts for public solutions appropriate to developing countries should not be rejected as unethical. The research context should be considered, and local decision-making should be the norm. Paternalism on the part of the richer countries towards poorer countries should be avoided. The challenge was to encourage research for local solutions to the burden of disease in much of the world, while providing clear guidance on protecting against exploitation of vulnerable communities and individuals.

Another group argued that such trials constituted, or risked constituting, exploitation of poor countries by rich countries and were inherently unethical. Economic factors should not influence ethical considerations, they said. It was within the capacity of rich countries

or the pharmaceutical industry to make established effective treatment available for comparator purposes. Certain low-resource countries had already made available from their own resources established effective treatment for their HIV/AIDS patients.

This conflict between the two sides complicated the revision and updating of the 1993 Guidelines. Ultimately, it became clear that the conflicting views could not be reconciled, though the proponents of the former view claimed that the new guidelines had built in effective safeguards against exploitation. The commentary on the Guideline concerned (Guideline 11) recognizes the unresolved, or irresolvable, conflict.

The revision/updating of the 1993 *Guidelines* began in December 1998, and a first draft prepared by the CIOMS consultant for the project was reviewed by the project Steering Committee, which met in May 1999. The committee proposed amendments and listed topics which the new or revised guidelines addressed. It recommended papers to be commissioned on those topics and invited authors and commentators for presentation and discussion of these papers at a CIOMS interim consultation office. It was considered that an interim consultation meeting, of members of the Steering Committee, together with the authors of commissioned papers and designated commentators, followed by further redrafting and electronic distribution and feedback, would better serve the purpose of the project than the process originally envisaged, which had been to complete the revision in one further step. The consultation was accordingly organized for March 2000, in Geneva.

At the consultation meeting, progress on the revision was reported and contentious matters reviewed. Eight commissioned papers previously distributed were presented, commented upon, and discussed. The consultation continued with ad hoc electronic working groups over the following several weeks, and the outcome was made available for the preparation of the third draft. The material commissioned for the consultation was made the subject of a CIOMS publication: *Biomedical Research Ethics: Updating International Guidelines. A Consultation* (December 2000).

An informal redrafting group of eight - from Africa, Asia, Latin America, the United States and the CIOMS secretariat - met in New York City in January 2001, and subsequently, its members interacted electronically with one another and with the CIOMS secretariat. A revised draft was posted on the CIOMS website in June 2001 and otherwise widely distributed. Many organizations and individuals commented, some extensively, some critically. Views on certain positions, notably on placebo-controlled trials, were contradictory. For the subsequent revision two members were added to the redrafting group, from Europe and Latin America. The new draft was posted on the website in January 2002 in preparation for the CIOMS Conference in February/March 2002.

The CIOMS Conference was convened to discuss and, as far as possible, endorse a final draft to be submitted to the CIOMS Executive Committee for final approval. Besides representation of member organizations of CIOMS, participants included experts in ethics and research from all continents. They reviewed the draft guidelines seriatim and suggested modifications. Guideline 11, *Choice of Control in Clinical Trials*, was redrafted at the conference in an effort to reduce disagreement. The redrafted text of that guideline was intensively discussed and generally well received. Some participants, however, continued to question the ethical acceptability of the exception to the general rule limiting the use of placebo medicines, given to patients, to the conditions set out in the guideline; they argued that research subjects should not be exposed to risk of serious or irreversible harm when an established effective intervention could prevent such harm, and that such exposure could constitute exploitation. Ultimately, the commentary of Guideline 11 reflects the opposing positions on the use of a comparator other than an established effective intervention for control purposes.

The new text, the 2002 text, which supersedes that of 1993, consists of a statement of general ethical principles, a preamble, and twenty one guidelines, with an introduction and a brief account of earlier declarations and guidelines. Like the 1982 and 1993 *Guidelines*, the present publication is designed to be of use, particularly to low-

resource countries, in defining national policies on the ethics of biomedical research, applying ethical standards in local circumstances, and establishing or redefining adequate mechanisms for the ethical review of research involving human subjects

Comments on the Guidelines are welcome and should be addressed to the Secretary-General, Council for International Organizations of Medical Sciences, c/o World Health Organization, CH-1211 Geneva 27, Switzerland; or by e-mail to cioms@who.int

Introduction Of The International Ethical Guidelines for Biomedical Research Involving Human Subjects (CIOMS)

This is the third in the series of international ethical guidelines for biomedical research involving human subjects issued by the Council for International Organizations of Medical Sciences (CIOMS) since 1982. Its scope and preparation reflect well the transformation that has occurred in the field of research ethics in the almost quarter century since CIOMS first undertook to make this contribution to medical sciences and the ethics of research. The CIOMS Guidelines, with their stated concern for the application of the Declaration of Helsinki in developing countries, reflect the conditions and the needs of biomedical research in those countries, and the implications for multinational or transnational research in which these countries may take part.

An issue, mainly related to those countries and perhaps less relevant now than in the past, has been the extent to which ethical principles are considered as universal or as culturally relative - the universalist versus the pluralist view. The challenge to international research ethics is to apply universal ethical principles to biomedical research in a multicultural world with a multiplicity of health-care systems and considerable variation in health care standards. From the point of view of he Guidelines, research involving human subjects must not violate any universally applicable ethical standards, but the Guidelines acknowledge that, in superficial aspects, the application of the ethical principles, e.g., in relation to individual autonomy and informed consent, needs to take account of cultural values, while respecting absolutely the ethical standards.

Related to this issue is the question of the human rights of research subjects, as well as of health professionals as researchers in a variety

of socio-cultural contexts, and the contribution that international human rights instruments can make in the application of the general principles of ethics to research involving human subjects. The issue concerns largely, though not exclusively, two principles: respect for autonomy and protection of dependent or vulnerable persons and populations. In the preparation of the *Guidelines*, the potential contribution in these respects of human rights instruments and norms was discussed, and the *Guideline* drafters have represented the views of commentators on safeguarding the corresponding rights of subjects.

Certain areas of research are not represented by specific guidelines. One such area is human genetics. It is, however, considered in Guideline 18 under *Issues of Complete Confidentiality in Genetics*. The ethics of genetics research was the subject of a commissioned paper and of the commentary it stimulated.

Another unrepresented area is research with products of conception (embryo and fetal research, and fetal tissue research). An attempt to craft a guideline on the topic proved unfeasible. The controversy continues over the moral status of embryos and fetuses and the degree to which risks to the life or well-being of these entities are ethically permissible.

In relation to the use of comparators in controls, commentators have raised the question of the standard of care to be provided to a control group. They emphasized that "standard of care" refers to more than the comparator drug or other intervention, and that research subjects in the poorer countries do not usually enjoy the same standard of comprehensive care enjoyed by subjects in richer countries. This issue is not addressed specifically in the *Guidelines*.

In one respect, the *Guidelines* depart from the terminology of the Declaration of Helsinki. 'Best current intervention' is the term most commonly used to describe the active comparator that is ethically preferred in controlled clinical trials. For many indications, however, there is more than one established "current" intervention and expert clinicians do not agree on which is superior. In other circumstances in which there are several established "current" interventions, some expert clinicians recognize one as superior to the rest; some commonly

prescribe another because the superior intervention may be locally unavailable, for example, or prohibitively expensive or unsuited to the capability of particular patients to adhere to a complex and rigorous regimen. "Established effective intervention" is the term used in Guideline 11 to refer to all such interventions, including the best and the various alternatives to the best. In some cases an ethical review committee may determine that it is ethically acceptable to use an established effective intervention as a comparator, even in cases where such an intervention is not considered the best current intervention.

The mere formulation of ethical guidelines for biomedical research involving human subjects will hardly resolve all the moral doubts that can arise in association with much research, but the Guidelines can at least draw the attention of sponsors, investigators and ethical review committees to the need to consider carefully the ethical implications of research protocols and the conduct of research, and thus conduce to high scientific and ethical standards of biomedical research.

International Instruments and Guidelines

The first international instrument on the ethics of medical research, the Nuremberg Code, was promulgated in 1947 as a consequence of the trial of physicians who had conducted atrocious experiments on prisoners and detainees, without obtaining the subjects' consent, during the second world war. The Code, designed to protect the integrity of the research subject, set out conditions for the ethical conduct of research involving human subjects, emphasizing their voluntary consent to research.

The United Nations General Assembly adopted the Universal Declaration of Human Rights in 1948. To give the Declaration greater legal, as well as moral, force, the General Assembly adopted in 1966 the International Covenant on Civil and Political Rights. Article 7 of the Covenant states that "*No one shall be subjected to torture or to cruel, inhuman, or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation.*" It is through this statement that society expresses the fundamental human value that is held to govern all research involving human subjects - the protection of the rights and welfare of all human subjects of scientific experimentation.

The Declaration of Helsinki, issued by the World Medical Association in 1964, is the fundamental document in the field of ethics in biomedical research and has influenced the formulation of international, regional and national legislation and codes of conduct. The Declaration, amended several times, most recently in 2000 (Appendix 2), is a comprehensive statement of the ethics of research involving human subjects. It sets out ethical guidelines for physicians engaged in both clinical and non-clinical biomedical research.

Since the publication of the CIOMS 1993 *Guidelines*, several international organizations have issued ethical guidance on clinical

trials. This has included, from the World Health Organization, in 1995, *Guidelines for Good Clinical Practice for Trials on Pharmaceutical Products*; and from the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), in 1996, *Guideline on Good Clinical Practice*, designed to ensure that data generated from clinical trials are mutually acceptable to regulatory authorities in the European Union, Japan and the United States of America. The Joint United Nations Program on HIV/AIDS (UNAIDS) published in 2000 the UNAIDS Guidance Document *Ethical Considerations in HIV Preventive Vaccine Research*, issued by the United Nations International Development Agency.

In 2001 the Council of Ministers of the European Union adopted a Directive on clinical trials, which will be binding in law in the countries of the Union from 2004. The Council of Europe, with more than 44 member States, is developing a Protocol on Biomedical Research, which will be an additional protocol to the Council's 1997 Convention on Human Rights and Biomedicine.

Not specifically concerned with biomedical research involving human subjects but clearly pertinent, as noted above, are international human rights instruments. These are mainly the Universal Declaration of Human Rights, which, particularly in its science provisions, was highly influenced by the Nuremberg Code; the International Covenant on Civil and Political Rights; and the International Covenant on Economic, Social, and Cultural Rights. Since the Nuremberg experience, human rights law has expanded to include the protection of women (Convention on the Elimination of All Forms of Discrimination Against Women) and children (Convention on the Rights of the Child). In terms of human rights, all these instruments endorse the general ethical principles published by CIOMS.

General Ethical Principles

"All research involving human subjects should be conducted in accordance with three basic ethical principles, namely respect for persons, beneficence, and justice. It is generally agreed that these principles, which in the abstract have equal moral force, guide the conscientious preparation of proposals for scientific studies. In varying circumstances they may be expressed differently and given different moral weight, and their application may lead to different decisions or courses of action. The present guidelines are directed at the application of these principles to research involving human subjects.

"Respect for persons incorporates at least two fundamental considerations related to professional ethics, namely:

a - respect for autonomy, which requires that those who are capable of deliberation about their personal choices should be treated with respect for their capacity for self-determination; and

b - protection of persons with impaired or diminished autonomy, which requires that those who are dependent or vulnerable be afforded security against harm or abuse."

Beneficence refers to the ethical obligation to maximize benefits and to minimize harms. This principle gives rise to norms requiring that the risks of research be reasonable in the light of the expected benefits, that the research design be sound, and that the investigators be competent both to conduct the research and to safeguard the welfare of research subjects. Beneficence further proscribes the deliberate infliction of harm on persons; this aspect of beneficence is sometimes expressed as a separate principle: *nonmaleficence* (do no harm).

Justice refers to the ethical obligation to treat each person in accordance with what is morally right and proper and to give each person what is due to him or her. In the ethics of research involving

human subjects, the principle refers primarily to *distributive justice*, which requires the equitable distribution of both the burdens and the benefits of participation in research. Differences in distribution of burdens and benefits are justifiable only if they are based on morally relevant distinctions between persons; one such distinction is vulnerability, which refers to a substantial incapacity to protect one's own interests owing to such impediments as lack of capability to give informed consent, lack of alternative means of obtaining medical care or other expensive necessities, or being a junior or subordinate member of a hierarchical group. Accordingly, special provision must be made for the protection of the rights and welfare of vulnerable persons.

Sponsors of research or investigators cannot, in general, be held accountable for unjust conditions where the research is conducted, but they must refrain from practices that are likely to worsen unjust conditions or contribute to new inequities. Neither should they take advantage of the relative inability of low-resource countries or vulnerable populations to protect their own interests, by conducting research inexpensively and avoiding the complex regulatory systems of industrialized countries in order to develop products for the lucrative markets of those countries.

In general, the research project should leave low-resource countries or communities better off or, at least, no worse off than before. The project should meet their health needs and priorities in that any product developed is made reasonably available to them. As far as possible, the project should leave the population in a better position to obtain effective health care and protect its own health.

Justice requires also that the research be responsive to the health conditions or needs of vulnerable subjects. The subjects selected should be the least vulnerable necessary to accomplish the purposes of the research. Risk to vulnerable subjects is most easily justified when it arises from interventions or procedures that hold out for them the prospect of direct health-related benefit. Risk that does not hold out such prospect must be justified by the anticipated benefit to the population of which the individual research subject is representative.

Preamble

The term "research" refers to a class of activity designed to develop or contribute to general knowledge. General knowledge consists of theories, principles, or relationships, or the accumulation of information on which they are based, that can be corroborated by accepted scientific methods of observation and inference. In the present context, "research" includes both medical and behavioral studies pertaining to human health. Usually "research" is modified by the adjective "biomedical" to indicate its relation to health.

Progress in medical care and disease prevention depends upon an understanding of physiological and pathological processes or epidemiological findings, and requires in some cases research involving human subjects. The collection, analysis, and interpretation of information obtained from research involving human beings contribute significantly to the improvement of human health.

Research involving human subjects includes:

- studies of a physiological, biochemical, or pathological process, or of the response to a specific intervention - whether physical, chemical or psychological - in healthy subjects or patients;
- controlled trials of diagnostic, preventive, or therapeutic measures in larger groups of persons, designed to demonstrate a specific generalizable response to these measures against a background of individual biological variation;
- studies designed to determine the consequences for individuals and communities of specific preventive or therapeutic measures; and
- studies concerning human health-related behavior in a variety of circumstances and environments.

Research involving human subjects may employ either observation or physical, chemical, or psychological intervention; it may also either generate records or make use of existing records containing biomedical

or other information about individuals who may or may not be identifiable from the records and information. The use of such records and the protection of the confidentiality of data obtained from those records are discussed in *International Guidelines for Ethical Review of Epidemiological Studies* (CIOMS, 1991).

The research may be concerned with the social environment, manipulating environmental factors in a way that could affect incidentally-exposed individuals. The definition of research is made in broad terms in order to embrace field studies of pathogenic organisms and toxic chemicals under investigation for health-related purposes.

Biomedical research with human subjects is distinguished from the practice of medicine, public health and other forms of health care, which is designed to contribute directly to the health of individuals or communities. Prospective subjects may find it confusing when research and practice are conducted simultaneously, as when research is designed to obtain new information about the efficacy of a drug or other therapeutic, diagnostic, or preventive modality.

As stated in Paragraph 32 of the Declaration of Helsinki,

> In the treatment of a patient, where proven prophylactic, diagnostic, and therapeutic methods do not exist or have been ineffective, the physician, with informed consent from the patient, must be free to use unproven or new prophylactic, diagnostic, and therapeutic measures, if in the physician's judgment it offers hope of saving life, re-establishing health, or alleviating suffering. Where possible, these measures should be made the object of research, designed to evaluate their safety and efficacy. In all cases, new information should be recorded and, where appropriate, published. The other relevant guidelines of this Declaration should be followed.

Professionals whose roles combine investigation and treatment have a special obligation to protect the rights and welfare of the patient-subjects. An investigator who agrees to act as physician-investigator undertakes some or all of the legal and ethical responsibilities of the subject's primary-care physician. In such a case, if the subject withdraws from the research owing to complications related to the research

or in the exercise of the right to withdraw without loss of benefit, the physician has an obligation to continue to provide medical care, to see that the subject receives the necessary care in the health-care system, or to offer assistance in finding another physician.

Research with human subjects should be carried out only by, or strictly supervised by, suitably qualified and experienced investigators and in accordance with a protocol that clearly states: the aim of the research, the reasons for proposing the involvement of human subjects in it, the nature and degree of any known risks to the subjects, the sources from which it is proposed to recruit subjects, and the means proposed for ensuring that subjects' consent will be adequately informed and voluntary. The protocol should be scientifically and ethically appraised by one or more suitably constituted review bodies, independent of the investigators.

New vaccines and medicinal drugs, before being approved for general use, must be tested on human subjects in clinical trials; such trials constitute a substantial part of all research involving human subjects.

The General Principles of Professional Ethics

Foreword

1 - Islam does not object to, but rather promotes, medical research. It encourages individuals to get involved in such research, as it has a public benefit and is closely related to a community obligation, which is medical advancement.

2 - The guidelines prepared by CIOMS in collaboration with WHO generally conforms with the basic principles inspired by human nature. They are aspects of wisdom, and conforming to them is a requirement of Islamic Law.

3 - At the request of the Islamic Organization of Medical Sciences (IOMS), experts of Islamic jurisprudence and of medical, anthropological, and legal studies have reviewed the guidelines in the light of the principles and rulings of Islamic Law in order to point out the Islamic point of view in each guideline, supported by evidence and citations from reliable jurisprudence sources. This undertaking aims at demonstrating that the guidelines are worthy of implementation by governments, medical establishments, and Islamic communities.

4 - These guidelines are based on the following major principles:

- respect of individuals (honoring human beings),
- benefit (attainment of benefits and prevention of harm), and
- justice (including the equitable distribution of burdens and of benefits).

One more principle is worth being added to these, and that is

- charity (in the sense of donating more than required by duty and the attainment of equity).

The Islamic Point of View Concerning The General Principles of Professional Ethics

The first principle, namely the respect for persons in the manner detailed above, is a basic rule of Islamic Law, for this respect is an aspect of the dignity of a human being, which is declared in the Holy Quran, where God says, "We have honored Adam's children" (*Al-Israa* XVII: 70).

a - In the case of a person with full competence, i.e. one who is capable of self-determination, it is obligatory to respect his autonomy and allow him to make his own choices and to have the full satisfaction and freedom of making the decision that suits him best, without any coercion, deceit, or exploitation.

The general rules of Islamic jurisprudence confirm this principle, for one of its provisions is that "No one is entitled to dispose of the right of a human being without his permission."(1) A person's right cannot be annulled without his permission;(2) Islam never annuls human rights.

b - In the case of a person with imperfect or no competence, i.e. one whose autonomy is deficient or lacking, Islamic Legislation observes his need to be protected from other people who might take advantage of his weakness and of misconduct against his own interest, due to being unable to manage his affairs and perceive his interests properly. Therefore, Islamic law prevents his autonomy in managing his affairs and does not hold him responsible for his statements, which might be exploited by others. Thus, the general rules of Islamic jurisprudence stipulate that "A

(1) Ibn Qaddama, *Al-Mughni*, IV: 552.

(2) Al-Kasaani, *Badaai' Al-Sanaai'*, V: 251.

statement of a person unable to act properly cannot be admitted."[3] It also stipulates that a guardian should be chosen to run the affairs and attend to the needs of such a person, safeguarding his interest and protecting him from exploitation by others.

The second principle - which is beneficence in the sense of ethical commitment to maximize benefits, prevent harm, refrain from the deliberate injury of others, and minimize inevitable injury - is also a confirmed rule of Islamic Law. It is covered by the general intent and overall objective of that law, namely "securing benefits for people and protecting them from harm." On this point Al-Qaraafi says, "God the Almighty sent his messengers, peace be upon them, to establish the benefits of people by induction, in the sense that whenever a benefit is discovered it is deemed most likely that it is required by law."[4]

As Judge Ibn Al-'Arabi says, what is meant by "benefit" is "every item that fulfills the rules of the Law and bring a general advantage to people."[5]

On the other hand, it is stipulated in the rules of Islamic jurisprudence that "Every action that leads to harm or prevents a benefit is forbidden."[6] Nor is an instance of harm to be absolutely rejected by reason and law for all times and by all people and entities.[7] This applies to cases of absolute harm.

In cases where benefit and harm are not absolute, the greater, more corruptive harm is prevented through the commission of the lesser one. This is stipulated in the following rules of jurisprudence: (1) "Prevention of the greater of two instances of harms through the lesser one is mandatory."[8] (2) "When there is a conflict between two reprehensive, forbidden, or injurious alternatives and they cannot be

(3) Al-Toofi, *Sharh Al-Rawdhah*, II: 208.

(4) Sharh Tanqeeh Al-Fusool, p. 446.

(5) Al-Qabas: Sharh Al-Muwatta, II: 779.

(6) Al-'Iz Ibn 'Abd Al-Salaam, *Al-Qawaa'ed Al-Kubra*, II: 158.

(7) Al-Toofi, *Sharh Al-Rawdhah*, III: 379.

(8) Al-Nawawi, *Tahtheeb Al-Asmaa wa Al-Lughaat*, II: 130.

both avoided, the less harmful one should be chosen."[9] (3) "The greater of two instances of harm should be prevented by tolerating the lesser one."[10] (4) "When two instances of harm are in conflict with each other, [prevention of] the greater is complied with through the commission of the lesser."[11] (5) "If a less substantial instance of harm and an outweighing benefit are in conflict, the harm is forgiven for the sake of the benefit."[12]

Ibn Taimiyah points out the basis of these rules, saying, "It is not right to ward off little harm with a lot of harm, nor to ward off a less serious injury with a more serious one; Islamic Law calls for recognition and completion of benefits and the prevention and reduction of harm. It requires that priority should be given to one of two benefits, if they cannot both be concurrently pursued, and that the worse of two instances of harm be prevented, if they cannot both be concurrently prevented."[13]

Justice, **the third principle**, in the sense of the ethical obligation to treat each person in accordance with what is morally right and proper and to give each person what is due to him or her, is likewise an established principle in Islamic Law. It is an application of the principle that justice and equity must prevail. The Law establishes the bases of that principle and regards it as the foundation of righteousness and success in this world. Indeed, the aim of all prophets, messengers of God, and divine books is to make that principle govern human life. God says, "We have sent Our messengers with explicit signs, and sent down with them the Book and the Scale, that people may stand in justice" (*Al-Hadeed* LVII: 25), which includes equity and fairness.

(9) Al-Wanshareesi, *Eedhaah Al-Masaalek*, p. 234; Al-Muqri, *Al-Qawaa'ed*, II: 456.

(10) Ibn Taimiyah, *Majmou' Fataawa Ibn Taimiyah*, XXIX: 485; Al-Sa'di, *Al-Maamool*, p. 31.

(11) Al-Majallah Al-'Adliyah, vol. 28; Al-Sayooti, *Al-Ashbaah wa Al-Nazhaaer*, p.178; Ibn Bakheem, p. 98.

(12) Al-Qaraafi, *Al-Thakheerah*, X: 190.

(13) Al-Massel Al-Mardeeniyah, p. 63.

Ibn Al-Qayyem says, "God makes clear, through the methods He prescribes, that His purpose is to establish equity among people and that they may stand in justice. Any method that brings out equity and justice is in harmony with, rather than in violation of, religious teachings."(14)

In *Al-Qawaa'ed Al-Kubra (Major Rules)*, Al-'Iz Ibn 'Abd Al-Salaam says:

> The most inclusive Quranic verse in promoting all benefits and admonishing all harm is that in which God, the Most Supreme, says, "God enjoins justice and charity" (*Al-Nahl* XVI: 90), where using the definite article before the [Arabic] nouns denoting justice and charity implies generalization and continuity. Every single aspect of justice and charity, whether a small detail or a major part, is included in His command that enjoins charity. Justice means equity and fairness, and charity is either the acquisition of a benefit or the prevention of harm.(15)

(14) Al-Turuq Al-Hakamiyah, p. 13.

(15) II: 315.

International Ethical Guidelines for Biomedical Research Involving Human Subjects (CIOMS)

Guideline 1
Ethical Justification and Scientific Validity of Biomedical Research Involving Human Beings

Islamic Perspective

The ethical justification of biomedical research involving human subjects is the prospect of discovering new ways of benefiting people's health. Such research can be ethically justifiable only if it is carried out in ways that respect and protect, and are fair to, the subjects of that research and are morally acceptable within the communities in which the research is carried out. Moreover, because scientifically invalid research is unethical in that it exposes research subjects to risks without possible benefit, investigators and sponsors must ensure that proposed studies involving human subjects conform to generally accepted scientific principles and are based on adequate knowledge of the pertinent scientific literature.

Commentary on Guideline 1

Among the essential features of ethically justified research involving human subjects, including research with identifiable human tissue or data, are that the research offers a means of developing information not otherwise obtainable, that the design of the research is scientifically sound, and that the investigators and other research personnel are competent. The methods to be used should be appropriate to the objectives of the research and the field of study. Investigators and sponsors must also ensure that all who participate in the conduct of

the research are qualified by virtue of their education and experience to perform their roles competently. These considerations should be adequately reflected in the research protocol submitted for review and clearance to scientific and ethical review committees (Appendix I).

Scientific review is discussed further in the Commentaries to Guidelines 2 and 3: *Ethical review committees* and *Ethical review of externally sponsored research.* Other ethical aspects are discussed in the remaining guidelines and their commentaries. The protocol designed for submission for review and clearance to scientific and ethical review committees should include, when relevant, the items specified in Appendix I, and should be carefully followed in conducting the research.

The Islamic Point of View Concerning Guideline 1 (Ethical Justification and Scientific Validity of Biomedical Research Involving Human Beings)

The Islamic Point of View

From the point of view of Islamic jurisprudence, justification and rationalization of such research is contingent on the following:

1 - The purpose of conducting it is to secure an absolute benefit, which enhances human health; prevent an instance of absolute harm, which impairs that health; or give priority to securing an outweighing benefit over preventing a less substantial instance of harm, if they are in conflict and only one of them can be realized, for "The majority [of scholars] agree that a less substantial harm is forgiven when coupled with an outweighing benefit."(16) Ibn Taimiyah says, "Islamic Law is built upon the recognition and completion of benefits and prevention and reduction of harm. It is required that the better of two good things should be given priority by abandoning the inferior one, and the worse of two evil things be prevented, even if the inferior one does take place."(17)

2 - The [absolute or outweighing] benefit must be real in the sense that it does not violate a legal stipulation made in the Quran or in the Prophet's *Sunna*, nor contradicts any of the firmly established, absolute principles or rulings of Islamic jurisprudence.

3 - The means to reach the goal, i.e. the research itself, should be legitimate, as the end does not justify the means, and both means and end must be legally permissible.

(16) As Al-Qarfi says *Al-Akheerah*, XIII: 322.

(17) *Majmou' Fataawa Ibn Taimiyah*, XXX: 193, and *Mukhtasar Al-Fataawa Al-Masriyah*, p. 383.

4 - The design of the research must be scientifically sound, which means that it should be more likely to achieve the sound purpose it is expected to accomplish. Otherwise, it would be in vain that man is honored and protected from being a guinea pip used in experiments. God says, "We have honored Adam's children" (*Al-Israa* XVII: 70). One rule of Islamic jurisprudence is that "Every action that ceases to pursue its objective is unacceptable."(18)

5 - The research team members must be qualified and competent enough to conduct their research successfully, since the desired end is contingent on their being so. A rule of Islamic Law is that, "Anything vital for the discharge of an obligation is itself an obligation."(19)

In addition, a rule of Islamic Law says that "the person placed to be placed in charge in every situation is the one most capable of achieving the interests involved in that situation."

(18) Al-'Iz Ibn 'Abd Al-Salaam, *Al-Qawaa'ed Al-Kubra*, II: 249.

(19) *Ibid.*, II: 337.

Guideline 2
Ethical Review Committees

All proposals to conduct research involving human subjects must be submitted to one or more scientific review and ethical review committees for review of their scientific merit and ethical acceptability. The review committees must be independent of the research team, and any direct financial or other material benefit they may derive from the research should not be contingent on the outcome of their review. The investigator must obtain their approval or clearance before undertaking the research. The ethical review committee should conduct further reviews as necessary in the course of the research, including monitoring of the progress of the study.

Commentary on Guideline 2

Ethical review committees may function at the institutional, local, regional, or national level, and in some cases at the international level. The regulatory or other governmental authorities concerned should promote uniform standards across committees within a country, and, under all systems, sponsors of research and institutions in which the investigators are employed should allocate sufficient resources to the review process. Ethical review committees may receive money for the activity of reviewing protocols, but under no circumstances may payment be offered or accepted for a review committee's approval or clearance of a protocol.

Scientific Review. According to the Declaration of Helsinki (*Paragraph 11*), medical research involving humans must conform to generally accepted scientific principles, and be based on a thorough knowledge of the scientific literature, other relevant sources of information, and adequate laboratory and, where indicated, animal experimentation. Scientific review must consider, inter alia, the study

design, including the provisions for avoiding or minimizing risk and for monitoring safety. Committees competent to review and approve scientific aspects of research proposals must be multidisciplinary.

Ethical Review. The ethical review committee is responsible for safeguarding the rights, safety, and well-being of the research subjects. Scientific review and ethical review cannot be separated: scientifically unsound research involving humans as subjects is *ipso facto* unethical in that it may expose them to risk or inconvenience to no purpose; even if there is no risk of injury, the wasting of subjects' and researchers' time in unproductive activities represents loss of a valuable resource. Normally, therefore, an ethical review committee considers both the scientific and the ethical aspects of proposed research. It must either carry out a proper scientific review or verify that a competent expert body has determined that the research is scientifically sound. Also, it considers provisions for the monitoring of data and safety.

If the ethical review committee finds a research proposal scientifically sound, or verifies that a competent expert body has found it so, it should then consider whether any known or possible risks to the subjects are justified by the expected benefits, direct or indirect, and whether the proposed research methods will minimize harm and maximize benefit. (See Guideline 8: *Benefits and Risks of Study Participation.*) If the proposal is sound and the balance of risks to anticipated benefits is reasonable, the committee should then determine whether the procedures proposed for obtaining informed consent are satisfactory and those proposed for the selection of subjects are equitable.

Ethical Review of Emergency Compassionate Use of an Investigational Therapy. In some countries, drug regulatory authorities require that the so-called compassionate or humanitarian use of an investigational treatment be reviewed by an ethical review committee as though it were research. Exceptionally, a physician may undertake the compassionate use of an investigational therapy before obtaining the approval or clearance of an ethical review committee, provided three criteria are met: a patient needs emergency treatment, there is some evidence of possible effectiveness of the investigational treatment, and

there is no other treatment available that is known to be equally effective or superior. Informed consent should be obtained according to the legal requirements and cultural standards of the community in which the intervention is carried out. Within one week the physician must report to the ethical review committee the details of the case and the action taken, and an independent health-care professional must confirm in writing to the ethical review committee the treating physician's judgment that the use of the investigational intervention was justified according to the three specified criteria. (See also Guideline **13 Commentary section:** ***Other Vulnerable Groups.)***

National (Centralized) or Local Review. Ethical review committees may be created under the aegis of national or local health administrations, national (or centralized) medical research councils, or other nationally representative bodies. In a highly centralized administration a national, or centralized, review committee may be constituted for both the scientific and the ethical review of research protocols. In countries where medical research is not centrally administered, ethical review is more effectively and conveniently undertaken at a local or regional level. The authority of a local ethical review committee may be confined to a single institution or may extend to all institutions in which biomedical research is carried out within a defined geographical area. The basic responsibilities of ethical review committees are:

- to determine that all proposed interventions, particularly the administration of drugs and vaccines, or the use of medical devices or procedures under development, are acceptably safe to be undertaken in humans or to verify that another competent expert body has done so;
- to determine that the proposed research is scientifically sound or to verify that another competent expert body has done so;
- to ensure that all other ethical concerns arising from a protocol are satisfactorily resolved both in principle and in practice;
- to consider the qualifications of the investigators, including education in the principles of research practice, and the conditions of the research site with a view to ensuring the safe conduct of the trial; and

- to keep records of decisions and to take measures to follow up on the conduct of ongoing research projects.

Committee Membership. National or local ethical review committees should be so composed as to be able to provide complete and adequate review of the research proposals submitted to them. It is generally presumed that their membership should include physicians, scientists, and other professionals such as nurses, lawyers, ethicists, and clergy, as well as lay persons qualified to represent the cultural and moral values of the community and to ensure that the rights of the research subjects will be respected. They should include both men and women. When uneducated or illiterate persons form the focus of a study they should also be considered for membership or invited to be represented and have their views expressed.

A number of members should be replaced periodically with the aim of blending the advantages of experience with those of fresh perspectives.

A national or local ethical review committee responsible for reviewing and approving proposals for externally sponsored research should have among its members or consultants persons who are thoroughly familiar with the customs and traditions of the population or community concerned and sensitive to issues of human dignity.

Committees that often review research proposals directed at specific diseases or impairments, such as HIV/AIDS or paraplegia, should invite or hear the views of individuals or bodies representing patients with such diseases or impairments, so that there views may be submitted or verbally expressed. Similarly, for research involving such subjects as children, students, elderly persons, or employees, committees should invite or hear the views of their representatives or advocates.

To maintain the review committee's independence from the investigators and sponsors and to avoid conflict of interest, any member with a special or particular, direct or indirect, interest in a proposal should not take part in its assessment if that interest could subvert the member's objective judgment. Members of ethical review committees should be held to the same standard of disclosure as scientific and

medical research staff with regard to financial or other interests that could be construed as conflicts of interest. A practical way of avoiding such conflict of interest is for the committee to insist on a declaration of possible conflict of interest by any of its members. A member who makes such a declaration should then withdraw, if to do so is clearly the appropriate action to take, either at the member's own discretion or at the request of the other members. Before withdrawing, the member should be permitted to offer comments on the protocol or to respond to questions of other members.

Multi-Center Research. Some research projects are designed to be conducted in a number of centers in different communities or countries. Generally, to ensure that the results will be valid, the study must be conducted in an identical way at each center. Such studies include clinical trials, research designed for the evaluation of health service programs, and various kinds of epidemiological research. For such studies, local ethical or scientific review committees are not normally authorized to change doses of drugs, to change inclusion or exclusion criteria, or to make other similar modifications. They should be fully empowered to prevent a study that they believe to be unethical. Moreover, changes that local review committees believe are necessary to protect the research subjects should be documented and reported to the research institution or sponsor responsible for the whole research program for consideration and due action, to ensure that all other subjects can be protected and that the research will be valid across sites.

To ensure the validity of multi-center research, any change in the protocol should be made at every collaborating center or institution, or, failing this, explicit inter-center comparability procedures must be introduced; changes made at some but not all will defeat the purpose of multi-center research. For some multi-center studies, scientific and ethical review may be facilitated by agreement among the centers to accept the conclusions of a single review committee; its members could include a representative of the ethical review committee at each of the centers at which the research is to be conducted, as well as individuals competent to conduct scientific review. In other circumstances, a

centralized review may be complemented by local review relating to the local participating investigators and institutions. The central committee could review the study from a scientific and ethical standpoint, and the local committees could verify the practicability of the study in their communities, including the infrastructures, the state of training, and ethical considerations of local significance.

In a large multi-center trial, individual investigators will not have authority to act independently, with regard to data analysis or to preparation and publication of manuscripts, for instance. Such a trial usually has a set of committees which operate under the direction of a steering committee and are responsible for such functions and decisions. The function of the ethical review committee in such cases is to review the relevant plans with the aim of avoiding abuses.

Sanctions. Ethical review committees generally have no authority to impose sanctions on researchers who violate ethical standards in the conduct of research involving humans. They may, however, withdraw ethical approval of a research project if judged necessary. They should be required to monitor the implementation of an approved protocol and its progression, and to report to institutional or governmental authorities any serious or continuing non-compliance with ethical standards as they are reflected in protocols that they have approved or in the conduct of the studies. Failure to submit a protocol to the committee should be considered a clear and serious violation of ethical standards.

Sanctions imposed by governmental, institutional, professional, or other authorities possessing disciplinary power should be employed as a last resort. Preferred methods of control include cultivation of an atmosphere of mutual trust, and education and support to promote in researchers and in sponsors the capacity for ethical conduct of research.

Should sanctions become necessary, they should be directed at the non-compliant researchers or sponsors. They may include fines or suspension of eligibility to receive research funding, to use investigational interventions, or to practice medicine. Unless there are persuasive reasons to do otherwise, editors should refuse to publish the

results of research conducted unethically, and retract any articles that are subsequently found to contain falsified or fabricated data or to have been based on unethical research. Drug regulatory authorities should consider refusal to accept unethically obtained data submitted in support of an application for authorization to market a product. Such sanctions, however, may deprive of benefit not only the errant researcher or sponsor but also that segment of society intended to benefit from the research; such possible consequences merit careful consideration.

Potential Conflicts of Interest Related to Project Support. Increasingly, biomedical studies receive funding from commercial firms. Such sponsors have good reasons to support research methods that are ethically and scientifically acceptable, but cases have arisen in which the conditions of funding could have introduced bias. It may happen that investigators have little or no input into trial design, limited access to the raw data, or limited participation in data interpretation, or that the results of a clinical trial may not be published if they are unfavorable to the sponsor's product. This risk of bias may also be associated with other sources of support, such as government or foundations. As the persons directly responsible for their work, investigators should not enter into agreements that interfere unduly with their access to the data or their ability to analyze the data independently, to prepare manuscripts, or to publish them. Investigators must also disclose potential or apparent conflicts of interest on their part to the ethical review committee or to other institutional committees designed to evaluate and manage such conflicts. Ethical review committees should therefore ensure that these conditions are met. See also *Multi-Center Research*, above.

The Islamic Point of View Concerning Guideline 2 Ethical Review Committees

From a jurisprudence point of view, it should be established, before research which involves human subject gets under way, that the conditions and controls set in guideline 1 are met. This should be done by one or more specialized scientific review committee, independent of the research team and funding sponsors, and by an Islamic jurisprudence (*fiqh*) committee that bases its legal decision on the data it receives from specialized scientific review committees. Nor should the determination of material and non-material reward obtained by a committee be contingent on the outcome of its review. An investigator should obtain the approval, or clearance, of such committees before he undertakes his research.

In the case of non-compliance by researchers and/or sponsors with the scientific and jurisprudence criteria stated in the commentary on guidelines 1 and 2, institutional or government authorities should undertake to impose disciplinary sanction on violators.

The review by specialized scientific and jurisprudence committee(s) to determine whether conducting the research is permissible, and the subsequent clearance or approval, has its basis in the unanimously-endorsed basic rule of Islamic Law which stipulates that "a responsible adult is not to embark on any undertaking before he finds out how it is regarded by God."(20)

As to the point that such specialized committee(s) should be independent of the research team and sponsors, this should be guided

(20) Al-Kittaani, *Al-Taraateeb Al-Idariyah*, II: 16; Al-Ghazaali, *Ihyaa 'Uloom Al-Deen*, II: 59 & 84.

by the regulations of testimony and arbitration, one of the conditions of which is to be undertaken by a neutral party who has no direct or indirect purpose or interest in the matter on which he testifies.

The rule that material and non-material rewards for the committees should not be contingent on the outcome of the review is based on the need to guarantee that their decisions are objective and free from suspicion, which is also a basic rule in regards to testimonies.

As for the sanctions imposed by institutional or government authorities in cases of non-compliance with and violation of criteria, they are required by Islamic Law, for legal decisions against individuals should be proportionate to the damage they cause. This is for the protection of an individual, i.e. a study subject, against the aggressive violation of his human dignity and his inviolable, personal concerns.

Such punishments should be discretionary, i.e. determined by the proper authorities, and should be deterrent.

Guideline 3
Ethical Review of Externally Sponsored Research

An external sponsoring organization and individual investigators should submit the research protocol for ethical and scientific review in the country of the sponsoring organization, and the ethical standards applied should be no less stringent than they would be for research carried out in that country. The health authorities of the host country, as well as a national or local ethical review committee, should ensure that the proposed research is responsive to the health needs and priorities of the host country and meets the requisite ethical standards.

Commentary on Guideline 3

Definition. The term *externally sponsored research* refers to research undertaken in a host country but sponsored, financed, and sometimes wholly or partly carried out by an external international or national organization or pharmaceutical company with the collaboration or agreement of the appropriate authorities, institutions and personnel of the host country.

Ethical and Scientific Review. Committees in both the country of the sponsor and the host country have responsibility for conducting both scientific and ethical review, as well as the authority to withhold approval of research proposals that fail to meet their scientific or ethical standards. As far as possible, there must be assurance that the review is independent and that there is no conflict of interest that might affect the judgment of members of the review committees in relation to any aspect of the research. When the external sponsor is an international organization, its review of the research protocol must be in accordance with its own independent ethical-review procedures and standards.

Committees in the external sponsoring country or international organization have a special responsibility to determine whether the

scientific methods are sound and suitable to the aims of the research; whether the drugs, vaccines, devices, or procedures to be studied meet adequate standards of safety; whether there is sound justification for conducting the research in the host country rather than in the country of the external sponsor or in another country; and whether the proposed research is in compliance with the ethical standards of the external sponsoring country or international organization.

Committees in the host country have a special responsibility to determine whether the objectives of the research are responsive to the health needs and priorities of that country. The ability to judge the ethical acceptability of various aspects of a research proposal requires a thorough understanding of a community's customs and traditions. The ethical review committee in the host country, therefore, must have as either members or consultants persons with such understanding; it will then be in a favorable position to determine the acceptability of the proposed means of obtaining informed consent and otherwise respecting the rights of prospective subjects as well as of the means proposed to protect the welfare of the research subjects. Such persons should be able, for example, to indicate suitable members of the community to serve as intermediaries between investigators and subjects, and to advise on whether material benefits or inducements may be regarded as appropriate in the light of a community's gift-exchange and other customs and traditions.

When a sponsor or investigator in one country proposes to carry out research in another, the ethical review committees in the two countries, by agreement, may undertake to review different aspects of the research protocol. In short, in respect of host countries either with developed capacity for independent ethical review or in which external sponsors and investigators are contributing substantially to such capacity, ethical review in the external, sponsoring country may be limited to ensuring compliance with broadly stated ethical standards. The ethical review committee in the host country can be expected to have greater competence for reviewing the detailed plans for compliance, in view of its better understanding of the cultural and moral values of the population in which it is proposed to conduct the

research; it is also likely to be in a better position to monitor compliance in the course of a study. However, in respect of research in host countries with inadequate capacity for independent ethical review, full review by the ethical review committee in the external sponsoring country or international agency is necessary.

The Islamic Point of View Concerning Guideline 3 Ethical Review of Externally Sponsored Research

In regards to research undertaken in a host country but sponsored, financed, and wholly or partly carried out by an external international or national organization or pharmaceutical company, with the collaboration or agreement of the appropriate authorities, institutions and personnel of the host country - from the perspective of Islamic jurisprudence (*fiqh*), the following should be observed.

1 - The scientific and ethical review should be conducted objectively, independently, and honestly in the country of the sponsoring organization, to guarantee that the ethical controls stated in guidelines 1 and 2 are applied. The ethical standards applied should be no less stringent when applied in another country, as all members of the human race should be treated equally and all forms of racial discrimination should be renounced. Equity for all people is the basis of the message of Islam and all divine religions, for God declares to us that "God enjoins justice" (*Al-Nahl* XVI: 90). He also says, "We have sent Our messengers with explicit signs, and sent down with them the Book and the Scale, that people may stand in justice" (*Al-Hadeed* LVII: 25). Ibn Al-Qayyem explains this principle, saying, "God, the Most Supreme, has sent His messengers and books so that people may apply justice, which is the equity on which the Earth and the Heavens are founded. Where indications of justice are clear and can be seen wherever one turns, God's Law and Creed prevail."(21)

2 - A similar ethical review should be conducted in the host country to achieve the desired goal and make sure that the proposed research meets the health needs and priorities of that country. It

(21) *Al-Turuq Al-Hamiyah*, p. 13.

is one of the purposes of Islamic Law is "to place everything in its right place [on the list of priorities], in light of reality and its requirements, so that what needs to take priority is not delayed, and what ought to be delayed is not given priority."(22) In the jurisprudence controls of priorities, it is stipulated that, "A more beneficial thing has priority over a less beneficial one;"(23) "Prevention of what causes more harm has priority over prevention of something less harmful;"(24) "The most outweighing item should be given priority when there is a congestion of benefits and harms;"(25) "What is needed immediately should be given precedence over what is needed without any special hurry;"(26) and "A person with a need should be attended to before one with no need."(27)

3 - If the host country is expected to gain very limited or no benefit from certain experiments, then the order of rules of necessity according to Islamic Law would be that decent human life has precedence over expected benefit from the research.

Moreover, if the country where research is conducted has no specialists in the relevant field who can safeguard its rights, the rule in Islamic Law is that the judiciary are guardian of a party with no other guardian. Therefore, the research projects, its purposes, the precautions taken, and the benefit expected should be submitted to the judiciary system to review them as thoroughly as to guarantee that the said rule is complied with.

(22) Al-Wakeeli, *Fiqh Al-Awlawiyaat*, p. 16.

(23) Ibid., p. 197.

(24) Ibid., p. 211.

(25) Ibid., p. 222.

(26) Ibid., p. 256.

(27) Ibid., p. 264.

Guideline 4
Individual Informed Consent

For all biomedical research involving humans the investigator must obtain the voluntary informed consent of the prospective subject or, in the case of an individual who is not capable of giving informed consent, the permission of a legally authorized representative in accordance with applicable law. Waiver of informed consent is to be regarded as uncommon and exceptional, and must in all cases be approved by an ethical review committee.

Commentary on Guideline 4

General considerations. Informed consent is a decision to participate in research, taken by a competent individual who has received the necessary information; who has adequately understood the information; and who, after considering the information, has arrived at a decision without having been subjected to coercion, undue influence or inducement, or intimidation.

Informed consent is based on the principle that competent individuals are entitled to choose freely whether to participate in research. Informed consent protects the individual's freedom of choice and respects the individual's autonomy. As an additional safeguard, it must always be complemented by independent ethical review of research proposals. This safeguard of independent review is particularly important as many individuals are limited in their capacity to give adequate informed consent; they include young children, adults with severe mental or behavioral disorders, and persons who are unfamiliar with medical concepts and technology (See *Guidelines* 13, 14, 15).

Process. Obtaining informed consent is a process that is begun when initial contact is made with a prospective subject and continues throughout the course of the study. By informing the prospective

subjects, by repetition and explanation, by answering their questions as they arise, and by ensuring that each individual understands each procedure, investigators elicit their informed consent and in so doing manifest respect for their dignity and autonomy. Each individual must be given as much time as is needed to reach a decision, including time for consultation with family members or others. Adequate time and resources should be set aside for informed-consent procedures.

Language. Informing the individual subject must not be simply a ritual recitation of the contents of a written document. Rather, the investigator must convey the information, whether orally or in writing, in language that suits the individual's level of understanding. The investigator must bear in mind that the prospective subject's ability to understand the information necessary to give informed consent depends on that individual's maturity, intelligence, education and belief system. It depends also on the investigator's ability and willingness to communicate with patience and sensitivity.

Comprehension. The investigator must then ensure that the prospective subject has adequately understood the information. The investigator should give each one full opportunity to ask questions and should answer them honestly, promptly and completely. In some instances the investigator may administer an oral or a written test or otherwise determine whether the information has been adequately understood.

Documentation of Consent. Consent may be indicated in a number of ways. The subject may imply consent by voluntary actions, express consent orally, or sign a consent form. As a general rule, the subject should sign a consent form, or, in the case of incompetence, a legal guardian or other duly authorized representative should do so. The ethical review committee may approve waiver of the requirement of a signed consent form if the research carries no more than minimal risk - that is, risk that is no more likely and not greater than that attached to routine medical or psychological examination - and if the procedures to be used are only those for which signed consent forms are not customarily required outside the research context. Such waivers may also be approved when existence of a signed consent form would be an unjustified threat to the subject's confidentiality. In some cases,

particularly when the information is complicated, it is advisable to give subjects information sheets to retain; these may resemble consent forms in all respects except that subjects are not required to sign them. Their wording should be cleared by the ethical review committee. When consent has been obtained orally, investigators are responsible for providing documentation or proof of consent.

Waiver of the Consent Requirement. Investigators should never initiate research involving human subjects without obtaining each subject's informed consent, unless they have received explicit approval to do so from an ethical review committee. However, when the research design involves no more than minimal risk and a requirement of individual informed consent would make the conduct of the research impracticable (for example, where the research involves only excerpting data from subjects' records), the ethical review committee may waive some or all of the elements of informed consent.

Renewing Consent. When material changes occur in the conditions or the procedures of a study, and also periodically in long-term studies, the investigator should once again seek informed consent from the subjects. For example, new information may have come to light, either from the study or from other sources, about the risks or benefits of products being tested or about alternatives to them. Subjects should be given such information promptly. In many clinical trials, results are not disclosed to subjects and investigators until the study is concluded. This is ethically acceptable if an ethical review committee has approved their non-disclosure.

Cultural Considerations. In some cultures an investigator may enter a community to conduct research or approach prospective subjects for their individual consent only after obtaining permission from a community leader, a council of elders, or another designated authority. Such customs must be respected. In no case, however, may the permission of a community leader or other authority substitute for individual informed consent. In some populations the use of a number of local languages may complicate the communication of information to potential subjects and the ability of an investigator to ensure that they truly understand it. Many people in all cultures are unfamiliar

with, or do not readily understand, scientific concepts such as those of placebo or randomization. Sponsors and investigators should develop culturally appropriate ways to communicate information that is necessary for adherence to the standard required in the informed consent process. Also, they should describe and justify in the research protocol the procedure they plan to use in communicating information to subjects. For collaborative research in developing countries the research project should, if necessary, include the provision of resources to ensure that informed consent can indeed be obtained legitimately within different linguistic and cultural settings.

Consent to Use for Research Purposes Biological Materials (Including Genetic Material) from Subjects in Clinical Trials. Consent forms for the research protocol should include a separate section for clinical-trial subjects who are requested to provide their consent for the use of their biological specimens for research. Separate consent may be appropriate in some cases (e.g., if investigators are requesting permission to conduct basic research which is not a necessary part of the clinical trial), but not in others (e.g., the clinical trial requires the use of subjects' biological materials).

Use of Medical Records and Biological Specimens. Medical records and biological specimens taken in the course of clinical care may be used for research without the consent of the patients/subjects only if an ethical review committee has determined that the research poses minimal risk, that the rights or interests of the patients will not be violated, that their privacy and confidentiality or anonymity are assured, and that the research is designed to answer an important question and would be impracticable if the requirement for informed consent were to be imposed. Refusal or reluctance of individuals to agree to participate would not be evidence of impracticability sufficient to warrant waiving informed consent. Records and specimens of individuals who have specifically rejected such uses in the past may be used only in the case of public health emergencies. (See the Commentary on Guideline 18, *Confidentiality between Physician and Patient)*

Secondary Use of Research Records or Biological Specimens. Investigators may want to use records or biological specimens that

another investigator has used or collected for use, in another institution in the same or another country. This raises the issue of whether the records or specimens contain personal identifiers, or can be linked to such identifiers, and by whom. (See also Guideline 18: *Safeguarding Confidentiality*.) If informed consent or permission was required to authorize the original collection or use of such records or specimens for research purposes, secondary uses are generally constrained by the conditions specified in the original consent. Consequently, it is essential that the original consent process anticipate, to the extent that this is feasible, any foreseeable plans for future use of the records or specimens for research. Thus, in the original process of seeking informed consent a member of the research team should discuss with prospective subject, and, when indicated, request their permission as to:

i - whether there will or could be any secondary use and, if so, whether such secondary use will be limited with regard to the type of study that may be performed on such materials;

ii - the conditions under which investigators will be required to contact the research subjects for additional authorization for secondary use;

iii - the investigators' plans, if any, to destroy or to strip of personal identifiers the records or specimens; and

iv - the rights of subjects to request destruction or anonymization of biological specimens or of records or parts of records that they might consider particularly sensitive, such as photographs, videotapes or audiotapes.

(See also Guidelines 5: *Obtaining Informed Consent: Essential Information for Prospective Research Subjects*; 6: *Obtaining Informed Consent: Obligations of Sponsors and Investigators*; and 7: *Inducement to Participate*.)

The Islamic Point of View Concerning Guideline 4 Individual Informed Consent

On the basis of the Islamic Law principle that calls for respect of the independence of every individual and his right to make his personal choices and arrive at decisions suitable for him, without any trace of coercion or deception, and to be protected from injury, misleading inducement, or exploitation by others - no biomedical research involving human subjects should be conducted unless the subject's explicit permission, i.e. voluntary informed consent, is obtained. It should be given willingly after the subject, if fully competent, receives and understands the necessary information. If the subject has only partial or no competence, his permission cannot be considered valid at all.

This rule is based on the following.

1 - Islamic law establishes the right of an individual to live and to be sound in body. It is a right safeguarded by the law. Therefore, no party is permitted to subject to experiments, trials, or research a fully competent individual without his voluntary permission, given while he is fully aware of the case.(28) This is stipulated in Islamic jurisprudence (*fiqh*), where a rule says, "No one is entitled to dispose of the right of a human being without his permission,"(29) and "no right of a human being can be canceled without his consent."(30)

(28) Resolution No. 67 (5/7) of the Islamic Jurisprudence Academy says:

3. d. When medical research is conducted, the consent of a fully competent subject is mandatory, and it should be free of any trace of coercion, as in the case of prisoners, or material inducement, as in the case of the needy. Moreover, no harm should result from such research.

(29) Ibn Qadaamah, *Al-Mughni*, VI: 552.

(30) Al-Kasaani, *Badaai' Al-Sanaai'*, V: 251.

Item 3/d of Resolution 67 of Islamic Jurisprudence Academy says, "In conducting medical research, the consent of a fully competent individual must be obtained, without any coercion, as may be exercised in the case of prisoners, or temptation, as may be exercised in the case of the needy. In addition, this research should involve no harm."

2 - Coercion, deception, and misleading inducement are flaws that spoil consent and annul a permission given under any of them.

3 - Providing the individual, i.e. subject, with full information on the research he is invited to be involved in and on its potential or certain risks is a prerequisite for consent validity. Unless the prerequisite is met, the conditional article is invalid. The consent of a person to the performance of something without awareness of its implications and full understanding of its nature, makes it contrary to his real intention and it is not given out of his truly free will. Real intention and truly free will are contingent on awareness and full understanding.(31) A rule of Islamic jurisprudence stipulates that "The rights of human beings are placed in safekeeping and under precautionary measures."(32)

4 - When the research involves no more than minimal risk, the risk that is no more likely and not greater than that involved in routine medical or psychological examination, there is no need to document the consent obtained, verbal consent being sufficient.

5 - The condition of informed consent may be waived in emergency situation which call for research interventions, when the subject is incapable of giving his informed consent, for the investigator has consent by inference. In jurisprudence it is stipulated that "an inferred permission is the same as an explicit one,"(33) "as it can

(31) Ibn Al-Qayyem, *I'lamm Al-Mawqi'ain*, III: 107 & 117.

(32) Al-Mawardi, *Al-Haawi*, VII: 243.

(33) Article 772, *Majallat Al-Ahkaam Al-'Adliyah*; Al-Sarkhi, *Al-Mabsoot*, IV: 145-46 and XII: 107 &113.

be made explicitly, a permission can be obtained by inference,"[34] and "what is established by inference ranks the same as that established by explicit expression."[35]

6 - In the case of an incompetent, or a partially competent, individual, who is unable to protect himself and handle his own affairs and needs someone else to handle them and guard his interests, his permission, i.e. "informed" consent, is by no means valid for conducting research involving him. Nor is permission by his guardian relevant,[36] except in very unusual cases which will be pointed out in the commentary on Guidelines 13 and 14.

Article 3/d of resolution 67 (5/7) of the Islamic Jurisprudence Academy says: "It is not permissible to conduct medical research involving subjects with only partial or no competence, even with the consent of guardians."

(34) Article 97, *Majallat Al-Ahkaam Al-'Adliyah*; Al-Sarkhi, *Al-Mabsoot*, XI: 19. Resolution No. 67 (5/7) of the Islamic Jurisprudence Academy says:

3. c. In cases of emergency, where a patient's life is at risk, treatment is not contingent on permission.

(35) Resolution No. 67 (5/7) of the Islamic Jurisprudence Academy says:

3. d. No medical research can involve people with only partial or no competenc3 even with the consent of their guardians.

(36) Resolution No. 67 (5/7) of the Islamic Jurisprudence Academy says:

3. d. No medical research involving incompetent, or not fully competent, subjects, even with the consent of their guardians.

Guideline 5
Obtaining Informed Consent: Essential Information for Prospective Research Subjects

Before requesting an individual's consent to participate in research, an investigator must provide the following information, in language or another form of communication that the individual can understand:

1 - that the individual is invited to participate in research, the reasons for considering the individual suitable for the research, and that participation is voluntary;

2 - that the individual is free to refuse to participate and will be free to withdraw from the research at any time without penalty or loss of benefits to which he or she would otherwise be entitled;

3 - the purpose of the research, the procedures to be carried out by the investigator and the subject, and an explanation of how the research differs from routine medical care;

4 - for controlled trials, an explanation of features of the research design (e.g., randomization, double-blinding), and that the subject will not be told of the assigned treatment until the study has been completed and the blind has been broken;

5 - the expected duration of the individual's participation (including number and duration of visits to the research center and the total time involved) and the possibility of early termination of the trial or of the individual's participation in it;

6 - whether money or other forms of material goods will be provided in return for the individual's participation and, if so, the kind and amount;

7 - that, after the completion of the study, subjects will be informed of the findings of the research in general, and individual subjects will be informed of any finding that relates to their particular health status;

8 - that subjects have the right of access to their data on demand, even if these data lack immediate clinical utility (unless the ethical review committee has approved temporary or permanent non-disclosure of data, in which case the subject should be informed of, and given, the reasons for such non-disclosure);

9 - any foreseeable risks, pain or discomfort, or inconvenience to the individual (or others) associated with participation in the research, including risks to the health or well-being of a subject's spouse or partner;

10 - the direct benefits, if any, expected to result to subjects from participating in the research

11 - the expected benefits of the research to the community or to society at large, or contributions to scientific knowledge;

12 - whether, when, and how any products or interventions proven by the research to be safe and effective will be made available to subjects after they have completed their participation in the research, and whether they will be expected to pay for them;

13 - any currently available alternative interventions or courses of treatment;

14 - the provisions that will be made to ensure respect for the privacy of subjects and for the confidentiality of records in which subjects are identified;

15 - the limits, legal or other, to the investigators' ability to safeguard confidentiality, and the possible consequences of breaches of confidentiality;

16 - policy with regard to the use of results of genetic tests and familial genetic information, and the precautions in place to prevent disclosure of the results of a subject's genetic tests to immediate family relatives or to others (e.g., insurance companies or employers) without the consent of the subject;

17 - the sponsors of the research, the institutional affiliation of the investigators, and the nature and sources of funding for the research;

18 - the possible research uses, direct or secondary, of the subject's medical records and of biological specimens taken in the course of clinical care (See also the Commentaries on *Guidelines* 4 and 18);

19 - whether it is planned that biological specimens collected in the research will be destroyed at its conclusion, and, if not, details about their storage (where, how, for how long, and final disposition) and possible future use, and that subjects have the right to decide about such future use, to refuse storage, and to have the material destroyed (See the Commentary on *Guideline* 4);

20 - whether commercial products may be developed from biological specimens, and whether the participant will receive monetary or other benefits from the development of such products;

21 - whether the investigator is serving only as an investigator or as both investigator and the subject's physician;

22 - the extent of the investigator's responsibility to provide medical services to the participant;

23 - that treatment will be provided free of charge for specified types of research-related injury or for complications associated with the research, the nature and duration of such care, the name of the organization or individual that will provide the treatment, and whether there is any uncertainty regarding funding of such treatment;

24 - in what way, and by what organization, the subject or the subject's family or dependants will be compensated for disability or death resulting from such injury (or, when indicated, that there are no plans to provide such compensation);

25 - whether or not, in the country in which the prospective subject is invited to participate in research, the right to compensation is legally guaranteed; and

26 - that an ethical review committee has approved or cleared the research protocol.

The Islamic Point of View Concerning Guideline 5 Obtaining Informed Consent: Essential Information for Prospective Research Subjects

It is a prerequisite for the validity of informed consent which an investigator must obtain from the subject that it should be given with full knowledge and correct understanding, on the part of the subject, of what he is consenting to. This means that data and other information which he needs to know should be made available to him before he makes his decision.

From the jurisprudence point of view, this rule is rooted in the fact that the validity of choice and consent, in the cases where Islamic Law makes either a requirement, is contingent on knowledge of the matter in question; no ignorance in such cases is allowed. Jurisprudence stipulations confirm this in saying that "mutual agreement cannot be reached under conditions of ignorance,"(37) and that "consent to an unknown thing and acquittal from an unknown thing are not valid."(38)

All the controls cited in the commentary on this guideline are based on the above-mentioned principles of (1) respect for person and (2) benefit.

(37) Al-Shawkaani, *Al-Sayl Al-Jarraar*, III: 94.

(38) Al-'Iz Ibn 'Abd Al-Salaam, *Al-Qawaa'ed Al-Kubra*, II: 299.

Guideline 6
Obtaining Informed Consent
Obligations of Sponsors and Investigators

Sponsors and investigators have a duty to:

- refrain from unjustified deception, undue influence, or intimidation;
- seek consent only after ascertaining that the prospective subject has adequate understanding of the relevant facts and of the consequences of participation and has had sufficient opportunity to consider whether to participate;
- as a general rule, obtain from each prospective subject a signed form as evidence of informed consent - investigators should justify any exceptions to this general rule and obtain the approval of the ethical review committee (See *Guideline* 4 Commentary, *Documentation of Consent*);
- renew the informed consent of each subject if there are significant changes in the conditions or procedures of the research or if new information becomes available that could affect the willingness of subjects to continue to participate; and
- renew the informed consent of each subject in long-term studies at pre-determined intervals, even if there are no changes in the design or objectives of the research.

Commentary on Guideline 6

The investigator is responsible for ensuring the adequacy of informed consent from each subject. The person obtaining informed consent should be knowledgeable about the research and capable of answering questions from prospective subjects. Investigators in charge of the study must make themselves available to answer questions at

the request of subjects. Any restrictions on the subject's opportunity to ask questions and receive answers before or during the research undermines the validity of the informed consent.

In some types of research, potential subjects should receive counseling about risks of acquiring a disease unless they take precautions. This is especially true of HIV/AIDS vaccine research (UNAIDS Guidance Document *Ethical Considerations in HIV Preventive Vaccine Research, Guidance Point 14*).

Withholding Information and Deception. Sometimes, to ensure the validity of research, investigators withhold certain information in the consent process. In biomedical research, this typically takes the form of withholding information about the purpose of specific procedures. For example, subjects in clinical trials are often not told the purpose of tests performed to monitor their compliance with the protocol, since if they knew their compliance was being monitored they might modify their behavior and hence invalidate results. In most such cases, the prospective subjects are asked to consent to remain uninformed of the purpose of some procedures until the research is completed; after the conclusion of the study they are given the omitted information. In other cases, because a request for permission to withhold some information would jeopardize the validity of the research, subjects are not told that some information has been withheld until the research has been completed. Any such procedure must receive the explicit approval of the ethical review committee.

Active deception of subjects is considerably more controversial than simply withholding certain information. Lying to subjects is a tactic not commonly employed in biomedical research. Social and behavioral scientists, however, sometimes deliberately misinform subjects to study their attitudes and behavior. For example, scientists have pretended to be patients to study the behavior of health-care professionals and patients in their natural settings.

Some people maintain that active deception is never permissible. Others would permit it in certain circumstances. Deception is not permissible, however, in cases in which the deception itself would disguise the possibility of the subject being exposed to more than

minimal risk. When deception is deemed indispensable to the methods of a study, the investigators must demonstrate to an ethical review committee that no other research method would suffice; that significant advances could result from the research; and that nothing has been withheld that, if divulged, would cause a reasonable person to refuse to participate. The ethical review committee should determine the consequences for the subject of being deceived, and whether and how deceived subjects should be informed of the deception upon completion of the research. Such informing, commonly called "debriefing", ordinarily entails explaining the reasons for the deception. A subject who disapproves of having been deceived should be offered an opportunity to refuse to allow the investigator to use information thus obtained. Investigators and ethical review committees should be aware that deceiving research subjects may wrong them as well as harm them; subjects may resent not having been informed when they learn that they have participated in a study under false pretences. In some studies there may be justification for deceiving persons other than the subjects by either withholding or disguising elements of information. Such tactics are often proposed, for example, for studies of the abuse of spouses or children. An ethical review committee must review and approve all proposals to deceive persons other than the subjects. Subjects are entitled to prompt and honest answers to their questions; the ethical review committee must determine for each study whether others who are to be deceived are similarly entitled.

Intimidation and Undue Influence. Intimidation in any form invalidates informed consent. Prospective subjects who are patients often depend for medical care upon the physician/investigator, who consequently has a certain credibility in their eyes, and whose influence over them may be considerable, particularly if the study protocol has a therapeutic component. They may fear, for example, that refusal to participate would damage the therapeutic relationship or result in the withholding of health services. The physician/investigator must assure them that their decision on whether to participate will not affect the

therapeutic relationship or other benefits to which they are entitled. In this situation the ethical review committee should consider whether a neutral third party should seek informed consent.

The prospective subject must not be exposed to undue influence. The borderline between justifiable persuasion and undue influence is imprecise, however. The researcher should give no unjustifiable assurances about the benefits, risks, or inconveniences of the research, for example, or induce a close relative or a community leader to influence a prospective subject's decision. (See also *Guideline* 4: *Individual Informed Consent.*)

Risks. Investigators should be completely objective in discussing the details of the experimental intervention, the pain and discomfort that it may entail, and known risks and possible hazards. In complex research projects it may be neither feasible nor desirable to inform prospective participants fully about every possible risk. They must, however, be informed of all risks that a 'reasonable person' would consider material to making a decision about whether to participate, including risks to a spouse or partner associated with trials of, for example, psychotropic or genital-tract medicaments. (See also the Commentary on *Guideline* 8, *Risks to Groups of Persons.*)

Exception to the Requirement for Informed Consent in Studies of Emergency Situations in Which the Researcher Anticipates That Many Subjects Will Be Unable to Consent. Research protocols are sometimes designed to address conditions occurring suddenly and rendering the patients/subjects incapable of giving informed consent. Examples are head trauma, cardiopulmonary arrest and stroke. The investigation cannot be done with patients who can give informed consent in time and there may not be time to locate a person having the authority to give permission. In such circumstances it is often necessary to proceed with the research interventions very soon after the onset of the condition in order to evaluate an investigational treatment or develop the desired knowledge. As this class of emergency exception can be anticipated, the researcher must secure the review and approval of an ethical review committee before initiating the study. This can be done readily, for example, if the condition is one that recurs periodically in

individuals; examples include grand mal seizures and alcohol binges. In such cases, prospective subjects should be contacted while fully capable of informed consent, and invited to consent to their involvement as research subjects during future periods of incapacitation. If they are patients of an independent physician who is also the physician-researcher, the physician should likewise seek their consent while they are fully capable of informed consent. In all cases in which approved research has begun without prior consent of patients/subjects incapable of giving informed consent because of suddenly occurring conditions, they should be given all relevant information as soon as they are in a state to receive it, and their consent to continued participation should be obtained as soon as is reasonably possible.

Before proceeding without prior informed consent, the investigator must make reasonable efforts to locate an individual who has the authority to give permission on behalf of an incapacitated patient. If such a person can be located and refuses to give permission, the patient may not be enrolled as a subject. The risks of all interventions and procedures will be justified as required by *Guideline* 9 (*Special limitations on risks when research involves individuals who are not capable of giving consent*). The researcher and the ethical review committee should agree to a maximum time of involvement of an individual without obtaining either the individual's informed consent or authorization according to the applicable legal system if the person is not able to give consent. If by that time the researcher has not obtained either consent or permission - owing either to a failure to contact a representative or to a refusal of either the patient or the person or body authorized to give permission - the participation of the patient as a subject must be discontinued. The patient or the person or body providing authorization should be offered an opportunity to forbid the use of data derived from participation of the patient as a subject without consent or permission.

Plans to conduct emergency research without prior consent of the subjects should be publicized within the community in which it will be carried out. In the design and conduct of the research, the ethical review committee, the investigators and the sponsors should be

responsive to the concerns of the community. If there is cause for concern about the acceptability of the research in the community, there should be a formal consultation with representatives designated by the community. The research should not be carried out if it does not have substantial support in the community concerned. (See the Commentary on Guideline 8, *Risks to Groups of Persons.*)

Exception to the Requirement of Informed Consent for Inclusion in Clinical Trials of Persons Rendered Incapable of Informed Consent by an Acute Condition. Certain patients with an acute condition that renders them incapable of giving informed consent may be eligible for inclusion in a clinical trial in which the majority of prospective subjects will be capable of informed consent. Such a trial would relate to a new treatment for an acute condition such as sepsis, stroke or myocardial infarction. The investigational treatment would hold out the prospect of direct benefit and would be justified accordingly, though the investigation might involve certain procedures or interventions that were not of direct benefit but carried no more than minimal risk; an example would be the process of randomization or the collection of additional blood for research purposes. For such cases the initial protocol submitted for approval to the ethical review committee should anticipate that some patients may be incapable of consent, and should propose for such patients a form of proxy consent, such as permission of the responsible relative. When the ethical review committee has approved or cleared such a protocol, an investigator may seek the permission of the responsible relative and enroll such a patient.

The Islamic Point of View Concerning Guideline 6 Obtaining Informed Consent Obligations of Sponsors and Investigators

The obligations of research and researcher sponsors cited in this guideline are, in general, in agreement with the principles of Islamic Law, for actually, they explain and elaborate on what Guidelines 4 and 5 mention in a more concise form. The basis in Islamic Law for endorsement of the basic idea of those guidelines, as well as their amplification and details, has already been specified, and it is sufficient and clear enough to render any repetition here unnecessary.

Guideline 7
Inducement to Participate

Subjects may be reimbursed for lost earnings, travel costs, and other expenses incurred in taking part in a study; they may also receive free medical services. Subjects, particularly those who receive no direct benefit from research, may also be paid or otherwise compensated for inconvenience and time spent. The payments should not be so large, however, or the medical services so extensive as to induce prospective subjects to consent to participate in the research against their better judgment ("undue inducement"). All payments, reimbursements and medical services provided to research subjects must have been approved by an ethical review committee.

Commentary on Guideline 7

Acceptable Recompense. Research subjects may be reimbursed for their transport and other expenses, including lost earnings, associated with their participation in research. Those who receive no direct benefit from the research may also receive a small sum of money for inconvenience due to their participation in the research. All subjects may receive medical services unrelated to the research and have procedures and tests performed free of charge.

Unacceptable Recompense. Payments in money or in kind to research subjects should not be so large as to persuade them to take undue risks or volunteer against their better judgment. Payments or rewards that undermine a person's capacity to exercise free choice invalidate consent. It may be difficult to distinguish between suitable recompense and undue influence to participate in research. An unemployed person or a student may view promised recompense differently from an employed person. Someone without access to medical care may or may not be unduly influenced to participate in

research simply to receive such care. A prospective subject may be induced to participate in order to obtain a better diagnosis or access to a drug not otherwise available; local ethical review committees may find such inducements acceptable. Monetary and in-kind recompense must, therefore, be evaluated in the light of the traditions of the particular culture and population in which they are offered, to determine whether they constitute undue influence. The ethical review committee will ordinarily be the best judge of what constitutes reasonable material recompense in particular circumstances. When research interventions or procedures that do not hold out the prospect of direct benefit present more than minimal risk, all parties involved in the research - sponsors, investigators and ethical review committees - in both funding and host countries should be careful to avoid undue material inducement.

Incompetent Persons. Incompetent persons may be vulnerable to exploitation for financial gain by guardians. A guardian asked to give permission on behalf of an incompetent person should be offered no recompense other than a refund of travel and related expenses.

Withdrawal from a Study. A subject who withdraws from research for reasons related to the study, such as unacceptable side-effects of a study drug, or who is withdrawn on health grounds, should be paid or recompensed as if full participation had taken place. A subject who withdraws for any other reason should be paid in proportion to the amount of participation. An investigator who must remove a subject from the study for willful noncompliance is entitled to withhold part or all of the payment.

The Islamic Point of View Concerning Guideline 7 Inducement to Participate

There is no objection in Islamic Law to the compensation of research subject for lost earnings and for transport and other expenses that might incur as a result of participation in the research. Actually, the rule of reparation and the principles of justice and fairness make it necessary to compensate the subjects adequately for what they have paid.

Any additional financial or in-kind payments, or any compensation that reach an extent that indicates they are being offered to influence the will of an individual (a research subject) and pressure him to give consent that is not based on conviction, are legally prohibited.

Guideline 8
Benefits and Risks of Study Participation

For all biomedical research involving human subjects, the investigator must ensure that potential benefits and risks are reasonably balanced and risks are minimized.

- Interventions or procedures that hold out the prospect of direct diagnostic, therapeutic, or preventive benefit for the individual subject must be justified by the expectation that they will be at least as advantageous to the individual subject, in the light of foreseeable risks and benefits, as any available alternative. Risks of such 'beneficial' interventions or procedures must be justified in relation to expected benefits to the individual subject.
- Risks of interventions that do not hold out the prospect of direct diagnostic, therapeutic, or preventive benefit for the individual must be justified in relation to the expected benefits to society (generalizable knowledge). The risks presented by such interventions must be reasonable in relation to the importance of the knowledge to be gained.

Commentary on Guideline 8

The Declaration of Helsinki deals in several paragraphs with the well-being of research subjects and the avoidance of risk. Thus, considerations related to the well-being of the human subject should take precedence over the interests of science and society (*Paragraph 5*); clinical testing must be preceded by adequate laboratory or animal experimentation to demonstrate a reasonable probability of success without undue risk (*Paragraph 11*); every project should be preceded by careful assessment of predictable risks and burdens in comparison with foreseeable benefits to the subject or to others (*Paragraph 16*); physician-researchers must be confident that the risks involved have

been adequately assessed and can be satisfactorily managed (*Paragraph 17*); and the risks and burdens to the subject must be minimized, and reasonable in relation to the importance of the objective or the knowledge to be gained (*Paragraph 18*).

Biomedical research often employs a variety of interventions of which some hold out the prospect of direct therapeutic benefit (beneficial interventions) and others are administered solely to answer the research question (non-beneficial interventions). Beneficial interventions are justified as they are in medical practice by the expectation that they will be at least as advantageous to the individuals concerned, in the light of both risks and benefits, as any available alternative. Non-beneficial interventions are assessed differently; they may be justified only by appeal to the knowledge to be gained. In assessing the risks and benefits that a protocol presents to a population, it is appropriate to consider the harm that could result from forgoing the research.

Paragraphs 5 and 18 of the Declaration of Helsinki do not preclude well-informed volunteers, capable of fully appreciating risks and benefits of an investigation, from participating in research for altruistic reasons or for modest remuneration.

Minimizing Risk Associated with Participation in a Randomized Controlled Trial. In randomized controlled trials, subjects risk being allocated to receive the treatment that proves inferior. They are allocated by chance to one of two or more intervention arms and followed to a predetermined end-point. (Interventions are understood to include new or established therapies, diagnostic tests, and preventive measures.) An intervention is evaluated by comparing it with another intervention (a control), which is ordinarily the best current method, selected from the safe and effective treatments available globally, unless some other control intervention such as placebo can be justified ethically (See *Guideline* 11).

To minimize risk when the intervention to be tested in a randomized controlled trial is designed to prevent or postpone a lethal or disabling outcome, the investigator must not, for purposes of conducting the trial, withhold therapy that is known to be superior to the

intervention being tested, unless the withholding can be justified by the standards set forth in Guideline 11. Also, the investigator must provide in the research protocol for the monitoring of research data by an independent board (Data and Safety Monitoring Board); one function of such a board is to protect the research subjects from previously unknown adverse reactions or unnecessarily prolonged exposure to an inferior therapy. Normally at the outset of a randomized controlled trial, criteria are established for its premature termination (stopping rules or guidelines).

Risks to Groups of Persons. Research in certain fields, such as epidemiology, genetics or sociology, may present risks to the interests of communities, societies, or racially or ethnically defined groups. Information might be published that could stigmatize a group or expose its members to discrimination. Such information, for example, could indicate, rightly or wrongly, that the group has a higher than average prevalence of alcoholism, mental illness, or sexually transmitted disease, or is particularly susceptible to certain genetic disorders. Plans to conduct such research should be sensitive to such considerations, to the need to maintain confidentiality during and after the study, and to the need to publish the resulting data in a manner that is respectful of the interests of all concerned, or in certain circumstances not to publish them. The ethical review committee should ensure that the interests of all concerned are given due consideration; often it will be advisable to have individual consent supplemented by community consultation.

[The ethical basis for the justification of risk is elaborated further in Guideline 9.]

The Islamic Point of View Concerning Guideline 8 Benefits and Risks of Study Participation

1 - The need to strike a balance between potential benefits and risks in research involving human subjects - with the prospective benefits being more likely, at least for individual subjects - and the need to minimize risks are both included in a basic principle of Islamic Law, expressed in the following rules of jurisprudence (*fiqh*): "Harm should be warded off whenever possible;"(39) "if a benefit and a instance of harm are in conflict priority should be given to the weightier of the two;"(40)
Ibn Taimiyah says, "The principle of the Law is that if an action involves harm, it is prohibited, unless this harm is in conflict with a weightier benefit, as in the case of permitting a person to eat the flesh of an animal corpse when he has to. The greater of two injuries is warded off by tolerating the lesser one."(41)

2 - It is acceptable from a religious perspective to use the expected, significant benefits to society as a justification of the risks of interventions that do not hold out the prospect of direct diagnostic, therapeutic, or preventive benefit for the individual. This is based on the rules of jurisprudence which say: "Public interests take precedence over private ones;"(42) "the concern of the Law for public interests is more comprehensive and complete than its concern for private ones;"(43) and "a public interest is the same as a private necessity,"(44) that is in permitting a forbidden thing.

(39) Al-Kasaani, *Badaai' Al-Sanaai'*, V: 286-87.

(40) Al-Sa'di, *Al-Maamool*, p. 142, and *Al-Qawaaed*, p.78, item 33.

(41) *Mukhtasar Al-Fataawa Al-Masriyah*, p. 383. See also Ibn Taimiyah, *Al-Massel Al-Mardeeniyah*, p. 63.

(42) Al-Shaatibi, *Al-Muwafaqaat*, II: 350 & 376.

(43) Al-'Iz Ibn 'Abd Al-Salaam, *Al-Qawaa'ed Al-Kubra*, II: 158.

(44) *Ibid.*, II: 314.

As for the criterion that distinguishes public from private interests, it is that a public, or collective, interest is "everything that involves the realization of a gain or the prevention of an injury that affects the whole nation, a large group, a province, or the like," while a private interest is "everything that involves the realization of a gain or the prevention of an injury or harm that affects a certain individual or few individuals."(45)

(45) Al-Ghazaali, *Shifaa Al-Ghaleel*, p. 210; Al-Taher Ibn 'Aashoor, *Maqaased Al-Shareeah*, pp. 78 & 86.

Guideline 9
Special Limitations on Risk When Research Involves Individuals Who Are Not Capable of Giving Informed Consent

When there is ethical and scientific justification to conduct research with individuals incapable of giving informed consent, the risk from research interventions that do not hold out the prospect of direct benefit for the individual subject should be no more likely and not greater than the risk attached to routine medical or psychological examination of such persons. Slight or minor increases above such risk may be permitted when there is an overriding scientific or medical rationale for such increases and when an ethical review committee has approved them.

Commentary on Guideline 9

The Low-Risk Standard: Certain individuals or groups may have limited capacity to give informed consent either because, as in the case of prisoners, their autonomy is limited, or because they have limited cognitive capacity. For research involving persons who are unable to consent, or whose capacity to make an informed choice may not fully meet the standard of informed consent, ethical review committees must distinguish between intervention risks that do not exceed those associated with routine medical or psychological examination of such persons and risks in excess of those.

When the risks of such interventions do not exceed those associated with routine medical or psychological examination of such persons, there is no requirement for special substantive or procedural protective measures apart from those generally required for all research involving members of the particular class of persons. When the risks are in excess of those, the ethical review committee must find:

1) that the research is designed to be responsive to the disease affecting the prospective subjects or to conditions to which they are particularly susceptible; 2) that the risks of the research interventions are only slightly greater than those associated with routine medical or psychological examination of such persons for the condition or set of clinical circumstances under investigation; 3) that the objective of the research is sufficiently important to justify exposure of the subjects to the increased risk; and 4) that the interventions are reasonably commensurate with the clinical interventions that the subjects have experienced or may be expected to experience in relation to the condition under investigation.

If such research subjects, including children, become capable of giving independent informed consent during the research, their consent to continued participation should be obtained.

There is no internationally agreed, precise definition of a "slight or minor increase" above the risks associated with routine medical or psychological examination of such persons. Its meaning is inferred from what various ethical review committees have reported as having met the standard. Examples include additional lumbar punctures or bone-marrow aspirations in children with conditions for which such examinations are regularly indicated in clinical practice. The requirement that the objective of the research be relevant to the disease or condition affecting the prospective subjects rules out the use of such interventions in healthy children.

The requirement that the research interventions be reasonably commensurate with clinical interventions that subjects may have experienced or are likely to experience for the condition under investigation is intended to enable them to draw on personal experience as they decide whether to accept or reject additional procedures for research purposes. Their choices will, therefore, be more informed even though they may not fully meet the standard of informed consent.

(See also *Guidelines* 4: *Individual Informed Consent*; 13: *Research Involving Vulnerable Persons;* 14: *Research Involving Children;* and 15: *Research Involving Individuals Who by Reason of Mental or Behavioral Disorders Are Not Capable of Giving Adequately Informed Consent.*)

The Islamic Point of View Concerning Guideline 9 Special Limitations on Risk When Research Involves Individuals Who Are Not Capable of Giving Informed Consent

1 - The general concept of the limitations set forth in this guideline are justified from the viewpoint of Islamic jurisprudence(*fiqh*), on the bases of a principle that is inclined to distinguish between a permission given by a fully competent person, capable of giving informed consent for what concerns him, and the permission given, in case of incompetence or deficient competence, by a legal guardian of an individual incapable of giving informed consent or making an informed choice.

The basis of this distinction is that a permission by a representative of an individual of the second type is legally contingent on its serving the absolute or, in the cases where there is a conflict between benefit and harm, outweighing interest of the charge. This interest is expressed by jurist as "what brings him fortune or pleasure." Therefore, to safeguard the rights and the inviolability of weak persons and protect them from violation, manipulation, or loss, a guardian is not entitled to give any consent that might entail risks of absolute or outweighing injury or harm. The rule here is unlike that in the case of a permission by an individual of the first type, who is less restricted and enjoys greater freedom, based on the respect Islamic Law accords to a person's right to manage his own affairs and freedom to choose what he likes and finds most appropriate for him, even if it involves some risk, as long as he is fully competent and capable of making his own choices.(46)

(46) Al-Zarqa, *Al-Madkhal Al-Fiqhi Al-'Aam*, II: 817ff.; Al-Sayooti, *Al-Nazhaaer*, p. 158; Ibn Bakheem,, *Al-Nazhaaer*, p. 186.

2 - It should be stressed that the four limitations listed in Guideline 9 and the following commentary are technical opinions based on conventional points of view held by professionals and specialists in the field. They can be endorsed by Islamic Law on the basis of the rule of "convention," as long as the conventions of workers in the field admit these limitations. They are, however, subject to modification and change, with any change in the convention, as what is admitted into Islamic Law through convention changes with its change.

Guideline 10
Research in Populations and Communities with Limited Resources

Before undertaking research in a population or community with limited resources, the sponsor and the investigator must make every effort to ensure that:

- the research is responsive to the health needs and the priorities of the population or community in which it is to be carried out; and
- any intervention or product developed, or knowledge generated, will be made reasonably available for the benefit of that population or community.

Commentary on Guideline 10

This guideline is concerned with countries or communities in which resources are limited to the extent that they are, or may be, vulnerable to exploitation by sponsors and investigators from the relatively wealthy countries and communities.

Responsiveness of Research to Health Needs and Priorities. The ethical requirement that research be responsive to the health needs of the population or community in which it is carried out calls for decisions on what is needed to fulfill the requirement. It is not sufficient simply to determine that a disease is prevalent in the population and that new or further research is needed: the ethical requirement of "responsiveness" can be fulfilled only if successful interventions or other kinds of health benefit are made available to the population. This is applicable especially to research conducted in countries where governments lack the resources to make such products or benefits widely available. Even when a product to be tested in a particular country is much cheaper than the standard treatment in some other countries, the government or individuals in that country

may still be unable to afford it. If the knowledge gained from the research in such a country is used primarily for the benefit of populations that can afford the tested product, the research may rightly be characterized as exploitative and, therefore, unethical.

When an investigational intervention has important potential for health care in the host country, the negotiation that the sponsor should undertake to determine the practical implications of "responsiveness", as well as "reasonable availability", should include representatives of stakeholders in the host country; these include the national government, the health ministry, local health authorities, and concerned scientific and ethics groups, as well as representatives of the communities from which subjects are drawn and non-governmental organizations such as health advocacy groups. The negotiation should cover the health-care infrastructure required for safe and rational use of the intervention, the likelihood of authorization for distribution, and decisions regarding payments, royalties, subsidies, technology and intellectual property, as well as distribution costs, when this economic information is not proprietary. In some cases, satisfactory discussion of the availability and distribution of successful products will necessarily engage international organizations, donor governments and bilateral agencies, international nongovernmental organizations, and the private sector. The development of a health-care infrastructure should be facilitated at the onset so that it can be of use during and beyond the conduct of the research.

Additionally, if an investigational drug has been shown to be beneficial, the sponsor should continue to provide it to the subjects after the conclusion of the study, and pending its approval by a drug regulatory authority. The sponsor is unlikely to be in a position to make a beneficial investigational intervention generally available to the community or population until some time after the conclusion of the study, as it may be in short supply and in any case cannot be made generally available before a drug regulatory authority has approved it.

For minor research studies and when the outcome is scientific knowledge rather than a commercial product, such complex planning

or negotiation is rarely, if ever, needed. There must be assurance, however, that the scientific knowledge developed will be used for the benefit of the population.

Reasonable Availability. The issue of "reasonable availability" is complex and will need to be determined on a case-by-case basis. Relevant considerations include the length of time for which the intervention or product developed, or other agreed benefit, will be made available to research subjects, or to the community or population concerned; the severity of a subject's medical condition; the effect of withdrawing the study drug (e.g., death of a subject); the cost to the subject or health service; and the question of undue inducement if an intervention is provided free of charge.

In general, if there is good reason to believe that a product developed or knowledge generated by research is unlikely to be reasonably available to, or applied to the benefit of, the population of a proposed host country or community after the conclusion of the research, it is unethical to conduct the research in that country or community. This should not be construed as precluding studies designed to evaluate novel therapeutic concepts. As a rare exception, for example, research may be designed to obtain preliminary evidence that a drug or a class of drugs has a beneficial effect in the treatment of a disease that occurs only in regions with extremely limited resources, and it could not be carried out reasonably well in more developed communities. Such research may be justified ethically even if there is no plan in place to make a product available to the population of the host country or community at the conclusion of the preliminary phase of its development. If the concept is found to be valid, subsequent phases of the research could result in a product that could be made reasonably available at its conclusion.

(See also Guidelines 3: *Ethical Review of Externally Sponsored Research*; 12, *Equitable Distribution of Burdens and Benefits*; 20: *Strengthening Capacity for Ethical and Scientific Review and Biomedical Research*; and 21: *Ethical* Obligation of External Sponsors to Provide Health-Care Services.)

The Islamic Point of View Concerning Guideline 10 Research in Populations and Communities with Limited Resources

1 - That the sponsor and the investigator should make every effort to guarantee the responsiveness of the research to the health needs and priorities of the population or community of limited resources in which it is carried out is a requirement recognized in Islamic Law. As already pointed out, one of the aims of that law is to take priorities in consideration and place all things in proper order, based on reality and its requirements, so that what needs to take priority may not be postponed and what needs to be postponed may not be given priority.(47)

2 - Making the research outcome reasonably (i.e. in a fair manner) available to the host population or community is a requirement of Islamic Law, for justice and charity are required by virtue of God's order: "God enjoins justice and charity" (*Al-Nahl* XVI: 90). In application of this injunction, whenever a new medicine results from the finings of research conducted in a certain country, equity dictates that in exchange for the burdens shouldered by its citizens in being research subjects, they should benefit from the material gains from that medicine.

(47) See the opinion of Islamic Law regarding guideline 3.

Guideline 11
Choice of Control in Clinical Trials

As a general rule, research subjects in the control group of a trial of a diagnostic, therapeutic, or preventive intervention should receive an established effective intervention. In some circumstances it may be ethically acceptable to use an alternative comparator, such as placebo or "no treatment."

Placebo may be used:

- when there is no established effective intervention;
- when withholding an established effective intervention would expose subjects to, at most, temporary discomfort or delay in relief of symptoms;
- when use of an established effective intervention as comparator would not yield scientifically reliable results and use of placebo would not add any risk of serious or irreversible harm to the subjects.

Commentary on Guideline 11

General Considerations for Controlled Clinical Trials. The design of trials of investigational diagnostic, therapeutic or preventive interventions raises interrelated scientific and ethical issues for sponsors, investigators, and ethical review committees. To obtain reliable results, investigators must compare the effects of an investigational intervention on subjects assigned to the investigational arm (or arms) of a trial with the effects that a control intervention produces in subjects drawn from the same population and assigned to its control arm. Randomization is the preferred method for assigning subjects to the various arms of the clinical trial unless another method, such as historical or literature controls, can be justified scientifically and ethically. Assignment to treatment arms by randomization, in addition to its usual

scientific superiority, offers the advantage of tending to render equivalent to all subjects the foreseeable benefits and risks of participation in a trial.

A clinical trial cannot be justified ethically unless it is capable of producing scientifically reliable results. When the objective is to establish the effectiveness and safety of an investigational intervention, the use of a placebo control is often much more likely than that of an active control to produce a scientifically reliable result. In many cases the ability of a trial to distinguish effective from ineffective interventions (its assay sensitivity) cannot be assured unless the control is a placebo. If, however, an effect of using a placebo would be to deprive subjects in the control arm of an established effective intervention, and thereby to expose them to serious harm, particularly if it is irreversible, it would obviously be unethical to use a placebo.

Placebo Control in the Absence of a Current Effective Alternative. The use of placebo in the control arm of a clinical trial is ethically acceptable when, as stated in the Declaration of Helsinki (Paragraph 29), "no proven prophylactic, diagnostic, or therapeutic method exists." Usually, in this case, a placebo is scientifically preferable to no intervention. In certain circumstances, however, an alternative design may be both scientifically and ethically acceptable, and preferable; an example would be a clinical trial of a surgical intervention, because, for many surgical interventions, either it is not possible or it is ethically unacceptable to devise a suitable placebo; for another example, in certain vaccine trials an investigator might choose to provide for those in the 'control' arm a vaccine that is unrelated to the investigational vaccine.

Placebo-Controlled Trials That Entail Only Minor Risks. A placebo-controlled design may be ethically acceptable, and preferable on scientific grounds, when the condition for which patients/subjects are randomly assigned to placebo or active treatment is only a small deviation in physiological measurements, such as slightly raised blood pressure or a modest increase in serum cholesterol; and if delaying or omitting available treatment may cause only temporary discomfort (e.g., common headache) and no serious adverse consequences. The

ethical review committee must be fully satisfied that the risks of withholding an established effective intervention are truly minor and short-lived.

Placebo Control When Active Control Would Not Yield Reliable Results. A related but distinct rationale for using a placebo control rather than an established effective intervention is that the documented experience with the established effective intervention is not sufficient to provide a scientifically reliable comparison with the intervention being investigated; it is then difficult, or even impossible, without using a placebo, to design a scientifically reliable study. This is not always, however, an ethically acceptable basis for depriving control subjects of an established effective intervention in clinical trials; only when doing so would not add any risk of serious harm, particularly irreversible harm, to the subjects would it be ethically acceptable to do so. In some cases, the condition at which the intervention is aimed (for example, cancer or HIV/AIDS) will be too serious to deprive control subjects of an established effective intervention.

This latter rationale (when active control would not yield reliable results) differs from the former (trials that entail only minor risks) in emphasis. In trials that entail only minor risks the investigative interventions are aimed at relatively trivial conditions, such as the common cold or hair loss; forgoing an established effective intervention for the duration of a trial deprives control subjects of only minor benefits. It is for this reason that it is not unethical to use a placebo-control design. Even if it were possible to design a so-called "non-inferiority," or "equivalency," trial using an active control, it would still not be unethical in these circumstances to use a placebo-control design. In any event, the researcher must satisfy the ethical review committee that the safety and human rights of the subjects will be fully protected, that prospective subjects will be fully informed about alternative treatments, and that the purpose and design of the study are scientifically sound. The ethical acceptability of such placebo-controlled studies increases as the period of placebo use is decreased, and when the study design permits change to active treatment ("escape treatment") if intolerable symptoms occur.

Exceptional Use of a Comparator Other than an Established Effective Intervention. An exception to the general rule is applicable in some studies designed to develop a therapeutic, preventive, or diagnostic intervention for use in a country or community in which an established effective intervention is not available and unlikely in the foreseeable future to become available, usually for economic or logistic reasons. The purpose of such a study is to make available to the population of the country or community an effective alternative to an established effective intervention that is locally unavailable. Accordingly, the proposed investigational intervention must be responsive to the health needs of the population from which the research subjects are recruited, and there must be assurance that, if it proves to be safe and effective, it will be made reasonably available to that population. Also, the scientific and ethical review committees must be satisfied that the established effective intervention cannot be used as comparator because its use would not yield scientifically reliable results that would be relevant to the health needs of the study population. In these circumstances an ethical review committee can approve a clinical trial in which the comparator is other than an established effective intervention, such as placebo or no treatment or a local remedy.

However, some people strongly object to the exceptional use of a comparator other than an established effective intervention because it could result in exploitation of poor and disadvantaged populations. The objection rests on three arguments:

- Placebo control could expose research subjects to risk of serious or irreversible harm when the use of an established effective intervention as comparator could avoid the risk.
- Not all scientific experts agree about conditions under which an established effective intervention used as a comparator would not yield scientifically reliable results.
- An economic reason for the unavailability of an established effective intervention cannot justify a placebo-controlled study in a country of limited resources when it would be unethical to conduct a study with the same design in a population with general access to the effective intervention outside the study.

Placebo Control When an Established Effective Intervention Is Not Available in the Host Country. The question addressed here is: when should an exception be allowed to the general rule that subjects in the control arm of a clinical trial should receive an established effective intervention?

The usual reason for proposing the exception is that, for economic or logistic reasons, an established effective intervention is not in general use or available in the country in which the study will be conducted, whereas the investigational intervention could be made available, given the finances and infrastructure of the country.

Another reason that may be advanced for proposing a placebo-controlled trial is that using an established effective intervention as the control would not produce scientifically reliable data relevant to the country in which the trial is to be conducted. Existing data about the effectiveness and safety of the established effective intervention may have been accumulated under circumstances unlike those of the population in which it is proposed to conduct the trial; this, it may be argued, could make their use in the trial unreliable. One reason could be that the disease or condition manifests itself differently in different populations, or other uncontrolled factors could invalidate the use of existing data for comparative purposes.

The use of placebo control in these circumstances is ethically controversial, for the following reasons:

- Sponsors of research might use poor countries or communities as testing grounds for research that would be difficult or impossible in countries where there is general access to an established effective intervention, and the investigational intervention, if proven safe and effective, is likely to be marketed in countries in which an established effective intervention is already available and it is not likely to be marketed in the host country.

- The research subjects, both active-arm and control-arm, are patients who may have a serious, possibly life-threatening, illness. They do not normally have access to an established effective intervention currently available to similar patients in many other countries. According to the requirements of a scientifically reliable trial, investigators, who may be

their attending physicians, would be expected to enroll some of those patients/subjects in the placebo-control arm. This would appear to be a violation of the physician's fiduciary duty of undivided loyalty to the patient, particularly in cases in which known effective therapy could be made available to the patients.

An argument for exceptional use of placebo control may be that a health authority in a country where an established effective intervention is not generally available or affordable, and unlikely to become available or affordable in the foreseeable future, seeks to develop an affordable intervention specifically for a health problem affecting its population. There may then be less reason for concern that a placebo design is exploitative, and therefore unethical, as the health authority has responsibility for the population's health, and there are valid health grounds for testing an apparently beneficial intervention. In such circumstances, an ethical review committee may determine that the proposed trial is ethically acceptable, provided that the rights and safety of subjects are safeguarded.

Ethical review committees will need to engage in careful analysis of the circumstances to determine whether the use of placebo rather than an established effective intervention is ethically acceptable. They will need to be satisfied that an established effective intervention is truly unlikely to become available and implementable in that country. This may be difficult to determine, however, as it is clear that, with sufficient persistence and ingenuity, ways may be found of accessing previously unattainable medicinal products, and thus avoiding the ethical issue raised by the use of placebo control.

When the rationale of proposing a placebo-controlled trial is that the use of an established effective intervention as the control would not yield scientifically reliable data relevant to the proposed host country, the ethical review committee in that country has the option of seeking expert opinion as to whether use of an established effective intervention in the control arm would invalidate the results of the research.

An "Equivalency Trial" as an Alternative to a Placebo-Controlled Trial. An alternative to a placebo-control design in these circum-

stances would be an "equivalency trial", which would compare an investigational intervention with an established effective intervention and produce scientifically reliable data. An equivalency trial in a country in which no established effective intervention is available is not designed to determine whether the investigational intervention is superior to an established effective intervention currently used somewhere in the world; its purpose is, rather, to determine whether the investigational intervention is, in effectiveness and safety, equivalent to, or almost equivalent to, the established effective intervention. It would be hazardous to conclude, however, that an intervention demonstrated to be equivalent, or almost equivalent, to an established effective intervention is better than nothing or superior to whatever intervention is available in the country; there may be substantial differences between the results of superficially identical clinical trials carried out in different countries. If there are such differences, it would be scientifically acceptable and ethically preferable to conduct such 'equivalency' trials in countries in which an established effective intervention is already available.

If there are substantial grounds for the ethical review committee to conclude that an established effective intervention will not become available and implementable, the committee should obtain assurances from the parties concerned that plans have been agreed for making the investigational intervention reasonably available in the host country or community once its effectiveness and safety have been established. Moreover, when the study has external sponsorship, approval should usually be dependent on the sponsors and the health authorities of the host country having engaged in a process of negotiation and planning, including justifying the study in regard to local health-care needs.

Means of Minimizing Harm to Placebo-Control Subjects. Even when placebo controls are justified on one of the bases set forth in the guideline, there are means of minimizing the possibly harmful effect of being in the control arm.

First, a placebo-control group need not be untreated. An add-on design may be employed when the investigational therapy and a standard treatment have different mechanisms of action. The treatment

to be tested and placebo are each added to a standard treatment. Such studies have a particular place when a standard treatment is known to decrease mortality or irreversible morbidity but a trial with standard treatment as the active control cannot be carried out or would be difficult to interpret [*International Conference on Harmonisation (ICH) Guideline: Choice of Control Group and Related Issues in Clinical Trials, 2000*]. In testing for improved treatment of life-threatening diseases such as cancer, HIV/AIDS, or heart failure, add-on designs are a particularly useful means of finding improvements in interventions that are not fully effective or may cause intolerable side-effects. They have a place also in respect of treatment for epilepsy, rheumatism, and osteoporosis, for example, because withholding of established effective therapy could result in progressive disability and/or unacceptable discomfort.

Second, as indicated in the Commentary on Guideline 8, when the intervention to be tested in a randomized controlled trial is designed to prevent or postpone a lethal or disabling outcome, the investigator minimizes harmful effects of placebo-control studies by providing in the research protocol for the monitoring of research data by an independent Data and Safety Monitoring Board (DSMB). One function of such a board is to protect the research subjects from previously unknown adverse reactions; another is to avoid unnecessarily prolonged exposure to an inferior therapy. The board fulfils the latter function by means of interim analyses of the data pertaining to efficacy to ensure that the trial does not continue beyond the point at which an investigational therapy is demonstrated to be effective. Normally, at the outset of a randomized controlled trial, criteria are established for its premature termination (stopping rules or guidelines).

In some cases the DSMB is called upon to perform "conditional power calculations", designed to determine the probability that a particular clinical trial could ever show that the investigational therapy is effective. If that probability is very small, the DSMB is expected to recommend termination of the clinical trial, because it would be unethical to continue it beyond that point.

In most cases of research involving human subjects, it is unnecessary to appoint a DSMB. To ensure that research is carefully monitored for the early detection of adverse events, the sponsor or the principal investigator appoints an individual to be responsible for advising on the need to consider changing the system of monitoring for adverse events or the process of informed consent, or even to consider terminating the study.

The Islamic Point of View Concerning Guideline 11 Choice of Control in Clinical Trials

There is no objection to the practice of administering new medicines to one group and administering placebo to another, for the purpose of studying the different effects and the results of using a new medicine, since that helps in conducting successful research that can bring benefit to all. This opinion is reinforced by the fact that the limits listed in the commentary on this guideline prevent the occurrence of any harm. Although a sort of deception is practiced, the consequences are safe.

Guideline 12
Equitable Distribution of Burdens and Benefits in the Selection of Groups of Subjects in Research

Groups or communities to be invited to be subjects of research should be selected in such a way that the burdens and benefits of the research will be equitably distributed. The exclusion of groups or communities that might benefit from study participation must be justified.

Commentary on Guideline 12

General Considerations: Equity requires that no group or class of persons should bear more than its fair share of the burdens of participation in research. Similarly, no group should be deprived of its fair share of the benefits of research, short-term or long-term; such benefits include the direct benefits of participation as well as the benefits of the new knowledge that the research is designed to yield. When burdens or benefits of research are to be apportioned unequally among individuals or groups of persons, the criteria for unequal distribution should be morally justifiable and not arbitrary. In other words, unequal allocation must not be inequitable. Subjects should be drawn from the qualifying population in the general geographic area of the trial without regard to race, ethnicity, economic status or gender unless there is a sound scientific reason to do otherwise.

In the past, groups of persons were excluded from participation in research for what were then considered good reasons. As a consequence of such exclusions, information about the diagnosis, prevention and treatment of diseases in such groups of persons is limited. This has resulted in a serious class injustice. If information about the management of diseases is considered a benefit that is distributed within a society, it is unjust to deprive groups of persons of that

benefit. Such documents as the Declaration of Helsinki and the UNAIDS Guidance Document *Ethical Considerations in HIV Preventive Vaccine Research,* and the policies of many national governments and professional societies, recognize the need to redress these injustices by encouraging the participation of previously excluded groups in basic and applied biomedical research.

Members of vulnerable groups also have the same entitlement to access to the benefits of investigational interventions that show promise of therapeutic benefit as persons not considered vulnerable, particularly when no superior or equivalent approaches to therapy are available.

There has been a perception, sometimes correct and sometimes incorrect, that certain groups of persons have been overused as research subjects. In some cases such overuse has been based on the administrative availability of the populations. Research hospitals are often located in places where members of the lowest socioeconomic classes reside, and this has resulted in an apparent overuse of such persons. Other groups that may have been overused because they were conveniently available to researchers include students in investigators' classes, residents of long-term care facilities, and subordinate members of hierarchical institutions. Impoverished groups have been overused because of their willingness to serve as subjects in exchange for relatively small stipends. Prisoners have been considered ideal subjects for Phase I drug studies because of their highly regimented lives and, in many cases, their conditions of economic deprivation (Appendix III).

Overuse of certain groups, such as the poor or the administratively available, is unjust for several reasons. It is unjust to recruit, selectively, impoverished people to serve as research subjects simply because they can be more easily induced to participate in exchange for small payments. In most cases, these people would be called upon to bear the burdens of research so that others who are better off could enjoy the benefits. However, although the burdens of research should not fall disproportionately on socio-economically disadvantaged groups, neither should such groups be categorically excluded from

research protocols. It would not be unjust to recruit, selectively, poor people to serve as subjects in research designed to address problems that are prevalent in their group - malnutrition, for example. Similar considerations apply to institutionalized groups or those whose availability to the investigators is for other reasons administratively convenient.

Not only may certain groups within a society be inappropriately overused as research subjects, but also entire communities or societies may be overused. This has been particularly likely to occur in countries or communities with insufficiently well-developed systems for the protection of the rights and welfare of human research subjects. Such overuse is especially questionable when the populations or communities concerned bear the burdens of participation in research but are extremely unlikely ever to enjoy the benefits of new knowledge and products developed as a result of the research. (See Guideline 10: *Research in Populations and Communities with Limited Resources.*)

The Islamic Point of View Concerning Guideline 12 Equitable Distribution of Burdens and Benefits in the Selection of Groups of Subjects in Research

The import of this guideline is in harmony with the Islamic Law principle that calls for justice in all affairs of life, for God, the Most Exalted, says, "God enjoins justice" (*Al-Nahl* XVI: 90).

Islamic Law prevents any discrimination against people on the basis of race, class, culture, or gender. The Prophet, blessings and peace be upon him, abolished all distinctions between people that are based on pride and made all of them equal, with no distinction between them as human beings.

Guideline 13
Research Involving Vulnerable Persons

Special justification is required for inviting vulnerable individuals to serve as research subjects and, if they are selected, the means of protecting their rights and welfare must be strictly applied.

Commentary on Guideline 13

Vulnerable persons are those who are relatively (or absolutely) incapable of protecting their own interests. More formally, they may have insufficient power, intelligence, education, resources, strength, or other needed attributes to protect their own interests.

General Considerations. The central problem presented by plans to involve vulnerable persons as research subjects is that such plans may entail an inequitable distribution of the burdens and benefits of research participation. Classes of individuals conventionally considered vulnerable are those with limited capacity or freedom to consent or to decline to consent. They are the subject of specific guidelines in this document (Guidelines 14,15) and include children, and persons who because of mental or behavioral disorders are incapable of giving informed consent. Ethical justification of their involvement usually requires that investigators satisfy ethical review committees that:

- the research could not be carried out equally well with less vulnerable subjects;
- the research is intended to obtain knowledge that will lead to improved diagnosis, prevention, or treatment of diseases or other health problems characteristic of, or unique to, the vulnerable class - either the actual subjects or other similarly situated members of the vulnerable class;
- research subjects and other members of the vulnerable class from which subjects are recruited will ordinarily be assured reasonable

access to any diagnostic, preventive, or therapeutic products that will become available as a consequence of the research;

- the risks attached to interventions or procedures that do not hold out the prospect of direct health-related benefit will not exceed those associated with routine medical or psychological examination of such persons unless an ethical review committee authorizes a slight increase over this level of risk (Guideline 9); and
- when the prospective subjects are either incompetent or otherwise substantially unable to give informed consent, their agreement will be supplemented by the permission of their legal guardians or other appropriate representatives.

Other Vulnerable Groups. The quality of the consent of prospective subjects who are junior or subordinate members of a hierarchical group requires careful consideration, as their agreement to volunteer may be unduly influenced, whether justified or not, by the expectation of preferential treatment if they agree or by fear of disapproval or retaliation if they refuse. Examples of such groups are medical and nursing students, subordinate hospital and laboratory personnel, employees of pharmaceutical companies, and members of the armed forces and the police. Because they work in close proximity to investigators, they tend to be called upon more often than others to serve as research subjects, and this could result in inequitable distribution of the burdens and benefits of research.

Elderly persons are commonly regarded as vulnerable. With advancing age, people are increasingly likely to acquire attributes that define them as vulnerable. They may, for example, be institutionalized or develop varying degrees of dementia. If and when they acquire such vulnerability-defining attributes, and not before, it is appropriate to consider them vulnerable and to treat them accordingly.

Other groups or classes may also be considered vulnerable. They include residents of nursing homes, people receiving welfare benefits or social assistance and other poor people and the unemployed, patients in emergency rooms, some ethnic and racial minority groups, homeless persons, nomads, refugees or displaced persons, prisoners, patients with incurable disease, individuals who are politically powerless, and

members of communities unfamiliar with modern medical concepts. To the extent that these and other classes of people have attributes resembling those of classes identified as vulnerable, the need for special protection of their rights and welfare should be reviewed and applied, where relevant.

Persons who have serious, potentially disabling or life-threatening diseases are highly vulnerable. Physicians sometimes treat such patients with drugs or other therapies not yet licensed for general availability because studies designed to establish their safety and efficacy have not been completed. This is compatible with the Declaration of Helsinki, which states in Paragraph 32: "In the treatment of a patient, where proven therapeutic methods do not exist or have been ineffective, the physician, with informed consent from the patient, must be free to use unproven or new therapeutic measures, if in the physician's judgment it offers hope of saving life, re-establishing health, or alleviating suffering." Such treatment, commonly called 'compassionate use,' is not properly regarded as research, but it can contribute to ongoing research into the safety and efficacy of the interventions used.

Although, on the whole, investigators must study less vulnerable groups before involving more vulnerable groups, some exceptions are justified. In general, children are not suitable for Phase I drug trials or for Phase I or II vaccine trials, but such trials may be permissible after studies in adults have shown some therapeutic or preventive effect. For example, a Phase II vaccine trial seeking evidence of immunogenicity in infants may be justified when the vaccine has shown evidence of preventing or slowing progression of an infectious disease in adults, or Phase I research with children may be appropriate because the disease to be treated does not occur in adults or is manifested differently in children (Appendix 3: *The Phases of Clinical Trials of Vaccines and Drugs*).

The Islamic Point of View Concerning Guideline 13 Research Involving Vulnerable Persons

1 - The content of and commentary on this guideline are subject to the same rulings as previous guidelines which aim at enforcing the principle of respect for individuals, particularly those considered vulnerable, who might succumb to moral pressure and be open to the influence of the researcher or the sponsor.

2 - Therefore, groups and industries that can also be considered vulnerable - such as emergency room patients, residents of nursing homes and similar establishments, prisoners, refugees, displaced people, and the like, who all need their rights and interests to be protected - should not be forced, pressured, deceived, or subjected to an exploitation of their psychological condition or financial difficulties in order to make them consent to be research subjects. Such a coercion or exploitation involves injustice that is disapproved by the principles of Islamic Law, which condemns all types and forms of injustice and inequality. In a divine tradition, the Prophet, blessings and peace be upon him, quotes his Lord, the most Glorious and Sublime, as saying, "My worshippers, I have forbidden injustice on my part and made it forbidden among you, so do not be unjust to one another."(48) The Prophet, blessings and peace be upon him, says, "Beware of injustice, for injustice is layers of darkness on the Day of Resurrection."(49)

Thus, a special justification of recruiting vulnerable individuals to serve as research subjects is required in Islamic Law, and, as stipulated in this guideline, strict measures to protect their personal rights and interests should be taken.

(48) Cited by Muslim and included in *Jame' Al-'Uloom wa Al-Hikam*, II: 32, and Al-Qurubi, *Al-Mufhem Lima Ashkal Min Talkhees Kitaab Muslim*, VI: 552.

(49) Cited by Muslim in his *Anthology*, annotated by Al-Nawawi, II: 37.

Guideline 14
Research Involving Children

Before undertaking research involving children, the investigator must ensure that:

- the research might not equally well be carried out with adults;
- the purpose of the research is to obtain knowledge relevant to the health needs of children;
- a parent or legal representative of each child has given permission;
- the assent of each child has been obtained to the extent of the child's capabilities; and
- a child's refusal to participate or continue in the research will be respected.

Commentary on Guideline 14

Justification of the Involvement of Children in Biomedical Research. The participation of children is indispensable for research into diseases of childhood and conditions to which children are particularly susceptible (cf. vaccine trials), as well as for clinical trials of drugs that are designed for children as well as adults. In the past, many new products were not tested for children though they were directed towards diseases also occurring in childhood; thus children either did not benefit from these new drugs or were exposed to them though little was known about their specific effects or safety in children. Now it is widely agreed that, as a general rule, the sponsor of any new therapeutic, diagnostic, or preventive product that is likely to be indicated for use in children is obliged to evaluate its safety and efficacy for children before it is released for general distribution.

Assent of the Child. The willing cooperation of the child should be sought, after the child has been informed to the extent that the child's

maturity and intelligence permit. The age at which a child becomes legally competent to give consent differs substantially from one jurisdiction to another; in some countries the "age of consent" established in their different provinces, states, or other political subdivisions varies considerably. Often children who have not yet reached the legally established age of consent can understand the implications of informed consent and go through the necessary procedures; they can therefore knowingly agree to serve as research subjects. Such knowing agreement, sometimes referred to as assent, is insufficient to permit participation in research unless it is supplemented by the permission of a parent, a legal guardian, or other duly authorized representative.

Some children who are too immature to be able to give knowing agreement, or assent, may be able to register a 'deliberate objection,' an expression of disapproval or refusal of a proposed procedure. The deliberate objection of an older child, for example, is to be distinguished from the behavior of an infant, who is likely to cry or withdraw in response to almost any stimulus. Older children, who are more capable of giving assent, should be selected before younger children or infants, unless there are valid scientific reasons related to age for involving younger children first.

A deliberate objection by a child to taking part in research should always be respected even if the parents have given permission, unless the child needs treatment that is not available outside the context of research, the investigational intervention shows promise of therapeutic benefit, and there is no acceptable alternative therapy. In such a case, particularly if the child is very young or immature, a parent or guardian may override the child's objections. If the child is older and more nearly capable of independent informed consent, the investigator should seek the specific approval or clearance of the scientific and ethical review committees for initiating or continuing with the investigational treatment. If child subjects become capable of independent informed consent during the research, their informed consent to continued participation should be sought and their decision respected.

A child with a likely fatal illness may object or refuse assent to continuation of a burdensome or distressing intervention. In such circumstances parents may press an investigator to persist with an investigational intervention against the child's wishes. The investigator may agree to do so if the intervention shows promise of preserving or prolonging life and there is no acceptable alternative treatment. In such cases, the investigator should seek the specific approval or clearance of the ethical review committee before agreeing to override the wishes of the child.

Permission of a Parent or Guardian. The investigator must obtain the permission of a parent or guardian in accordance with local laws or established procedures. It may be assumed that children over the age of 12 or 13 years are usually capable of understanding what is necessary to give adequately informed consent, but their consent (assent) should normally be complemented by the permission of a parent or guardian, even when local law does not require such permission. Even when the law requires parental permission, however, the assent of the child must be obtained.

In some jurisdictions, some individuals who are below the general age of consent are regarded as "emancipated" or "mature" minors and are authorized to consent without the agreement or even the awareness of their parents or guardians. They may be married or pregnant or be already parents or living independently. Some studies involve investigation of adolescents' beliefs and behavior regarding sexuality or use of recreational drugs; other research addresses domestic violence or child abuse. For studies on these topics, ethical review committees may waive parental permission if, for example, parental knowledge of the subject matter may place the adolescents at some risk of questioning or even intimidation by their parents.

Because of the issues inherent in obtaining assent from children in institutions, such children should only exceptionally be subjects of research. In the case of institutionalized children without parents, or whose parents are not legally authorized to grant permission, the ethical review committee may require sponsors or investigators to

provide it with the opinion of an independent, concerned, expert advocate for institutionalized children as to the propriety of undertaking the research with such children.

Observation of Research by a Parent or Guardian. A parent or guardian who gives permission for a child to participate in research should be given the opportunity, to a reasonable extent, to observe the research as it proceeds, so as to be able to withdraw the child if the parent or guardian decides it is in the child's best interests to do so.

Psychological and Medical Support. Research involving children should be conducted in settings in which the child and the parent can obtain adequate medical and psychological support. As an additional protection for children, an investigator may, when possible, obtain the advice of a child's family physician, pediatrician, or other health-care provider on matters concerning the child's participation in the research.

(See also *Guideline* 8: *Benefits and Risks of Study Participation*; *Guideline* 9: *Special Limitations on Risks When Subjects Are Not Capable Of Giving Consent*; and *Guideline* 13: *Research Involving Vulnerable Persons*.)

The Islamic Point of View Concerning Guideline 14 Research Involving Children

1 - Since a child under the age of puberty is, in Islamic jurisprudence, entirely incompetent, his "informed" consent to participate in biomedical research is not valid. Legally, such a child does not have the freedom to take an action that is absolutely harmful to him or that wavers between benefit and harm, including the consent referred to above, and if he does take such an action, it is not valid. This rule aims at protecting such a child from misconduct in his own affairs, as he may give permission to something that will cause him absolute harm or harm that outweighs any benefit, being unable to appreciate the potential consequences of his behavior. A jurisprudence (*fiqh*) rule says, "Statements by a person whose action is not valid are not admitted."(50)

2 - Moreover, the basic position of Islamic jurisprudence is that the permission of a legal guardian to subject his ward to such research is not legitimate. Article 3/d of resolution 67 (5/7) of the Islamic Jurisprudence Academy says: "It is not permissible to conduct medical research involving subjects with only partial or no competence, even with the consent of guardians."

Exception to this basic principle, however, can be made, when a guardian does give his consent, in either of the following cases:

a - When there is an absolute or outweighing benefit, or when a child urgently needs to participate in research, which is to be determined, confirmed, and cleared by an ethical review committee.

Even if a non-perceptive child resists or objects, his objec-

(50) Burhaan Al-Deen Ibn Mufleh, *Al-Mubde'*, X: 146.

tions are not taken into consideration, so that he can be protected from jeopardizing his interests or harming himself. On the other hand, if the child is perceptive (he is close to puberty and his perceptive skills have developed sufficiently although he is still under a guardian), any objection on his part should be taken into consideration and should be submitted to review committees for decision.

b - When there is a general, indisputable need to conduct research relevant to children diseases, vaccines, and drugs, and at the same time, the potential risks to the subject child are not greater than, or slightly exceed, those attached to routine medical or psychological examination, and an ethical review committee approves the involvement. This ruling is based on the principle that a special need, i.e. one needed by a group of people with a common attribute, is ranked in Islamic Law as a necessity that renders permissible what is originally forbidden. (See the Islamic point of view for *Guideline* 13.)

Guideline 15
Research Involving Individuals Who by Reason of Mental or Behavioral Disorders Are Not Capable of Giving Adequately Informed Consent

Before undertaking research involving individuals who by reason of mental or behavioral disorders are not capable of giving adequately informed consent, the investigator must ensure that:

- such persons will not be subjects of research that might equally well be carried out on persons whose capacity to give adequately informed consent is not impaired;
- the purpose of the research is to obtain knowledge relevant to the particular health needs of persons with mental or behavioral disorders;
- the consent of each subject has been obtained to the extent of that person's capabilities, and a prospective subject's refusal to participate in research is always respected, unless, in exceptional circumstances, there is no reasonable medical alternative and local law permits overriding the objection; and
- in cases where prospective subjects lack capacity to consent, permission is obtained from a responsible family member or a legally authorized representative in accordance with applicable law.

Commentary on Guideline 15

General Considerations. Most individuals with mental or behavioral disorders are capable of giving informed consent; this Guideline is concerned only with those who are not capable or who, because their condition deteriorates, become temporarily incapable. They should never be subjects of research that might equally well be carried out on

persons in full possession of their mental faculties, but they are clearly the only subjects suitable for a large part of research into the origins and treatment of certain severe mental or behavioral disorders.

Consent of the Individual. The investigator must obtain the approval of an ethical review committee to include in research persons who by reason of mental or behavioral disorders are not capable of giving informed consent. The willing cooperation of such persons should be sought to the extent that their mental state permits, and any objection on their part to taking part in any study that has no components designed to benefit them directly should always be respected. The objection of such an individual to an investigational intervention intended to be of therapeutic benefit should be respected unless there is no reasonable medical alternative and local law permits overriding the objection. The agreement of an immediate family member or other person with a close personal relationship with the individual should be sought, but it should be recognized that these proxies may have their own interests that may call their permission into question. Some relatives may not be primarily concerned with protecting the rights and welfare of the patients. Moreover, a close family member or friend may wish to take advantage of a research study in the hope that it will succeed in "curing" the condition. Some jurisdictions do not permit third-party permission for subjects lacking capacity to consent. Legal authorization may be necessary to involve in research an individual who has been committed to an institution by a court order.

Serious Illness in Persons Who because of Mental or Behavioral Disorders Are Unable to Give Adequately Informed Consent. Persons who because of mental or behavioral disorders are unable to give adequately informed consent and who have, or are at risk of, serious illnesses such as HIV infection, cancer or hepatitis should not be deprived of the possible benefits of investigational drugs, vaccines or devices that show promise of therapeutic or preventive benefit, particularly when no superior or equivalent therapy or prevention is

available. Their entitlement to access to such therapy or prevention is justified ethically on the same grounds as is such entitlement for other vulnerable groups.

Persons who are unable to give adequately informed consent by reason of mental or behavioral disorders are, in general, not suitable for participation in formal clinical trials except those trials that are designed to be responsive to their particular health needs and can be carried out only with them.

(See also *Guidelines* 8: *Benefits and Risks of Study Participation;* 9: *Special Limitations on Risks When Subjects Are Not Capable of Giving Consent;* and 13: *Research Involving Vulnerable Persons.*)

The Islamic Point of View Concerning Guideline 15 Research Involving Individuals Who by Reason of Mental or Behavioral Disorders Are Not Capable of Giving Adequately Informed Consent

This type or group of individuals fall, in Islamic Law terminology, under the category of demented or feebleminded people. A demented person is one that has little comprehension and does not understand the terms denoting actions or the consequences of these actions. A feebleminded person is an idiot who is unable to choose the proper, propitious, or beneficial option.(51) Persons of both groups have imperfect of flawed competence that prevents, in Islamic legal principle, their being involved in biomedical research. The right of a human being to live his life and have a sound body is protected by Islamic Law, and therefore no research should involve him without his permission, i.e. his informed consent and full approval, based on adequate comprehension of what he is consenting to and approving.

Since such individuals lack adequate comprehension and awareness and do not have the required faculty to appreciate consequences and protect themselves and their interests, it is not enough to obtain their informed consent to get involved in research, though that consent is required in as much as their mental condition allows.(52) Such consent is based on deficient approval and, therefore, has to be combined with permission from their legal guardians in the following exceptional cases:

(51) Dr. Nazeeh Hammaad, *Nathariyat Al-Wilayah*, p. 60.

(52) In cases where the prospective research subjects lack the ability to give their informed consent, such consent should be obtained from their legal guardian in the exceptional cases pointed out.

1 - when an absolute or an outweighing benefit is involved, or there is a pressing need for this type of subject in particular;

2 - when this category of people have a special health need to participate in the research and the expected risk is not greater than, or slightly exceeds, that involved in routine medical or psychological examination, and is, therefore, cleared by an ethical review committee; and

3 - when the need is certain in the sense that no reasonable medical alternative is available. If the goal can be reached by involving ordinary, fully competent persons in the research, that need, which justifies the exception, would no longer exist.(53)

(53) Dr. Nazeeh Hammaad, *Al-Mawaad Al-Muharramah wa Al-Najisah fi Al-Ghithaa wa Al-Dawaa*, p. 60.

Guideline 16
Women as Research Subjects

Investigators, sponsors, or ethical review committees should not exclude women of reproductive age from biomedical research. The potential for becoming pregnant during a study should not, in itself, be used as a reason for precluding or limiting participation. However, a thorough discussion of risks to the pregnant woman and to her fetus is a prerequisite for the woman's ability to make a rational decision to enroll in a clinical study. In this discussion, if participation in the research might be hazardous to a fetus or a woman if she becomes pregnant, the sponsors/investigators should guarantee the prospective subject a pregnancy test and access to effective contraceptive methods before the research commences. Where such access is not possible, for legal or religious reasons, investigators should not recruit for such possibly hazardous research women who might become pregnant.

Commentary on Guideline 16

Women in most societies have been discriminated against with regard to their involvement in research. Women who are biologically capable of becoming pregnant have been customarily excluded from formal clinical trials of drugs, vaccines and medical devices owing to concern about undetermined risks to the fetus. Consequently, relatively little is known about the safety and efficacy of most drugs, vaccines, or devices for such women, and this lack of knowledge can be dangerous.

A general policy of excluding from such clinical trials women biologically capable of becoming pregnant is unjust in that it deprives women as a class of persons of the benefits of the new knowledge derived from the trials. Further, it is an affront to their right of self-determination. Nevertheless, although women of childbearing age

should be given the opportunity to participate in research, they should be helped to understand that the research could include risks to the fetus if they become pregnant during the research.

Although this general presumption favors the inclusion of women in research, it must be acknowledged that in some parts of the world women are vulnerable to neglect or harm in research because of their social conditioning to submit to authority, to ask no questions, and to tolerate pain and suffering. When women in such situations are potential subjects in research, investigators need to exercise special care in the informed consent process to ensure that they have adequate time and a proper environment in which to take decisions on the basis of clearly given information.

Individual Consent of Women. In research involving women of reproductive age, whether pregnant or non-pregnant, only the informed consent of the woman herself is required for her participation. In no case should the permission of a spouse or partner replace the requirement of individual informed consent. If women wish to consult with their husbands or partners or seek voluntarily to obtain their permission before deciding to enroll in research, that is not only ethically permissible but in some contexts highly desirable. A strict requirement of authorization of spouse or partner, however, violates the substantive principle of respect for persons.

A thorough discussion of risks to the pregnant woman and to her fetus is a prerequisite for the woman's ability to make a rational decision to enroll in a clinical study. For women who are not pregnant at the outset of a study but who might become pregnant while they are still subjects, the consent discussion should include information about the alternative of voluntarily withdrawing from the study and, where legally permissible, terminating the pregnancy. Also, if the pregnancy is not terminated, they should be guaranteed a medical follow-up.

The Islamic Point of View Concerning Guideline 16 Women as Research Subjects

It is not right to exclude women of reproductive age from biomedical research, for the mere possibility of their becoming pregnant during a study, which may involve risks to the pregnant woman and to her fetus. This social segment has a pressing need to benefit from the outcome of formal trials of drugs, vaccines, and medical devices used in tests. Sufficient precautions should be taken to spare a woman, if she becomes pregnant, and her fetus any hazards. It is an instance of injustice and inequity to exclude women, as a social group, from the benefits gained through the new information learned through such trials.

However, the participation of a woman in research is, the same as in the case of a man, contingent on her voluntary, informed consent, given after she receives adequate information and proper understanding based on specific data of what she is consenting to, and after she is told all potential hazards and consequences that she needs to know. (See the Islamic Point of View in regards to Guideline 5.)

Therefore, an investigator must obtain the **personal**, voluntary consent of an adult female to participate in research. In Islamic Law, it is unacceptable for the permission of a husband to replace that of his wife, because that would be an affront to her human rights, as members of both sex enjoy full competence. An individual's independence, whether male or female, should be respected, and he/she should be allowed to make his/her personal choice and make the decision suitable for him/her in regards to involvement in research. This should be done, however, without any coercion, undue influence, deception, or exploitation, and after the person concerned receives the necessary information and comprehends it fully.

Still, out of consideration, to maintain a better and stronger marital relationship, and to avoid family problems, it is preferable to obtain the husband's consent.

Guideline 17
Pregnant Women as Research Participants

Pregnant women should be presumed to be eligible for participation in biomedical research. Investigators and ethical review committees should ensure that prospective subjects who are pregnant are adequately informed about the risks and benefits to themselves, their pregnancies, the fetus and their subsequent offspring, and their fertility.

Research in this population should be performed only if it is relevant to the particular health needs of a pregnant woman or her fetus, or to the health needs of pregnant women in general, and, when appropriate, if it is supported by reliable evidence from animal experiments, particularly as to risks of teratogenicity and mutagenicity.

Commentary on Guideline 17

The justification of research involving pregnant women is complicated by the fact that it may present risks and potential benefits to two beings, the woman and the fetus, as well as to the person the fetus is destined to become. Though the decision about the acceptability of risk should be made by the mother as part of the informed consent process, it is desirable in research directed at the health of the fetus to obtain the father's opinion also, when possible. Even when evidence concerning risks is unknown or ambiguous, the decision about the acceptability of risk to the fetus should be made by the mother as part of the informed consent process.

Especially in communities or societies in which cultural beliefs accord more importance to the fetus than to the woman's life or health, women may feel constrained to participate, or not to partici-

pate, in research. Special safeguards should be established to prevent undue inducement to pregnant women to participate in research in which interventions hold out the prospect of direct benefit to the fetus.

Where fetal abnormality is not recognized as an indication for abortion, pregnant women should not be recruited for research in which there is a realistic basis for concern that fetal abnormality may occur as a consequence of participation as a subject in research. Investigators should include in protocols on research on pregnant women a plan for monitoring the outcome of the pregnancy with regard to both the health of the woman and the short-term and long-term health of the child.

The Islamic Point of View Concerning Guideline 17 Pregnant Women as Research Participants

1 - Because of the need pregnant women and their fetuses have for the prospective benefits of biomedical research, there is no objection in Islamic Law to the participation of this group of women in such research, provided that the mother or fetus is likely to gain an absolute or outweighing benefit and that risks or prospects of fetus mutation, or similar things, resulting from the mother's involvement in the research, are nominal and unlikely.

2 - A condition for that involvement is to obtain the voluntary, informed consent of the pregnant woman, after she receives specific information concerning the potential hazards and benefits, and after all the risks and consequences to her and her fetus are explained to her.

3 - When there are potential risks for the fetus, even when they are minor or outweighed, the investigator should also obtain the consent of the father, who naturally has an interest in the fetus, based on his full knowledge and awareness of the consequences of his consent.

4 - In case there are potential risks for a pregnant woman involved in biomedical research in which the benefit hoped for serves the interest of the fetus, without any direct benefit to the mother, the risks should be made clear to her, so that her consent would be given out of altruistic motives and with the awareness that she is making a sacrifice. She should not be under any illusion that the research will positively influence the success of her conception, which is an instinctive desire of every prospective mother, so that she may not be influenced by her emotions, rather than her reason, into giving her consent.

Guideline 18
Safeguarding Confidentiality

The investigator must establish secure safeguards of the confidentiality of subjects' research data. Subjects should be told the limits, legal or other, to the investigators' ability to safeguard confidentiality and the possible consequences of breaches of confidentiality.

Commentary on Guideline 18

Confidentiality between Investigator and Subject. Research relating to individuals and groups may involve the collection and storage of information that, if disclosed to third parties, could cause harm or distress. Investigators should arrange to protect the confidentiality of such information by, for example, omitting information that might lead to the identification of individual subjects, limiting access to the information, anonymizing data, or other means. During the process of obtaining informed consent, the investigator should inform the prospective subjects about the precautions that will be taken to protect confidentiality.

Prospective subjects should be informed of limits to the ability of investigators to ensure strict confidentiality and of the foreseeable adverse social consequences of breaches of confidentiality. Some jurisdictions require the reporting to appropriate agencies of, for instance, certain communicable diseases or evidence of child abuse or neglect. Drug regulatory authorities have the right to inspect clinical-trial records, and a sponsor's clinical-compliance audit staff may require and obtain access to confidential data. These and similar limits to the ability to maintain confidentiality should be anticipated and disclosed to prospective subjects.

Participation in HIV/AIDS drug and vaccine trials may impose upon the research subjects significant associated risks of social

discrimination or harm; such risks merit consideration equal to that given to adverse medical consequences of the drugs and vaccines. Efforts must be made to reduce their likelihood and severity. For example, subjects in vaccine trials must be enabled to demonstrate that their HIV seropositivity is due to their having been vaccinated rather than to natural infection. This may be accomplished by providing them with documents attesting to their participation in vaccine trials, or by maintaining a confidential register of trial subjects, from which information can be made available to outside agencies at a subject's request.

Confidentiality between Physician and Patient. Patients have the right to expect that their physicians and other health-care professionals will hold all information about them in strict confidence and disclose it only to those who need, or have a legal right to, the information, such as other attending physicians, nurses, or other health-care workers who perform tasks related to the diagnosis and treatment of patients. A treating physician should not disclose any identifying information about patients to an investigator unless each patient has given consent to such disclosure and unless an ethical review committee has approved such disclosure.

Physicians and other health care professionals record the details of their observations and interventions in medical and other records. Epidemiological studies often make use of such records. For such studies it is usually impracticable to obtain the informed consent of each identifiable patient; an ethical review committee may waive the requirement for informed consent when this is consistent with the requirements of applicable law and provided that there are secure safeguards of confidentiality. (See also the Commentary on *Guideline* 4: *Waiver of the Consent Requirement.*) In institutions in which records may be used for research purposes without the informed consent of patients, it is advisable to notify patients generally of such practices; notification is usually by means of a statement in patient-information brochures. For research limited to patients' medical records, access

must be approved or cleared by an ethical review committee and must be supervised by a person who is fully aware of the confidentiality requirements.

Issues of Confidentiality in Genetic Research. An investigator who proposes to perform genetic tests of known clinical or predictive value on biological samples that can be linked to an identifiable individual must obtain the informed consent of the individual or, when indicated, the permission of a legally authorized representative. Conversely, before performing a genetic test that is of known predictive value or gives reliable information about a known heritable condition, and individual consent or permission has not been obtained, investigators must see that biological samples are fully anonymized and unlinked; this ensures that no information about specific individuals can be derived from such research or passed back to them.

When biological samples are not fully anonymized and when it is anticipated that there may be valid clinical or research reasons for linking the results of genetic tests to research subjects, the investigator in seeking informed consent should assure prospective subjects that their identity will be protected by secure coding of their samples (encryption) and by restricted access to the database, and explain to them this process.

When it is clear that for medical or possibly research reasons the results of genetic tests will be reported to the subject or to the subject's physician, the subject should be informed that such disclosure will occur and that the samples to be tested will be clearly labeled.

Investigators should not disclose results of diagnostic genetic tests to relatives of subjects without the subjects' consent. In places where immediate family relatives would usually expect to be informed of such results, the research protocol, as approved or cleared by the ethical review committee, should indicate the precautions in place to prevent such disclosure of results without the subjects' consent; such plans should be clearly explained during the process of obtaining informed consent.

The Islamic Point of View Concerning Guideline 18 Safeguarding Confidentiality

Resolution 79 (10/8) of the Islamic Jurisprudence (*Fiqh*) Academy in Jeddah sets forth, in articles 4, 5, and 6, the rulings on confidentiality in medical professions, as follows:

Fourth: Safeguarding confidentiality is a definite requirement for all workers in professions where releasing confidential information creates disorder, such as the medical professions. People who need advice and assistance seek the help of such professionals and confide in them information and data that may help in the performance of the vital tasks required, including details that a person normally conceals from everyone else, including those closest to him.

Fifth: Exceptions from the requirement of safeguarding confidentiality are made in cases where concealing the confidential information causes greater harm, for the person involved, than that caused by revealing it, or when revealing it brings a benefit that outweighs that of concealing it. Such cases are of two types:

A - The first types is that of cases where revealing confidential information is required in accordance with the rule that calls for commission of the slighter of two injuries to prevent the greater, or the rule of pursuing public interest, which calls for tolerating a private instance of harm to prevent a public one, when necessary. Such cases fall into two categories:
  - cases of preventing social harm, and
  - cases of preventing individual harm.

B - The second type is that of cases where revealing confidential information is permitted, because it
  - brings a social benefit, or
  - prevents public harm.

In all these cases the objectives and priorities of Islamic Law - namely, the preservation of faith, life, reason, offspring and wealth - must be observed.

Sixth: Exceptions relevant to cases that require, or allow, the disclosure of confidential information should be provided for in the practice regulations of medical professions. They should be listed clearly and inclusively, with details explaining how and to whom the disclosure should be made. Concerned authorities should make everybody aware of these cases.

These rules follow the third article of the resolution which says, "The normal thing is to prohibit any disclosure of confidential information, and revealing it without a justification entails legal liability."

Guideline 19
Right of Injured Subjects to Treatment and Compensation

Investigators should ensure that research subjects who suffer injury as a result of their participation are entitled to free medical treatment for such injury and to such financial or other assistance as would compensate them equitably for any resultant impairment, disability, or handicap. In the case of death as a result of their participation, their dependants are entitled to compensation. Subjects must not be asked to waive the right to compensation.

Commentary on Guideline 19

Guideline 19 is concerned with two distinct but closely related entitlements. The first is the uncontroversial entitlement to free medical treatment and compensation for accidental injury inflicted by procedures or interventions performed exclusively to accomplish the purposes of research (non-therapeutic procedures). The second is the entitlement of dependants to material compensation for death or disability occurring as a direct result of study participation. Implementing a compensation system for research-related injuries or death is likely to be complex, however.

Equitable Compensation and Free Medical Treatment. Compensation is owed to research subjects who are disabled as a consequence of injury from procedures performed solely to accomplish the purposes of research. Compensation and free medical treatment are generally not owed to research subjects who suffer expected or foreseen adverse reactions to investigational therapeutic, diagnostic, or preventive interventions when such reactions are not different in kind from those known to be associated with established interventions in standard medical practice. In the early stages of drug testing (Phase I and early

Phase II), it is generally unreasonable to assume that an investigational drug holds out the prospect of direct benefit for the individual subject; accordingly, compensation is usually owed to individuals who become disabled as a result of serving as subjects in such studies.

The ethical review committee should determine in advance:

(1) the injuries for which subjects will receive free treatment and, in case of impairment, disability, or handicap resulting from such injuries, be compensated; and

(2) the injuries for which they will not be compensated.

Prospective subjects should be informed of the committee's decisions, as part of the process of informed consent. As an ethical review committee cannot make such advance determination in respect of unexpected or unforeseen adverse reactions, such reactions must be presumed compensable and should be reported to the committee for prompt review as they occur.

Subjects must not be asked to waive their rights to compensation or required to show negligence or lack of a reasonable degree of skill on the part of the investigator in order to claim free medical treatment or compensation. The informed consent process or form should contain no words that would absolve an investigator from responsibility in the case of accidental injury, or that would imply that subjects would waive their right to seek compensation for impairment, disability, or handicap. Prospective subjects should be informed that they will not need to take legal action to secure the free medical treatment or compensation for injury to which they may be entitled. They should also be told what medical service or organization or individual will provide the medical treatment and what organization will be responsible for providing compensation.

Obligation of the Sponsor with Regard to Compensation. Before the research begins, the sponsor, whether a pharmaceutical company or other organization or institution, or a government (where government insurance is not precluded by law), should agree to provide compensation for any physical injury for which subjects are entitled to compensation, or come to an agreement with the investigator concern-

ing the circumstances in which the investigator must rely on his or her own insurance coverage (for example, for negligence or failure of the investigator to follow the protocol, or where government insurance coverage is limited to negligence). In certain circumstances it may be advisable to follow both courses. Sponsors should seek adequate insurance against risks to cover compensation, independent of proof of fault.

The Islamic Point of View Concerning Guideline 19 Right of Injured Subjects to Treatment and Compensation

1 - Research subjects are entitled to free medical treatment when they catch any disease as a result of their involvement and to equitable compensation for any impairment, disability, or handicap that results from their participation. Their entitlement is based on the following:

   a - The principles of justice and equity advocated by Islam and all divine creeds must be observed and firmly established in people's lives. God says, "God enjoins justice" (*Al-Nahl* XVI: 90). He also says, "We have sent Our messengers with explicit signs, and sent down with them the Book and the Scale, that people may stand in justice" (*Al-Hadeed* LVII: 25).

   b - The Islamic legal rule of reparation, which makes it an obligation for a person who causes any damage to another to make equitable compensation for the loss.

   c - The implicit agreement between research sponsor(s) and involved subjects entails a religious responsibility on the part of the former party to make up for the damages suffered by a subject as a result of participation in the research.

2 - Therefore, no investigator should ask subjects to waive, or be indifferent to, their rights to treatment and/or compensation, as that involves injustice, inequity, departure from fairness, and denial of rights. There is, however, no conflict between an individual's right to waive his right voluntarily, as long as he is not subjected to any pressure, enticement or deception practiced after the injury.

3 - When a subject dies as a result of his participation in research, his heirs are entitled to the compensation due to him as stipulated in Islamic Legislation.

Guideline 20
Strengthening Capacity for Ethical and Scientific Review and Biomedical Research

Many countries lack the capacity to assess or ensure the scientific quality or ethical acceptability of biomedical research proposed or carried out in their jurisdictions. In externally sponsored collaborative research, sponsors and investigators have an ethical obligation to ensure that biomedical research projects for which they are responsible in such countries contribute effectively to national or local capacity to design and conduct biomedical research, and to provide scientific and ethical review and monitoring of such research. Capacity-building may include, but is not limited to, the following activities:

- establishing and strengthening independent and competent ethical review processes and committees;
- strengthening research capacity;
- developing technologies appropriate to health-care and biomedical research;
- training of research and health-care staff; and
- educating the community from which research subjects will be drawn.

Commentary on Guideline 20

External sponsors and investigators have an ethical obligation to contribute to a host country's sustainable capacity for independent scientific and ethical review and biomedical research. Before undertaking research in a host country with little or no such capacity, external sponsors and investigators should include in the research protocol a plan that specifies the contribution they will make. The amount of capacity building reasonably expected should be propor-

tional to the magnitude of the research project. A brief epidemiological study involving only review of medical records, for example, would entail relatively little, if any, such development, whereas a considerable contribution is to be expected of an external sponsor of, for instance, a large-scale vaccine field-trial expected to last two or three years.

The specific objectives of building a host-country's research-conducting capacity should be determined and achieved through dialogue and negotiation between external sponsors and authorities of that country. External sponsors would be expected to employ and, if necessary, train local individuals to function as investigators, research assistants, or data managers, for example, and to provide, as necessary, reasonable amounts of financial, educational, and other assistance for capacity-building. To avoid conflict of interest and safeguard the independence of review committees, financial assistance should not be provided directly to them; rather, funds should be made available to appropriate authorities in the host-country government or to the host research institution.

(See also *Guideline* 10: *Research in Populations and Communities with Limited Resources*)

The Islamic Point of View Concerning Guideline 20 Strengthening Capacity for Ethical and Scientific Review and Biomedical Research

Being an idea introduced by contemporary human thought and an outcome of accumulative knowledge and modern scientific human experimentation, the stipulation of this guideline is not discussed in any text of Islamic Law, nor any considered opinion by a Muslim jurist. It falls, however, under the general principle of enjoining justice and charity established by God, the Most Glorious, when He says, "God enjoins justice and charity" (*Al-Nahl* XVI: 90). God also says, "Cooperate in charity and piety" (*Al-Maeda* V: 2).

Guideline 21
Ethical Obligation of External Sponsors to Provide Health-Care Services

External sponsors are ethically obliged to ensure the availability of:

- health-care services that are essential to the safe conduct of the research;
- treatment for subjects who suffer injury as a consequence of research interventions; and,
- services that are a necessary part of the commitment of a sponsor to make a beneficial intervention or product developed as a result of the research reasonably available to the population or community concerned.

Commentary on Guideline 21

Obligations of external sponsors to provide health-care services will vary with the circumstances of particular studies and the needs of host countries. The sponsors' obligations in particular studies should be clarified before the research is begun. The research protocol should specify what health-care services will be made available, during and after the research, to the subjects themselves, to the community from which the subjects are drawn, or to the host country, and for how long. The details of these arrangements should be agreed by the sponsor, officials of the host country, other interested parties, and, when appropriate, the community from which subjects are to be drawn. The agreed arrangements should be specified in the consent process and document.

Although sponsors are, in general, not obliged to provide health-care services beyond that which is necessary for the conduct of the research, it is morally praiseworthy to do so. Such services typically

include treatment for diseases contracted in the course of the study. It might, for example, be agreed to treat cases of an infectious disease contracted during a trial of a vaccine designed to provide immunity to that disease, or to provide treatment of incidental conditions unrelated to the study.

The obligation to ensure that subjects who suffer injury as a consequence of research interventions obtain medical treatment free of charge, and that compensation be provided for death or disability occurring as a consequence of such injury, is the subject of Guideline 19, on the scope and limits of such obligations.

When prospective or actual subjects are found to have diseases unrelated to the research, or cannot be enrolled in a study because they do not meet the health criteria, investigators should, as appropriate, advise them to obtain, or refer them for, medical care. In general, also, in the course of a study, sponsors should disclose to the proper health authorities information of public health concern arising from the research.

The obligation of the sponsor to make reasonably available for the benefit of the population or community concerned any intervention or product developed, or knowledge generated, as a result of the research is considered in Guideline 10: *Research in Populations and Communities with Limited Resources.*

The Islamic Point of View Concerning Guideline 21 Ethical Obligation of External Sponsors to Provide Health-Care Services

1 - The ethical commitment of institutions sponsoring research and studies to provide free essential medical care services, so that the research will proceed safely, falls under the concept of justice and charity, which are enjoined by Islamic Law.

2 - The commitment of those institutions to provide treatment for patients who suffer injury as a result of their participation in research falls under the Islamic rule of reparation, which makes it an obligation for a person who causes any damage to another to make repair for it by removing it and its effects and making equitable compensation for the loss suffered by the injured party.

PART TWO

B - APPENDIX

APPENDIX 1

Items to Be Included in a Protocol
(or Associated Documents)
for Biomedical Research Involving Human Subjects

Appendix 1

Items to Be Included in a Protocol (or Associated Documents) for Biomedical Research Involving Human Subjects

(Include the items relevant to the study/project in question)

1 - Title of the study.

2 - A summary of the proposed research in lay, non-technical language.

3 - A clear statement of the justification for the study, its significance in development and in meeting the needs of the country/population in which the research is carried out.

4 - The investigators' views of the ethical issues and considerations raised by the study and, if appropriate, how it is proposed to deal with them.

5 - Summary of all previous studies on the topic, including unpublished studies known to the investigators and sponsors, and information on previously published research on the topic, including the nature, extent, and relevance of animal studies and other preclinical and clinical studies.

6 - A statement that the principles set out in these *Guidelines* will be implemented.

7 - An account of previous submissions of the protocol for ethical review and their outcome.

8 - A brief description of the site(s) where the research is to be conducted, including information about the adequacy of facilities for the safe and appropriate conduct of the research, and relevant demographic and epidemiological information about the country or region concerned.

9 - Name and address of the sponsor.

10 - Names, addresses, institutional affiliations, qualifications, and experience of the principal investigator and other investigators.

11 - The objectives of the trial or study, its hypotheses or research questions, its assumptions, and its variables.

12 - A detailed description of the design of the trial or study. In the case of controlled clinical trials, the description should include, but not be limited to, whether assignment to treatment groups will be randomized (including the method of randomization), and whether the study will be blinded (single blind, double blind), or open.

13 - The number of research subjects needed to achieve the study objective, and how this was statistically determined.

14 - The criteria for inclusion or exclusion of potential subjects, and justification for the exclusion of any groups on the basis of age, gender, social or economic factors, or other reasons.

15 - The justification for involving as research subjects any persons with limited capacity to consent or members of vulnerable social groups, and a description of special measures to minimize risks and discomfort to such subjects.

16 - The process of recruitment, e.g., advertisements, and the steps to be taken to protect privacy and confidentiality during recruitment.

17 - Description and explanation of all interventions (the method of treatment administration, including route of administration, dose, dose interval, and treatment period for investigational and comparator products used).

18 - Plans and justification for withdrawing or withholding standard therapies in the course of the research, including any resulting risks to subjects.

19 - Any other treatment that may be given or permitted, or contra-indicated, during the study.

20 - Clinical and laboratory tests and other tests that are to be carried out.

21 - Samples of the standardized case-report forms to be used, the methods of recording therapeutic response (description and evaluation of methods and frequency of measurement), the follow-up procedures, and, if applicable, the measures proposed to determine the extent of compliance of subjects with the treatment.

22 - Rules or criteria according to which subjects may be removed from the study or clinical trial, or (in a multi-centre study) a centre may be discontinued, or the study may be terminated.

23 - Methods of recording and reporting adverse events or reactions, and provisions for dealing with complications.

24 - The known or foreseen risks of adverse reactions, including the risks attached to each proposed intervention and to any drug, vaccine, or procedure to be tested.

25 - For research carrying more than minimal risk of physical injury, details of plans, including insurance coverage, to provide treatment for such injury, as well as the funding of treatment, and to provide compensation for research-related disability or death.

26 - Provision for continuing access of subjects to the investigational treatment after the study, indicating its modalities, the individual or organization responsible for paying for it, and for how long it will continue.

27 - For research on pregnant women, a plan, if appropriate, for monitoring the outcome of the pregnancy with regard to both the health of the woman and the short-term and long-term health of the child.

28 - The potential benefits of the research to subjects and to others.

29 - The expected benefits of the research to the population, including new knowledge that the study might generate.

30 - The means proposed to obtain individual informed consent and the procedure planned to communicate information to prospective subjects, including the name and position of the person responsible for obtaining consent.

31 - When a prospective subject is not capable of informed consent, satisfactory assurance that permission will be obtained from a duly authorized person, or, in the case of a child who is sufficiently mature to understand the implications of informed consent but has not reached the legal age of consent, that knowing agreement, or assent, will be obtained, as well as the permission of a parent, a legal guardian, or another duly authorized representative.

32 - An account of any economic or other inducements or incentives to prospective subjects to participate, such as offers of cash payments, gifts, or free services or facilities, and of any financial obligations assumed by the subjects, such as payment for medical services.

33 - Plans and procedures, and the persons responsible, for communicating to subjects information arising from the study (on harm or benefit, for example), or from other research on the same topic, that could affect subjects' willingness to continue in the study.

34 - Plans to inform subjects about the results of the study.

35 - The provisions for protecting the confidentiality of personal data, and respecting the privacy of subjects, including the precautions that are in place to prevent disclosure of the results of a subject's genetic tests to immediate family relatives without the consent of the subject.

36 - Information about how the code, if any, for the subjects' identity is established, where it will be kept and when, how, and by whom it can be broken in the event of an emergency.

37 - Any foreseen further uses of personal data or biological materials.

38 - A description of the plans for statistical analysis of the study, including plans for interim analyses, if any, and criteria for prematurely terminating the study as a whole if necessary.

39 - Plans for monitoring the continuing safety of drugs or other interventions administered for purposes of the study or trial and, if appropriate, the appointment for this purpose of an independent data-monitoring (data and safety monitoring) committee.

40 - A list of the references cited in the protocol.

41 - The source and amount of funding of the research: the organization that is sponsoring the research and a detailed account of the sponsor's financial commitments to the research institution, the investigators, the research subjects, and, when relevant, the community.

42 - The arrangements for dealing with financial or other conflicts of interest that might affect the judgment of investigators or other research personnel: informing the institutional conflict-of-interest committee of such conflicts of interest; the communication by that committee of the pertinent details of the information to the ethical review committee; and the transmission by that committee to the research subjects of the parts of the information that it decides should be passed on to them.

43 - The time schedule for completion of the study.

44 - For research that is to be carried out in a developing country or community, the contribution that the sponsor will make to capacity-building for scientific and ethical review and for biomedical research in the host country, and an assurance that the capacity-building objectives are in keeping with the values and expectations of the subjects and their communities.

45 - Particularly in the case of an industrial sponsor, a contract stipulating who possesses the right to publish the results of the study, and a mandatory obligation to prepare with, and submit to, the principal investigators the draft of the text reporting the results.

46 - In the case of a negative outcome, an assurance that the results will be made available, as appropriate, through publication or by reporting to the drug registration authority.

47 - Circumstances in which it might be considered inappropriate to publish findings, such as when the findings of an epidemiological, sociological or genetics study may present risks to the interests of a community or population or of a racially or ethnically defined group of people.

48 - A statement that any proven evidence of falsification of data will be dealt with in accordance with the policy of the sponsor to take appropriate action against such unacceptable procedures.

APPENDIX 2

WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI

Appendix 2

WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI

Ethical Principles
For
Medical Research Involving Human Subjects

Adopted by the 18th World Medical Association General Assembly
Helsinki, Finland, June 1964

and amended by the
29th WMA General Assembly, Tokyo, Japan, October 1975;
35th WMA General Assembly, Venice, Italy, October 1983;
41st WMA General Assembly, Hong Kong, September 1989;
48th WMA General Assembly, Somerset West,
Republic of South Africa, October 1996
and the
52nd WMA General Assembly, Edinburgh, Scotland, October 2000

A. INTRODUCTION

1 - The World Medical Association has developed the Declaration of Helsinki as a statement of ethical principles to provide guidance to physicians and other participants in medical research involving human subjects. Medical research involving human subjects includes research on identifiable human material or identifiable data.

2 - It is the duty of a physician to promote and safeguard the health of the people. The physician's knowledge and conscience should be dedicated to the fulfillment of this duty.

3 - The Declaration of Geneva of the World Medical Association binds the physician with the words, "The health of my patient will be my first consideration," and the International Code of Medical Ethics declares that, "A physician shall act only in the patient's interest when providing medical care which might have the effect of weakening the physical and mental condition of the patient."

4 - Medical progress is based on research which ultimately must rest in part on experimentation involving human subjects.

5 - In medical research on human subjects, considerations related to the well-being of the human subject should take precedence over the interests of science and society.

6 - The primary purpose of medical research involving human subjects is to improve prophylactic, diagnostic, and therapeutic procedures and the understanding of the aetiology and pathogenesis of disease. Even the best proven prophylactic, diagnostic, and therapeutic methods must continuously be challenged through research for their effectiveness, efficiency, accessibility, and quality.

7 - In current medical practice and in medical research, most prophylactic, diagnostic, and therapeutic procedures involve risks and burdens.

8 - Medical research is subject to ethical standards that promote respect for all human beings and protect their health and rights. Some research populations are vulnerable and need special protection. The particular needs of the economically and medically disadvantaged must be recognized. Special attention is also required for those who cannot give or refuse consent for themselves, for those who may be subject to giving consent under duress, for those who will not benefit personally from the research, and for those for whom the research is combined with care.

9 - Research Investigators should be aware of the ethical, legal and regulatory requirements for research on human subjects in their

own countries as well as applicable international requirements. No national, ethical, legal or regulatory requirement should be allowed to reduce or eliminate any of the protections for human subjects set forth in this Declaration.

B - BASIC PRINCIPLES FOR ALL MEDICAL RESEARCH

10 - It is the duty of a physician in medical research to protect the life, health, privacy, and dignity of the human subject.

11 - Medical research involving human subjects must conform to generally accepted scientific principles and be based on a thorough knowledge of the scientific literature and other relevant sources of information, and on adequate laboratory and, where appropriate, animal experimentation.

12 - Appropriate caution must be exercised in the conduct of research which may affect the environment, and the welfare of animals used for research must be respected.

13 - The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol. This protocol should be submitted for consideration, comment, guidance, and where appropriate, approval to a specially appointed ethical review committee, which must be independent of the investigator, the sponsor, or any other kind of undue influence. This independent committee should be in conformity with the laws and regulations of the country in which the research experiment is performed. The committee has the right to monitor ongoing trials. The researcher has the obligation to provide monitoring information to the committee, especially any serious adverse events. The researcher should also submit to the committee, for review, information regarding funding, sponsors, institutional affiliations, other potential conflicts of interest, and incentives for subjects.

14 - The research protocol should always contain a statement of the ethical considerations involved and should indicate that there is compliance with the principles enunciated in this Declaration.

15 - Medical research involving human subjects should be conducted only by scientifically qualified persons and under the supervision of a clinically competent medical person. The responsibility for the human subject must always rest with a medically qualified person and never rest on the subject of the research, even though the subject has given consent.

16 - Every medical research project involving human subjects should be preceded by careful assessment of predictable risks and burdens in comparison with foreseeable benefits to the subject or to others. This does not preclude the participation of healthy volunteers in medical research. The design of all studies should be publicly available.

17 - Physicians should abstain from engaging in research projects involving human subjects unless they are confident that the risks involved have been adequately assessed and can be satisfactorily managed. Physicians should cease any investigation if the risks are found to outweigh the potential benefits or if there is conclusive proof of positive and beneficial results.

18 - Medical research involving human subjects should only be conducted if the importance of the objective outweighs the inherent risks and burdens to the subject. This is especially important when the human subjects are healthy volunteers.

19 - Medical research is only justified if there is a reasonable likelihood that the populations in which the research is carried out stand to benefit from the results of the research.

20 - The subjects must be volunteers and informed participants in the research project.

21 - The right of research subjects to safeguard their integrity must always be respected. Every precaution should be taken to respect the privacy of the subject and the confidentiality of the patient's information and to minimize the impact of the study on the subject's physical and mental integrity and on the personality of the subject.

22 - In any research on human beings, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study, and the discomfort it may entail. The subject should be informed of the right to abstain from participation in the study or to withdraw consent to participate at any time without reprisal. After ensuring that the subject has understood the information, the physician should then obtain the subject's freely-given informed consent, preferably in writing. If the consent cannot be obtained in writing, the non-written consent must be formally documented and witnessed.

23 - When obtaining informed consent for the research project, the physician should be particularly cautious if the subject is in a dependent relationship with the physician or may consent under duress. In that case, the informed consent should be obtained by a well-informed physician who is not engaged in the investigation and who is completely independent of this relationship.

24 - For a research subject who is legally incompetent, is physically or mentally incapable of giving consent, or is a legally incompetent minor, the investigator must obtain informed consent from the legally authorized representative in accordance with applicable law. These groups should not be included in research unless the research is necessary to promote the health of the population represented and this research cannot instead be performed on legally competent persons.

25 - When a subject deemed legally incompetent, such as a minor child, is able to give assent to decisions about participation in research, the investigator must obtain that assent in addition to the consent of the legally authorized representative.

26 - Research on individuals from whom it is not possible to obtain consent, including proxy or advance consent, should be done only if the physical/mental condition that prevents obtaining informed consent is a necessary characteristic of the research population. The specific reasons for involving research subjects with a condi-

tion that renders them unable to give informed consent should be stated in the experimental protocol for consideration and approval of the review committee. The protocol should state that consent to remain in the research should be obtained as soon as possible from the individual or a legally authorized surrogate.

27 - Both authors and publishers have ethical obligations. In publication of the results of research, the investigators are obliged to preserve the accuracy of the results. Negative as well as positive results should be published or otherwise publicly available. Sources of funding, institutional affiliations and any possible conflicts of interest should be declared in the publication. Reports of experimentation not in accordance with the principles laid down in this Declaration should not be accepted for publication.

C - ADDITIONAL PRINCIPLES FOR MEDICAL RESEARCH COMBINED WITH MEDICAL CARE

28 - The physician may combine medical research with medical care, only to the extent that the research is justified by its potential prophylactic, diagnostic, or therapeutic value. When medical research is combined with medical care, additional standards apply to protect the patients who are research subjects.

29 - The benefits, risks, burdens, and effectiveness of a new method should be tested against those of the best current prophylactic, diagnostic, and therapeutic methods. This does not exclude the use of placebo, or no treatment, in studies where no proven prophylactic, diagnostic, or therapeutic method exists.

30 - At the conclusion of the study, every patient entered into the study should be assured of access to the best proven prophylactic, diagnostic, and therapeutic methods identified by the study.

31 - The physician should fully inform the patient which aspects of the care are related to the research. The refusal of a patient to participate in a study must never interfere with the patient-physician relationship.

32 - In the treatment of a patient, where proven prophylactic, diagnostic, and therapeutic methods do not exist or have been

ineffective, the physician, with informed consent from the patient, must be free to use unproven or new prophylactic, diagnostic, and therapeutic measures, if in the physician's judgment they offers hope of saving life, reestablishing health, or alleviating suffering. Where possible, these measures should be made the object of research, designed to evaluate their safety and efficacy. In all cases, new information should be recorded and, where appropriate, published. The other relevant guidelines of this Declaration should be followed.

NOTE OF CLARFICATION ON PARAGRAPH 29 OF THE WMA DECLARATION OF HELSINKI

The WMA is concerned that paragraph 29 of the revised Declaration of Helsinki (October 2000) has led to diverse interpretations and possible confusion. It hereby reaffirms its position that extreme care must be taken in making use of a placebo-controlled trial and that in general this methodology should only be used in the absence of existing proven therapy. However, a placebo-controlled trial may be ethically acceptable, even if proven therapy is available, under the following circumstances:

- Where for compelling and scientifically sound methodological reasons its use is necessary to determine the efficacy or safety of a prophylactic, diagnostic or therapeutic method;
- Where a prophylactic, diagnostic or therapeutic method is being investigated for a minor condition and the patients who receive placebo will not be subject to any additional risk of serious or irreversible harm.

All other provisions of the Declaration of Helsinki must be adhered to, especially the need for appropriate ethical and scientific review.

APPENDIX 3

The Phases of Clinical Trials of Vaccines and Drugs

Appendix 3

The Phases of Clinical Trials of Vaccines and Drugs

Vaccine Development

Phase I refers to the first introduction of a candidate vaccine into a human population for initial determination of its safety and biological effects, including immunogenicity. This phase may include studies of dose and route of administration, and usually involves fewer than 100 volunteers.

Phase II refers to the initial trials examining effectiveness in a limited number of volunteers (usually between 200 and 500); the focus of this phase is immunogenicity.

Phase III trials are intended for a more complete assessment of safety and effectiveness in the prevention of disease, involving a larger number of volunteers in a multi-center adequately controlled study.

Drug Development

Phase I refers to the first introduction of a drug into humans. Normal volunteer subjects are usually studied to determine levels of drugs at which toxicity is observed. Such studies are followed by dose-ranging studies in patients for safety and, in some cases, early evidence of effectiveness.

Phase II investigation consists of controlled clinical trials designed to demonstrate effectiveness and relative safety. Normally, these are performed on a limited number of closely monitored patients.

Phase III trials are performed after a reasonable probability of effectiveness of a drug has been established and are intended to gather

additional evidence of effectiveness for specific indications and more precise definition of drug-related adverse effects. This phase includes both controlled and uncontrolled studies.

Phase I and phase II trials must be comply with Section C (articles 28-32) of the Helsinki Declaration, which deals with medical research combined with medical care.

Phase IV trials are conducted after the national drug registration authority has approved a drug for distribution or marketing. These trials may include research designed to explore a specific pharmacological effect, to establish the incidence of adverse reactions, or to determine the effects of long-term administration of a drug. Phase IV trials may also be designed to evaluate a drug in a population not studied adequately in the pre-marketing phases (such as children or the elderly) or to establish a new clinical indication for a drug. Such research is to be distinguished from marketing research, sales promotion studies, and routine post-marketing surveillance for adverse drug reactions in that these categories ordinarily need not be reviewed by ethical review committees (see *Guideline* 2).

PART 3

THE ARGUMENTS OF ISLAMIC LAW RULINGS ON RECENT MEDICAL ISSUES

Based on the Recommendations of
The Islamic Organization for Medical Sciences (IOMS)

Contents

In the Name of God, the Beneficent, the Merciful

Introduction

It is an honorable record that the Islamic Organization of Medical Sciences(IOMS) in Kuwait has had since it was established by Dr. Abdul-Rahman Abdullah Al-'Awadhi, may God protect him and handsomely reward the scholars and physicians involved.

Participating in the celebration of the beginning of the fifteenth century of the Islamic Hijri calendar, the IOMS made a great contribution by holding its first conference during the period of 6 - 10 Rabee' I, 1401 H. (12 - 16 January, 1981). A succession of IOMS blessed activities followed, for the enrichment of scholarly knowledge that combines Islamic Law and the facts of life in various fields of medicine and health. The IOMS has raised a number of specific research issues that relate to human existence and future for specialists to look into. Probably some of these issues have been brought to the attention of Islamic law professors for the first time.

The IOMS addressed scores of challenging, complex questions of Islamic jurisprudence (*fiqh*), recruiting an elite group of specialists and interested scholars, who responded to its call and held twenty-seven scholarly meetings: conferences, seminars, and panel discussions.

No bias characterizes the work of the IOMS. Its approach is that of all Muslims, and it strives to eliminate any borders that set Muslims apart, acting on the belief that "the lowest in rank binds the whole nation with his pledge."

The IOMS strived to get together a team of concerned Muslim physicians from the Americas, Europe, and various other countries of the world and elite groups of scholars of Islamic law and jurisprudence (*fiqh*), as well as renowned Muslim personalities, to enrich the discussion, search for the truth, and realize general benefit.

The Organization made a point of diversifying the locations of its meetings, which were held in Kuwait, Egypt, Turkey, the United Arab Emirates, Jordan, Morocco, and Pakistan.

Today is the 11th of December 2004 (29 Shawaal 1425 H.), the day on which the IOMS has decided to hold its eighth conference to discuss "The Islamic Document of Medical Ethics," which will be in three parts:

1 - Research works that deal with Man within the framework of the International Document of Medical Research;

2 - The physician's professional relations with his patients, his colleagues, and society at large; and

3 - Recent medical developments and how they are viewed by Islam, based on IOMS discussions in its legal-medical seminars and supported by the views of the Islamic Academy.

In my opinion, the IOMS, through this conference, is making a worthy conclusion of a momentous stage of its glorious history in the service of the venerable Islamic Law. It is also undertaking the task of setting off to a new stage with greater responsibility and more accurate judgment.

In this conference, the Organization is making a record of the yields of its praisework. It is like writing down the historical minutes of the topics that have opened for hundreds of researchers extensive scientific and scholarly horizons and have enabled scholars of jurisprudence (*fiqh*), or at least some of their elite, to take a huge cultural stride for which they will always be grateful. They have been unaware of what goes on in the laboratories and research of medicine and allied medical sciences, and, for the first time, they have been introduced, through IOMS seminars, to the facts of animal and human cloning, as well as genetic breakthroughs, the genetic imprint, and genetic guidance and treatment. They have learned the facts related to human milk, fetus, and skin banks, as well as other new developments, all of which require the controls of Islamic Law, with its wise and merciful aim of achieving benefit and preventing harm.

I want to thank the Organization for its confidence in me, as reflected in assigning to me, in the middle of last month, the task of making an inclusive list of the new medical issues that the Organization has dealt with so far; summing up the contents of the papers submitted on these issues and the recorded debates, with the argu-

ments made and the evidence offered to cover each issue comprehensively; and then stating the viewpoint adopted by the IOMS in its recommendations.

I had no illusion that this was an easy task, and the difficulties I expected had several forms, such as the frequent ambiguity in the terminology, due to the various translations used by physicians, and the continuous updating of scientific facts, so that no sooner does a physician make a definite statement in one seminar, he updates it in the following one with new findings in the field.

Another form of difficulty is the impatience of some jurisprudence (*fiqh*) scholars at the successive scientific developments, particularly in the field of the human genome, opting to suspend discussions until the research in the field settles or until the application of new medical developments becomes common.

I frequently came upon a scholar who argued his position, set down in his paper, with considerable enthusiasm, only to back from that position or modify it, as a result of the heat and natural development of the debate. In fact, a scholar occasionally adopted at one session of the discussion a particular argument, then in the following session, he candidly announced his mistake and espoused a different argument.

These and other similar things did not bother me, and I admit that they rather gave me pleasure as I got so absorbed in examining this unlimited wealth of scholarship that I sometimes forgot to eat, drink, or sleep. In one week, I sorted out eighteen issues of new medical developments.

The truly unpleasant feeling was my fear that the time of the conference would arrive before my task was completed. This fear proved to be justified. His Excellency Dr. Ahmad Rajai Al-Gendy, the Assistant Secretary General of the IOMS, contacted me one week after the assignment of the task to me and while I was working on the eighteenth topic, and asked for a change of methodology. He wanted me, in dealing with the remaining issues, to limit myself to a definition of the question involved and then write down the jurisprudence (*fiqh*) ruling chosen by the IOMS. He gave me one day or two to finish that

task and said I could resume my original methodology when the conference was over. The purpose of this was to give the participants at the conference a chance to have a sufficient idea of all the new medical developments covered by the Organization.

I have been able to finish that task, listing forty topics discussed at the IOMS seminars, in addition to other topics that I covered in brief.

In order that no discrepancy would be detected by the reader between my treatment of the first eighteen issue and the subsequent ones, I summed up the former in order to make the work uniform in the work material offered to the conference participants.

I chose to present these issues in the order of their discussion by the IOMS, unless the nature of the topic warranted a change of that order. An example is the topic of "The Ruling on the Restoration to Life of a Person Whose Brainstem Has Died," discussed in the ninth IOMS seminar in 1996, which I placed before its chronological spot in order to have it follow the topic of "Definition of Death Which Terminates Human Life," discussed in the second and fourth seminars of 1985 and 1988, as well as the ninth seminar of 1996.

In arranging the IOMS seminars, I followed the real chronological order, taking into consideration the fact that some errors were made when the minutes of the seminars were published.

I would like to express my thanks to Dr. Ahmad Rajai Al-Gendy and his team, who, have shown their dedication under pressure. They voluntarily gave up their rest and worked on Fridays and throughout the Fitr holiday to ensure the success of this conference and get the material prepared for the participants published. This was a demonstration of love on their part for the Organization whose emblem they wore on their chests.

May God favor with peace and blessings our master Muhammed, his kin and Companions, and all who follows their example until Doomsday.

Sa'd Al-Deen Sa'd Al-Hilaali, Ph.D.
November 23, 2004

Topic One
Mixed Human Milk Bank[54]

Definition

A milk bank collects milk that is offered voluntarily or for financial payment, and then stored, either through refrigeration or by being dried and sterilized, to be used in feeding premature babies,[55] without breast nursing.[56]

The Legal Position Chosen by the IOMS and Its Argument

The IOMS refrained from taking a definite position on the question of mixed human milk banks, addressed in the seminar on human reproduction, and merely surveyed some points of view offered by scholars. However, the Organization discourages the establishment of such banks. The recommendations of the seminar say:

(54) The Islamic Organization of Medical Sciences (IOMS) was the first to submit this question to a discussion from the point of view of Islamic jurisprudence (*fiqh*) in its first seminar, the Seminar on Reproduction in Islam, in May 26, 1983. The first recommendation of the seminar addressed this topic. This was followed by further interest in the subject on the part of specialists. A report was published in the Cairo *Al-Ahram* daily on August 23 and 29, 1983, under the title "Milk Banks for Mothers: Permitted or Prohibited?"

(55) A premature baby is a baby born before its due time, which calls for its isolation in an incubator for a period that could be short or long until the mother can feed it with her own milk. (Dr. Maher Hathoot, "Banks of Mixed Human Milk," *The Seminar on Human Reproduction*, p. 35.)

(56) Dr. Maher Hathoot, *ibid.*, p. 35; the report in *Al-Ahram* daily of Cairo, published on August 23 and 29, 1983; *The Seminar on Human Reproduction*, pp. 458 & 462. Here and in consequent references to the seminars held by IOMS, the page numbers refer to the minutes of the seminar published in book form in Arabic.

The setting up of banks of mixed human milk is to be discouraged. If medical need calls for them, banks of human milk may be set up for premature babies.

A group of participants believe, on the basis of the opinion of the majority of jurisprudence (*fiqh*) scholars, that the collection of milk should be done in a way that guarantees the identification of each donor and each baby receiver. Each nursing incidence should be written down in records that are kept, and everyone involved should be notified to avoid the marriage of persons who have a milk relationship entailing the prohibition of their marriage.

Other participants, however, believe there is no need to identify the donors and receivers on the basis of the opinion of Al-Laith Ibn Sa'd and the scholars of Al-Zhahiriyah School and their followers, who believe that milk relationships result only when a baby sucks the breast of a milk mother.

Topic Two
Controlling the Gender of a Human Embryo[57]
Sex Selection

Definition

Control of the sex of a human embryo is done through one of two procedures.

The first is that, at the request of a married couple, a physician extracts, with a needle, some of the liquid surrounding the embryo in the uterus to determine its sex. If it is not the desired sex, the pregnant woman asks for abortion. This procedure is repeated until a pregnancy with an embryo of the desired sex occurs.

In the second procedure, a physician, at the request of a married couple, stimulates male sperms in order for the embryo to be male, or female sperms to have a female embryo.[58]

The Legal Position Chosen by the IOMS and Its Argument

The IOMS refrained from taking a definite position on the question of fetal gender, addressed in the Seminar on Human Reproduction, and merely surveyed some points of view offered by scholars. The recommendations of the seminar, however, include the following:

There was an agreement that the Islamic legal viewpoint is that fetal sex selection is unlawful when practiced at a national level.

(57) The Islamic Organization of Medical Sciences (IOMS) discussed this question in its first seminar, the Seminar on Reproduction in Islam, on May 26, 1983.

(58) Dr. Hassaan Hathoot, "Fetal Sex-Selection," *The Seminar on Human Reproduction*, p. 37.

On an individual level, however, some of the scholars participating in the Seminar believe there is nothing legally wrong with the attempt to fulfill the wish of a married couple to have a boy or a girl through available medical means, while other scholars believe it is unlawful, for fear that one sex might outnumber the other.

Topic Three
Plant, Animal, and Human Cloning[59]

Definition

Cloning is the common term used to describe the method in which the goat Dolly was produced. The recommendations of the tenth IOMS seminar say, "The technology that led to the production of the goat Dolly was depositing the nucleus of a body cell inside an ovum whose own nucleus had been removed, so that the ovum would start to divide and form an embryo."[60]

Cloning is conducted on plants, animals, and human beings.

The scientists of bio-technologies say that cloning is a general term for three types.

The first type is embryonic (twin producing) cloning, which means the splitting of an embryo (a zygote that has multiplied) so that each of the new cells may form a separate embryo. This technique was revealed by scientists Jerry Hall and Robert Stillman in October, 1993.

The second type is ordinary or body cloning, which means the production of infants from adult body cells, which are implanted into an ovum whose nucleus is removed in order to divide and form an embryo. The produced infant will be an exact reproduction of the

(59) The IOMS addressed this question in two seminars. The first was the Seminar on Reproduction in Islam, the first of the Organization's seminars in the period of May 24 - 26, 1983. The second was the tenth, which addressed *Certain Contemporary Medical Questions* and washeld in Casablanca in the period of June 16 - 17, 1997.

(60) Recommendations of the *Tenth Seminar*, p. 510.

original. The application of this type in the cattle group of the mammal class was announced in February 1997 by a team of Scottish scientists, led by Ian Wilmot.

The third type of cloning is organ cloning, which is the cloning of certain organs, such as liver, heart, or skin. There are details related to this type which will shortly be mentioned, and it will be also casually mentioned in explaining the ruling on using stem cells of aborted embryos or surplus embryos in a test-tube baby procedure.(61)

The Legal Position Chosen by the IOMS on Plant Cloning and Its Argument

The IOMS reached the same ruling on the permissibility of plant cloning in its first seminar, Reproduction in Islam, in 1983, and tenth seminar in 1997.

One of the recommendations of the Reproduction seminar says, "There is an agreement that it is lawful to apply genetic engineering technology to microorganism, by using recombinant DNA in the field of producing therapeutic drugs in abundant quantities."

The recommendations of the tenth seminar include the following: "The seminar finds no objection to the employment of cloning and genetic engineering technologies in the fields of plants and animals under the recognized controls."

The Legal Position Chosen by the IOMS on Animal Cloning and Its Argument

In its tenth seminar, the IOMS supported the view held by the majority of scholars, which permits animal cloning. In its recommendations, the seminar, as quoted above, "finds no objection to the employment of cloning and genetic engineering technologies in the fields of plants and animals under the recognized controls."

(61) The papers and discussions on cloning in the first (*Reproduction*) seminar of 1983 and the tenth of 1997.

The Viewpoint of the Islamic Jurisprudence Academy on Plant and Animal Cloning

The Academy - in its tenth session in Jedda, Safar 23 - 28, 1418 H. (June 28 - July 3, 1997) - approved the technology of plant and animal cloning and recommended that "It is permissible in Islamic Law to apply the technologies of cloning and genetic engineering to germs, all other microorganisms, plants and animals, under the controls of Islamic Law and in a manner that achieves benefits and prevents harm."

The Legal Position Chosen by the IOMS on Human Embryonic (Twin-Producing) Cloning and Its Argument

1 - In its first seminar, the one on Reproduction, in 1983, the IOMS refrained from adopting an absolute ruling on human cloning. "The seminar recommends further medical and jurisprudence (*fiqh*) study of the question related to human cloning, and does not favor a hasty ruling on this matter."

2 - Later, in its tenth seminar of 1997, the IOMS approved this kind of cloning. The seminar's recommendations quote one part of the discussion of the subject and say:

> The seminar finds the method of twin-producing cloning sound in principle, but its evaluation, as to benefit and harm, is to be left to the future. Its immediate benefits include the possibility of applying diagnostic measures to one of the two embryos or to some of its cells. If the embryo is found to be healthy, it can be deposited in the uterus. Another immediate benefit is that it copes with some sterility problems. All the controls relevant to test-tube babies are applicable to this kind of cloning.

The Legal Position Chosen by the IOMS on Ordinary Human Cloning or Body Cloning and Its Argument

1 - In its first seminar in 1983, the IOMS refrained from reaching an absolute ruling on human cloning. It recommended "further

medical and jurisprudence (*fiqh*) study of the question related to human cloning" and said that it "does not favor a hasty ruling on this matter."

2 - Later, the IOMS opted for allowing an opening by which body cloning is exceptionally permitted under Islamic legal controls, although more weight is given to abstaining as a principle and prohibition of application. This is a recommendation of the tenth seminar of 1997, which refers to part of the debate on the question. It says:

Some scholars argue that human cloning should be categorically prohibited. Others prefer to allow for present or future exceptions if certain procedures prove to be useful and fall within the limits of Islamic Law, provided that each case be considered separately.

At any rate, it is much too soon to speak of human cloning, as the present assessment of benefits and adverse effects may have to be reconsidered after a long period of time.

The recommendations of the seminar include "the prevention of ordinary human cloning. If exceptional cases surface in the future, they will have to be submitted for consideration so that the legal ruling that applies to them, whether permission or prohibition may be arrived at."

The Legal Position Chosen by the IOMS on the Cloning of Human Organs

The IOMS overlooked the question of human organ cloning and gave it no mention in its recommendations. Probably that was because the practical application of that type of cloning was very unlikely or because the ruling on organ transplants applies to it.

Topic Four
Test-Tube Babies
(*In Vitro* Fertilization and Embryo Transplants)[62]

Definition

What is meant by a test tube baby procedure is that through which an embryo begins to form in an external vessel rather than inside body of its mother. An ovum is extracted out of the ovaries and is exposed to the husband's semen to get a sperm to unite with it. The resulting embryo is later implanted into the uterus through the vaginal opening. The growth of this embryo continues inside the uterus.[63]

The Legal Position Chosen by the IOMS and Its Argument

In the seminar on Human Reproduction in Islam in 1983, the IOMS opted for the viewpoint favored by the majority of participating scholars, which is the lawfulness of test-tube babies under Islamic Law controls. The seminar's minutes say that "the seminar concludes that the test-tube baby procedure is lawful if it only involves a married couple while the marriage is valid, and sufficient and meticulous care is taken to avoid any confusion of lineage. Still, some scholars have voiced some reservation under the pretext of pre-emptive prohibition."

The Viewpoint of the Islamic jurisprudence (*fiqh*) Academy

In its seventh session in 1992, the Islamic Jurisprudence (*fiqh*) Academy of Mecca favored the permission of test-tube babies in

(62) The IOMS discussed this question in its first seminar, the Seminar on Reproduction in Islam, in 1983.

(63) Dr. Hassaan Hathoot, "Test-Tube Babies," *The Seminar on Human Reproduction*, p. 189.

principle, although the academy asserts that the procedure is not free from doubt-raising factors. Its decision on the subject says, "The method is, in principle, acceptable in itself from the point of view of Islamic Law. It is, however, not completely devoid of the possibilities of confusion in its requirements and the circumstances under which it is conducted. Therefore, it should be resorted to only in cases of extreme necessity and when general legal controls are in operation."

Topic Five
The Surrogate Uterus (Embryo Transplant)[64]

Definition

A surrogate uterus is that of a volunteer or hired woman who offers her service to a wife wishing to have an ovum of hers, which is inseminated with her husband's semen, implanted in the surrogate uterus, so that the volunteer or hired woman would suffer the burden and pain of pregnancy. This is done on condition that the born baby would be surrendered to the woman who has produced the ovum and whose uterus, in most cases, is incapable of supporting pregnancy. A test-tube baby is also referred to as "embryo transplant."[65]

The Legal Position Chosen by the IOMS and Its Argument

1 - In the seminar on Human Reproduction in Islam, the first IOMS seminar, the Organization adopted the view favored by the majority of scholars, which found the surrogate uterus procedure entirely unlawful. Under the title of "The Surrogate Uterus," a recommendation of the seminar says, "It is agreed that it [i.e. conception] is unlawful if it involves a third party, whether in the form of a sperm, ovum, fetus, or womb."

2 - The IOMS reaffirmed this decision to forbid the surrogate uterus procedure in its tenth seminar, held in Casablanca in 1997. Its recommendations on cloning include the following: "All cases that

(64) The IOMS addressed this issue in two seminars, the first, the Seminar on Reproduction, in 1983, and the tenth, the Seminar on Certain Contemporary Medical Questions, in 1997.

(65) I wrote this definition on the basis of the papers and discussions of the subject.

involve a third party, foreign to the marital relationship, are unlawful, whether that party is in the form of a uterus, sperm, ovum, or a body cell intended to be cloned."

The Viewpoint of the Islamic Jurisprudence (fiqh) Academy

The point of view of the Jurisprudence (*fiqh*) Academy in Mecca coincides with the other tendency among scholars, which regards the surrogate uterus procedure permissible when it involves wives of the same man.

Topic Six
Determining Who the Mother Is in Surrogate Uterus Cases[66]

Definition

When pregnancy does take place as a result of a surrogate uterus procedure, who is the real mother to whom the baby should be assigned and who has the right to inherit him and be inherited by him. Is she the woman who produces the fertilized ovum or the one who carries the embryo from an early stage of its formation until its birth?[67]

The Viewpoint of Islamic Jurisprudence (fiqh)

Researchers and participants differed in their discussion of the surrogate uterus question in the Reproduction Seminar of 1983. There were three different opinions.

The first opinion holds that the actual mother in a surrogate uterus case is the woman who bears and delivers the baby. The most outspoken advocate of this argument was Sheikh Badr Al-Mutawalli Abd Al-Baaset, and others supported him.[68]

They base their argument on the following:

1 - God, the Most Sublime, says, "Mothers give suck to their children" (II: 233); He dose not say, "nursemaids." Mothers[69] are the ones who deliver the baby, after having born and fed the fetus for nine months (or less).

(66) This question is associated with the topic of the surrogate uterus and the research and discussion related to it.

(67) In writing this definition I rephrased statements made in the papers and discussions on the subject.

(68) The Seminar on *Reproduction in Islam*, pp. 169ff.

(69) There are two words for "mother" in Arabic. The one used here and in the quoted Quarn verse is the word "*Walidah*," derived from the root verb "*walada*," which means "to deliver." (Translator's Note)

2 - God, the Most Sublime, also says, "Their mothers are those who delivered them" (LVIII: 2). This is a statement that uses delivery as the criterion of determining who the mother is.

3 - God says, "... his mother bears him with much pain and delivers him with much pain" (XLVI: 15), which is a clear statement that the actual mother is the one who bears the child.

The second opinion is that the actual mother is the ovum producer. This was the argument of Dr. Muhammad Fawzi Faidh Allah and others,[70] who maintain that

1 - The hired "mother" is similar to a nursing maid or a wet nurse. Regardless of the amount of milk - which forms the flesh and bone - fed by the latter to the child, she can never be the actual mother. So the actual mother is the ovum producer.

2 - The ovum-producer/mother is the one that gives genetic characteristics to the child, so the child must be attributed to her.

The third opinion is that motherhood is shared by both the ovum producer and the woman with the surrogate uterus. This was the view held of Dr. Muhammad Al-Ashqar and others.[71] Their argument goes as follows:

1 - Motherhood is not determined by genetic factors alone; it is also associated with the pains of bearing the child.

2 - The two previous arguments can be reconciled.

The Legal Position Chosen by the IOMS and Its Argument

The IOMS bypassed the question of determining who the actual mother is when a surrogate uterus is involved. Its recommendations include nothing on the subject, and the IOMS goes no further than giving an account of the papers and discussions.

(70) *Ibid.*, p. 227.

(71) *Ibid.*, p. 221.

The Legal Position Chosen by the Islamic Jurisprudence (fiqh) Academy

In its seventh session, held in Mekkah in 1992, the Council of the Islamic Jurisprudence (*fiqh*) Academy reached a decision that supports the genetic point of view, which considers the actual mother to be the ovum producer. The resolutions of the Council include the following:

> The Council decides that an infant's lineage is established as that of the married couple who produce the two seeds. Inheritance and other rights are contingent on the establishment of lineage. When the lineage is established in favor of a man and a woman, the rules of inheritance and other matters are confirmed for the child and for those whose lineage it assumes.
>
> As for a wife who volunteers to bear a child for her fellow wife, the former has the same status as the milk mother of a child, as it derives from her body and organism more than what an infant receives from its wet nurse when it takes an amount of milk equal to or greater than that which is sufficient to make it her milk child. Thus the same prohibition applies to that relationship that applies to that of lineage.

Topic Seven
Surgical Contraception[72]
(Sterilization)

Definition

This refers to a surgical operation that permanently ends a woman's or a man's ability to have children, but does not affect sexual desire or performance. The surgical procedure in the case of a man involves tying the sperm ducts, and in the case of a woman, it involves tying or cutting the Fallopian tubes. Other contraceptive methods may be used.[73]

The Legal Position Chosen by the IOMS and Its Argument

In its first seminar, the one on Reproduction, of 1983, the IOMS adopted, on the question of surgical contraception (sterilization), the argument supported by the majority of participants, which is the permission of sterilization. One of the recommendations of the seminar is as follows:

> Surgical contraception is lawful on the individual level in cases of necessity as determined by a Muslim trustworthy physician and when other alternatives have been exhausted.
>
> On the level of the Islamic nation at large, it is unlawful, and the seminar denounces turning sterilization into a general campaign and warns against its exploitation in demographic wars that aim at turning Muslims into minorities in their own countries or in the world as a whole.

(72) The IOMS discussed this question in its first seminar, the Seminar on Reproduction in Islam, in 1983.

(73) Dr. Hassaan Hathoot, "Surgical Contraception: An Islamic Point of View," *The Seminar on Human Reproduction*, p. 183, and his comments (rephrased here), pp. 198, 203, and 208.

Topic Eight
Abortion[74]

Definition

Abortion is a woman's ejection of her fetus before it is sufficiently developed. It may occur naturally, as when caused by the woman's weakness for example, and it may be unnatural, as when it is deliberately induced. Often scholars refer to abortion by one of its synonyms, such as miscarriage, expulsion, ejection, or discharge.[75]

The Legal Position Chosen by the IOMS and Its Argument

On the subject of abortion, The IOMS adopted, in its first seminar that was held in 1983 and dealt with reproduction, the opinion that considers abortion permissible, in cases of extremely pressing medical necessity, before the spirit is breathed into the fetus. This opinion was confirmed by the IOMS in its second seminar, Human Life: Its Inception and End as Viewed in Islam, in 1985. In its fourth seminar, Health Policy: Ethics and Values, the IOMS did not conclude its discussion of the papers on abortion with any recommendation.

The Seminar on Human Reproduction in Islam makes the following recommendation:

(74) The Islamic Organization of Medical Sciences (IOMS) discussed this topic in three different seminars: the first seminar, the Seminar on Reproduction in Islam, in 1983; the second seminar, "Human Life: Its Inception and End as Viewed by Islam," in 1985; and the fourth, the Seminar on Health Policy: Ethics and Human Values from an Islamic Perspective, in 1988.

(75) Dr. Tawfeeq Al-Wa'ii, "The Islamic Verdict on Abortion," *The Seminar on Human Reproduction*, p. 266; Dr. Sa'd Al-Hilaali, "The Ruling on Aborting a Rape Embryo," *Journal of the College of Islamic Law in Kuwait*, no. 41, p. 250.

> Going over the views expressed by earlier jurisprudence (*fiqh*) scholars, with the keen insight and sound judgment they demonstrate; noting that they unanimously forbid abortion after the spirit is breathed in, i.e. after the first four months of pregnancy, and that they differ over abortion before spirit is breathed in, with some opting for categorical prohibition or considering it reprehensible, and others prohibiting it after the first forty days and allowing it before that, with some difference over the necessity for justifying reasons; and benefiting from a review of contemporary medical and scientific advances as established by modern medical research and technology - the seminar concludes that an embryo is a living organism from the moment of conception, and its life is to be respected in all its stages, especially after the spirit is breathed in. Aggression against it, in the form of abortion, is unlawful except in cases of maximum medical necessity. Some participants, however, disagree and believe that abortion before the fortieth day, particularly when there is justification, is lawful.

The recommendations of the seminar of 1985, which dealt with the subject of Human Life, include the following:

> From the moment a zygote settles inside a woman's body, it deserves a unanimously-recognized degree of respect, and a number of legal stipulations apply to it.
>
> When it arrives at the spirit-breathing stage, the time of which is subject to controversy, being either forty or 120 days, the fetus acquires greater sanctity, as all scholars agree, and additional legal stipulations apply to it.
>
> Among the most important of these stipulations are those that govern abortion as pointed out in Article Seven of the recommendations of the seminar on Reproduction in Islam.

Topic Nine
The Case of the Private Parts('Awra) of a Member of One Sex Being Viewed by a Member of the Other Sex for Purposes of Medical Diagnosis, Treatment, and Education(76)

Definition

Islam sets limits to body exposure before other people with the aim of keeping genitals covered and guarding against hateful seduction.

The viewpoint of the majority of scholars is that a man's *'awra* (parts that should not be exposed) before a woman other than his wife is the part of his body between his navel and knees, a woman's *'awra* before a man other than her husband and her unmarriageable relatives includes all her body except for her face and hands, her *'awra* before her unmarriageable relatives is what she usually keeps covered while at home, the *'awra* of a person before a member of the same sex is the sexual organ and the rectal area, and there is no *'awra* between husband and wife.

Still, in their contact with each other, people may need to expose parts of their bodies for purposes of medical diagnosis, treatment, and education. What is then the ruling on such exposure?(77)

The Legal Position Chosen by the IOMS and Its Argument

On the question of the exposure of *'awra* between members of the two sexes for purposes of medical examination, treatment and educa-

(76) The Islamic Organization of Medical Sciences (IOMS) discussed this question in its first seminar, the Seminar on Reproduction, in 1983.

(77) This definition is based on the discussions of the Seminar on Reproduction, pp. 325-42.

tion, the IOMS supported in its first seminar, the one on Reproduction, in 1983 the opinion that allowed such exposure when a need calls for it. The seminar's recommendations say:

8 - It is lawful for a person to look at the *'awra* of a member of the other sex for purposes of medical diagnosis, treatment, and education. The exposure, however, should be limited to what the need calls for.

9 - Efforts should be made to include in the curricula of medical schools in the Islamic World a study of the subjects of Islamic Law related to health, disease, and treatment, and to include medical subjects in the curricula of colleges of Islamic studies.

10- A permanent committee composed of jurisprudence (*fiqh*) scholars, physicians, and scientists should be established to look when necessary into cases that require technical knowledge and Islamic ruling.

Remarks on the recommendations of the Reproduction seminar of 1983 concerning exposure to the other sex:

1 - The seminar recommended that the curricula of medical schools in the Islamic World should cover subjects of Islamic Law related to health, and that the curricula of colleges of Islamic studies should include medical subjects. To what extent has this recommendation been followed?

2 - The seminar recommended that a permanent committee composed of jurisprudence (*fiqh*) scholars and physicians should be established to look when necessary into cases that require technical knowledge. How is this recommendation carried out?

The Position of the Islamic Jurisprudence (*fiqh*) Academy:

The Islamic Jurisprudence (*fiqh*) Academy ruled that it is lawful for a person to expose his/her *'awra* to a member of the other sex for medical purposes when necessary. In the decisions of its seventh session, the Academy says:

It is unlawful for a Muslim woman, under any conditions other than those sanctioned by Islamic Law as legitimate justifications, to expose herself before any person other than that who may legitimately have sexual intercourse with her. A woman's need for treatment when suffering a harmful disease or an abnormal, disturbing condition in her body is considered a legitimate justification for exposure before a person other than her husband for the purpose of treatment, as long as the exposure is restricted in degree to what is necessary for that purpose.

Topic Ten
The Inception of Human Life(78)
(The Point and the Stage at Which Fetal Life becomes Human)

Definition

From the moment of its birth, an infant is unanimously referred to as a human being, an actual member of the human race. This is based on a tradition attributed to the Prophet by Abu Dawood which says, "As soon as it is born, a baby is entitled to inheritance." Before that, it is a fetus in its mother's abdomen, but it starts to grow from the moment of insemination, until spirit is breathed into it. Its organs assume their full form, and then it is born. from the moment of insemination, an embryo is entitled to certain rights, which are reaffirmed and added to as spirit is breathed into it. Between the beginning of life and the breathing of the spirit, Jurisprudence (*fiqh*) scholars are at some loss as to determining the rights of an embryo and the rulings related to it. So where do we start in determining these rights and rulings?(79)

The Legal Position Chosen by the IOMS and Its Argument

In both the first and second seminars of the IOMS in 1983 and 1985 (on Reproduction and on Human Life: Its Inception and End), agreement was reached that an embryo is entitled to respect and has sanctity from the moment of insemination, and that this sanctity increases at the time of spirit breathing.

(78) The IOMS discussed this question mainly in its second seminar in1985, which was devoted to Human Life: Its Inception and End. The subject had casually been raised in the discussion of abortion in the first seminar, the one on Reproduction, in 1983. The issue was again discussed by the IOMS in its third discussion of abortion in its fourth seminar, Health Policy: Ethics and Values, in 1988.

(79) This definition is based on a review of the papers and discussions.

Meanwhile, the fifth seminar, Health Policy: Ethics and Moral Values, held in 1988, did not make any recommendations, although it addressed the question in its papers and discussions.

1 - The recommendations of the second seminar, held in 1985 to discuss Human Life: Its Inception and End, say:

> **First:** The inception of life occurs with the union of a sperm and an ovum, forming a zygote which carries the full genetic code of the human species in general and of the particular individual, who is different from all others throughout the ages. The zygote begins a process of cleavage that yields a growing and developing embryo, which progresses through the stages of gestation until birth.
>
> **Second:** From the moment a zygote settles in a woman's body, it deserves a unanimously-recognized degree of respect, and several legal stipulations, known to scholars, apply to it.
>
> **Third:** When it arrives at the spirit-breathing stage, the time of which is subject to controversy, being either forty or 120 days, the fetus acquires greater sanctity, as all scholars agree, and additional legal stipulations apply to it.
>
> **Fourth:** Among the most important of these stipulations are those that govern abortion as pointed out in Article Seven of the recommendations of the seminar on "Reproduction in Islam."

2 - Earlier, the recommendations of the Reproduction seminar in 1983 included the following:

> Benefiting from a review of contemporary medical and scientific advances as established by modern medical research and technology - the seminar concludes that an embryo is a living organism from the moment of conception, and its life is to be respected in all its stages, especially after the spirit is breathed in. Aggression against it, in the form of abortion, is unlawful except in cases of maximum medical necessity. Some participants, however, disagree and believe abortion before the fortieth day, particularly when there is justification, is lawful.

Topic Eleven
Definition of Death Which Terminates Human Life and for Which a Death Certificate Is Issued[80]

Definition

People used to recognize death through one of its clear signs, which include respiration, pulse, and motion. With the great progress in medicine and its technologically-sophisticated equipment, it has been possible, in some cases, to restore respiration and heart beat when the brain stem has suffered no injury. If damage directly hits the brain stem, death symptoms follow each other in succession: consciousness is lost, breathing ceases, the heart stops, and one by one, the other organs die. There is no way to replace damaged brain cells, even through artificial respirators and vascular nutrition, which keep alive organs of the human body other than the brain for a period that ranges approximately between few hours and two weeks.[81]

This medical progress has raised questions about the true nature of death and the time at which legal stipulations related to it become valid, whether it is when the brain stem dies, but not the heart and other organs, or when respiration and the heart stop, but not the brain stem. It is unanimously agreed that a person is dead when both his brain and his heart die.

(80) The IOMS addressed this question in three seminars:
a. the second, entitled "Human Life: Its Inception and End," in 1985;.
b. the fourth, entitled "Health Policy: Ethics and Human Values" in 1988; and
c. the ninth, entitled "The Medical Definition of Death," in 1996.

(81) Paraphrased from Dr. Mukhtaar Mahdi, "The End of Human Life," *The Seminar on Human Life*, pp. 337-41.

This question entails that

1 - the living organs of a person ruled to be dead can be used in organ transplant procedures;

2 - respirators may be removed in the case of people ruled to be dead, and resuscitation should be applied to a person whose heart stops while his brain is still alive; and

3 - arrangements have to be made concerning those entitled to inheritance, and other rulings concerning the dead have to be applied.

The Legal Position Chosen by the IOMS and Its Argument

In its second seminar, Human Life: Its Inception and End, the IOMS adopted the ruling favored by the majority of participating physicians, which holds that death occurs with brain death as technically defined. This ruling is quite close to the majority opinion of the participating jurisprudence (*fiqh*) scholars, who hold that brain death should be the decisive factor for certain stipulations concerning death.

The fourth seminar, Health Policy: Ethics and Human Values, in 1988 had no recommendations on the subject. However, the ninth seminar, The Medical Definition of Death, in 1996 reaffirmed the recommendations of the 1985 seminar.

Some of the recommendations of the second seminar, Human Life: Its Inception and End, are:

> **Fourth:** It was clear to the seminar after hearing the presentations of physicians that what they recognize as a sign of human death is the inactivity of the brain area that performs the vital functions, and this is referred to as death of the brain stem.
>
> **Fifth:** Scholars of jurisprudence (*fiqh*) tend, on the basis of the presentation made by physicians, to the view that when a person enters the certain stage of brain stem death, he has departed from life, and some of the rulings pertaining to the dead apply to him in analogy - albeit the clear difference of

the two cases - with the jurisprudence (*fiqh*) handling of the case of an injured person who shows the symptoms of being slain. As for applying the rest of those rulings, the conferring scholars are inclined to have them postponed until his major systems cease to function. The seminar recommends that another detailed study should be conducted to decide which rulings should apply immediately and which should be postponed.

Issued as a statement, the Recommendations of the ninth seminar, The Medical Definition of Death, in December 1996 include the following:

A person is regarded as dead in the case of

1 - a complete and irreversible cessation of the functions of the respiratory and cardio-vascular systems, or

2 - a complete and irreversible cessation of all functions of the brain, including those of the brain stem.

The occurrence of one of these two cases should be determined in accordance with recognized medical criteria.The Opinion of the Islamic Jurisprudence (fiqh) Academy

The Islamic Jurisprudence (*fiqh*) Academy, in its conference in Amman in October 1986, endorsed the ruling that brain death or the death of the heart coupled with complete cessation of respiration, is the decisive criterion of death. Resolution No. (5) of the conference stipulates that

In Islamic Law, a person is regarded as dead, and all the legal consequences of death become operative, if one of the following symptoms is detected:

1 - if his heart and respiratory system stop completely and physicians decide that this cessation is irrevocable, or

2 - if all functions of his brain cease completely, physicians decide that this cessation is irrevocable, and his brain is subjected to analysis.

Topic Twelve
Ruling on the Restoration to Life of a Person Whose Brain Has Died[82]

Definition

After the scientific medical point of view in the early 1980s that actual death is brain death - a federal law was passed in the United States in 1981 determining death as "the irrevocable loss of the brain functions of a human being" - some newspapers and television stations reported that some physicians in Egypt and elsewhere were questioning the internationally dominant notion that the complete death of the brain is the decisive factor in determining the moment of death. Some media have recently reported stories of people who came back to life after it had been declared that their brains were dead. Does this, then, negate the theory of brain death, or does it indicate a misapplication of the theory? This was the question brought before the participating physicians in this special seminar.[83]

The Legal Position Chosen by the IOMS and Its Argument

In its ninth seminar held in 1996 to discuss the Medical Definition of Death, the IOMS accepted the viewpoint held by the majority of participating researcher physicians, which affirms the impossibility of

(82) This subject was discussed by the IOMS in its ninth seminar, held in 1996 under the title: The Medical Definition of Death. Although chronologically it comes after subjects that are discussed later here, it is placed at this point because it is related to the preceding subject, which is "Definition of Death Which Terminates Human Life and for Which a Death Certificate Is Issued."

(83) This definition is a paraphrase of the definition offered in papers and discussions at the seminar.

life being restored to a person whose brain is completely dead, when his case is diagnosed according to the special technical criteria applicable in such cases. The recommendations of the seminar say:

> It was clear to the participants that there has been no case in which life was restored after the diagnosis of brain and brain stem death had been confirmed. In no case life was restored after the conditions of brain and brain stem death diagnosis were met. All the cases used as evidence by those who question this notion have been either cases in which diagnosis criteria were not meticulously observed or cases in which there was an error in diagnosis, inference, or deduction.
>
> It is now clear to the participants that nothing new has developed in regards to this question, which makes the Organization hold to its previous recommendation, made in the seminar on Human Life: Its Inception and End, which was held in Kuwait in 1985.

Topic Thirteen
Ruling on (1) Extending Aid When the Heart Is Dead but Not the Brain and (2) Removing Life-Supporting Equiment When Brain Death Is Confirmed[84]

Definition

It has been stated that the end of a human being can take one of three forms. They are:

1 - when both the brain and all major organs die, and it is unanimously agreed that such a person is dead;

2 - when the brain stem dies, but not all the major organs, such as the heart, and this is a case on which the majority of physicians and some jurists believe to be that of a dead person, subject to the rulings that apply to the dead; and

3 - when the heart or any other major organ dies, but the brain continues to function.

These forms raise the question of the rulings on the two cases mentioned above, in the title, which are discussed here:

The First Issue: Extending Aid When the Heart Is Dead but Not the Brain - The Medical Point of View

Participating physicians are unanimous in maintaining that the cessation of the heart and respiration, but not the brain and brain

(84) This topic is subsidiary of the question of brain death. The IOMS discussed it in the three seminars, listed above, in which the definition of death was addressed, but the ninth seminar, held in 1996, is the closest to this topic by virtue of its area of concentration.

stem, is not a decisive indication that death has occurred. Aid can be extended to the person concerned by using a substitute pump to circulate the blood through the circulatory system, by massaging the heart, or by using electric shocks with artificial respiration. In some cases, the heart resumes its function, involuntary respiration resumes as well, and the person regains consciousness.

In most cases, however, what happens is that the heart stops, cessation of respiration immediately follows, and then the other organs die, with the brain going first, within few minutes. If it proves possible to give aid to the heart just as it stops, and it responds, the patient's life may be saved.

As stated by Dr. Mukhtar Al-Mahdi, a chairman of a department of neurosurgery, every physician who is available at the moment when the heart stops should attempt this type of aid as much as possible. If he fails to do so, he would be guilty of one form of treatment negligence.(85)

The Legal Position Chosen by the IOMS and Its Argument

In its second seminar, Human Life: Its Inception and End, in 1985 and ninth, The Medical Definition of Death, in 1996, the IOMS accepted the opinion agreed upon by participating physicians and scholars, which is to regard the stopping of the heart as a medical case that can be treated.

The recommendations of the second seminar stipulate that "any vital organ or function, such as the heart or respiration, may temporarily stop, but as long as the brain stem is alive, that organ or function can be revived."

The IOMS cited the recommendation of the Human Life seminar on that point in the recommendations of the ninth seminar, held in December 1996.

(85) It has already been mentioned and documented in the account given on the question of death as seen by physicians; i.e. the question of the Definition of Death Which Terminates Human Life and for Which a Death Certificate Is Issued. It is repeated here for the reader's easy reference and because this is an independent question.

The Ruling of the Islamic Jurisprudence (fiqh) Academy

The Islamic Jurisprudence (*fiqh*) Academy, in a meeting held in Amman in October 1996, maintained that it is permissible to remove artificial respirators in the case of a patient whose heart is dead and whose respiration has stopped, even if his brain is not dead yet. Resolution No. (5) D 3/07/6 of the Academy stipulates that,

In Islamic Law, a person is regarded as dead, and all the legal consequences of death become operative, if one of the following symptoms is detected:

1 - if his heart and respiratory system stop completely and physicians decide that this cessation is irrevocable, or

2 - if all functions of his brain cease completely.

When this is the case, the artificial life-supporting equipment attached to the patient may be removed, even if some organs, such as the heart, continue to function automatically by virtue of the attached equipment.

The Second Issue: Removing Life-Supporting Equipment in the Case of a Patient with a Dead Brain

The Medical Point of View

When the brain is no longer capable to live, it is irreparable, nor can it be replaced immediately or even within a short time. Therefore, as things stand at present, the final death of the brain leads to the death of its owner.

This is something that is established and commonly accepted in international medical circles. In no way can a person with a dead brain come back to life at present or in the near or even remote future, provided that correct technical criteria are observed in the diagnosis. This means that the life-supporting equipment can no longer benefit the patient, although it might be able to keep major functions, such as the heart's, going on for as long as two weeks, or a little longer.(86)

(86) See what has already been mentioned in the account of the medical opinion on the question of defining the death that ends a human being's life and for which a death certificate is issued.

The Legal Position Chosen by the IOMS and Its Argument

In both its second (Human Life) and ninth (The Medical Definition of Death) seminars, the IOMS endorsed the statement that it is permissible, but not obligatory, to remove life-supporting equipment when a patient's brain is actually dead, taking into consideration that the IOMS recognizes brain death as actual death. The recommendations of the second seminar say, "It is agreed that if brain stem death is confirmed through the report of a specialized medical committee, it is lawful to turn off artificial life-supporting equipment." The IOMS reaffirmed this recommendation in the statement (recommendations) of the seminar on the Medical Definition of Death in December 1996.

The Ruling of the Islamic Jurisprudence (fiqh) Academy

The Islamic Jurisprudence (*fiqh*) Academy, in a meeting held in Amman in October 1996, endorsed the position that it is lawful to remove life-sustaining equipment. Resolution No. (5) says on this subject, "In this case, it is proper to remove any life-sustaining system used for such a person, even if some organs, such as the heart, continue to operate mechanically due to the systems attached."

Topic Fourteen
Confidentiality in the Medical Profession[87]

Definition

A physician gets to know many of the personal secrets of a patient of his, which even the patient's spouse may not know. Some of these secrets may relate to other areas, such as religion, morality, and the law. Some might relate to other individuals, such as the patient's fiancé(e), spouse, or guardian, or any other person closely-associated with the patient. A question arises as to the extent of the physician's right and responsibility to disclose or keep such secrets.

The Legal Position Chosen by the IOMS and Its Argument

On the subject of confidentiality in the medical profession, the IOMS - in its third seminar, the Islamic View Concerning Certain Medical Practices, held in 1987 - endorsed the position taken by jurisprudence (*fiqh*) scholars in their definition of a "secret," and the subject as it generally applies to all professions. It also supported the majority opinion that considers that, as a principle, violating professional confidentiality is unlawful, although it is permitted in exceptional cases.

The recommendations of the third seminar state the following:

1 - a - A secret is what is communicated by one person to another with a prior or subsequent request to keep that communication to himself. This includes all methods that usually signify

(87) The IOMS addressed this question in both its first convention, which was part of Kuwait's celebrations of the beginning of the fifteenth century of the Hijri Calendar, and its third seminar on Islamic View Concerning Certain Medical Practices, in April, 1987.

a request of keeping something secret or that is supposed, by convention, to be kept secret. It also includes the privacy and defects of a person which he hates to be revealed to others.

b - Secrets are trusts, and the person they are entrusted to is obliged to keep them in accordance with the stipulations of Islamic Law. This is also called for by gallant behavior and by the ethics of dealing with others.

c - In principle, the disclosure of a secret is prohibited and calls for religious, professional, and legal discipline.

d - The obligation of keeping secrets is stressed in the case of a profession, such as medical professions, where disclosure disrupts the profession itself, since people who need advice and assistance approach the professionals invoved and reveal to them all details that help them to perform their critical tasks. Such details may include secrets a person usually keeps from those closest to him.

2 - Exceptions to the obligation to keep a secret are the cases in which keeping it results in greater harm to the person involved than revealing it and the cases where the disclosure brings a benefit that carries more weight than the harm it causes. The latter cases are of two types:

a - Cases in which a secret must be disclosed in accordance with the rule of "allowing the lesser harm" or the rule of "realizing a general interest," which calls for tolerating individual harm to avoid general harm when the latter can be avoided only by tolerating the former. There are two types of such cases: (1) situations that involve avoiding social harm and (2) situations that involve avoiding individual harm.

b - Cases in which a secret may be disclosed because of what it involves of (1) realizing a social benefit or (2) avoiding general harm. In these the purposes and priorities of Islamic Law must be observed, namely the preservation of faith, life, reason, offspring, and wealth.

c - Added to the above are cases where the patient accepts the disclosure of his secret, which means that he gives his consent, as it is he who has the right to waive his demand (of keeping it secret).

d - The exceptions relating to the cases when disclosure is obligatory or permissible should be incorporated in the bylaws of medical practice, and other laws. They should be stated clearly and inclusively, with details of how they should or may be disclosed and to whom. Concerned authorities should undertake sufficient education about these exceptions.

3 - A Muslim physician - who shoulders part of the public responsibility in his capacity as reformer, counselor, and prevention factor to ward off any harm before it takes place - should make an attempt, before resorting to one of the exceptions regarding secret disclosure, to avoid it by exercising his role as a reformer with the hope of protecting patients and others who are exposed to some hazard. He can do so by outlining to the patient the straight way for rising after his fall and thus escape the dangers involved. In doing so the physician would be encouraging the patient's self reform, and he (the physician) will not lack the proper arguments that involve no denial of rights or fabrication of facts.

Topic Fifteen
The Conflict between Secular Law or Administrative Instruction and Islamic Law in Health Practice(88)

Definition

A physician might find himself in a religious dilemma due to a law or an administrative instruction from his superior that is in conflict with the stipulations of Islamic Law. How should he act in such a situation? Is obedience of the law or instruction an excuse that waives his responsibility? Examples of such conflicts are the following.

1 - Human law may permit the disclosure of a patient's secret, while keeping it is considered necessary in Islamic Law. An example is revealing to a husband that his wife has had a hymen patching surgery before their wedding, when no suspicion of a criminal action is being involved, or a case where the law forbids disclosing a patient's secret while Islamic Law requires advice to be extended on the basis of that secret, such as telling a person that his fiancé(e) has a hereditary disease.

2 - The law makes no distinction between male and female physicians in treating a patient, with his consent, regardless of the patient's gender. Meanwhile, sometimes a husband insists on following some considered opinions (*fatwas*) of Islamic Law which forbid having his wife treated by a male physician, although a delay of her treatment may be hazardous.

3 - Some human laws prohibit abortion even when it is medically necessary to save the mother's life. On the other hand, some laws

(88) This is a question raised spontaneously in the discussion of Confidentiality in the Medical Profession. The IOMS addressed it as a separate subject in its third seminar, the Islamic View Concerning Certain Medical Practices, in 1987.

permit abortion after the spirit is breathed into the fetus, which means a physician's refusal to fulfill the wish of a patient amounts to declining to perform his job, which he has sworn to perform for friend and foe.(89)

The Legal Position Chosen by the IOMS and Its Argument

The IOMS adopted in its third seminar, the Islamic View Concerning Certain Medical Practices, in 1987 the position of some researchers and participants in the discussion, which holds that an employed physician may not use an administrative instruction as an excuse, and should not worry about obedience to his superior. The IOMS recommended educating physicians on this point.

The IOMS also endorsed the point of view of most scholars that, in general, a conflict between human and Islamic Law does not exist in practical life. The recommendations of the seminar say:

> The seminar has discussed the subject of "The conflict between the Law and Islamic Legislation," and on the basis of the cited examples of cases in medical practice in Islamic countries, it is clear that, in general, there is actually no situation that causes a dilemma to a physician while performing his job.
>
> Observing the rules of Islamic Law is a general obligation for all Muslims, whether they are workers in health professions or not. If man-made law gets in conflict with Islamic legislation, the former should be revised to correspond to the latter. A Muslim physician has no choice other than observing Islamic Law.
>
> The seminar recommends that the syllabi of courses taught in medical schools and health science institutes, as well as courses of continuing training, should include materials that introduce to students the stipulations of both Islamic and human law which regulate their rights, obligations, jurisdiction, and responsibilities in their practice of health professions.

(89) The above-mentioned third seminar, pp. 754-55.

Topic Sixteen
Legitimate Ways of Human Organ Acquisition for Life-Saving Purposes (Organ Donation and Sale)[90]

Definition and Describing the Bases of Human Organ Sale

Following the success of human organ transplant operations, and in light of their legitimacy, the question has been raised as to the legitimate manner of obtaining organs for such operations from people who give their organs to save the life of a person or a damaged function of his body. That manner should be defined so that human beings would not turn into barbarians who kidnap each other.[91]

This subject is part of another important one, which is "the ruling on human organ transplants." But that subject has not been addressed by the IOMS, on the belief that it has been already discussed by trustworthy committees and academies of Islamic jurisprudence (*fiqh*). Thus, the recommendations of the third seminar in 1987, which discussed the topic of "Organ Donation and Sale," say:

> In light of the legal position taken by jurisprudence (*fiqh*) academies and legal opinion (*fatwa*) committees in the Islamic

(90) The IOMS discussed this subject in seven papers and the subsequent discussions in the third seminar in 1987 and issued some recommendations, and in the fourth seminar in 1988, but no recommendations were made. The subject was also discussed along with other topics introduced by researchers in the second seminar in 1985.

(91) I used my discretion in writing this definition on the basis of the discussions of the subject. To make the subject more specific, I added the phrase "life-saving purposes" in the title although it is not included in the submitted papers.

> World, which permit organ transplantation to patients under the circumstances and conditions stipulated by Islamic Law, the seminar discussed the subject of organ sale.(92)

The IOMS continued to discuss the Islamic legal ruling on organ sale, devoting a seminar to study the rulings on the sale of human organs which are of a special nature, such as brain cell transplants and genital organ transplants. That was the sixth seminar in 1989.

The recommendations of the third seminar endorse resolution no.(1)d4/08/88, of the council of the Islamic Jurisprudence (*fiqh*) Academy in its fourth session on organ transplants, quoting the text of the resolution, which says:

> **First:** It is permissible to transplant an organ from one location to another in the body of a person, after making sure that the benefit expected from this operation is of greater weight than the harm it causes, provided that the operation is

(92) The Egyptian House of Giving Legal Opinion issued in 1959 its opinion (*fatwa*) that permits blood transfusion and cornea transplants from the eyes of dead individuals. In 1973, the opinion of Sheikh Muhammad Khater, the Mufti of Egyptian Lands at the time, gave his opinion (*fatwa*) that allows the skinning of a dead person to treat the burnt skin of a living one. In Saudi Arabia, the Commission of Senior Scholars issued a decision in 1978 concerning cornea transplantation from one person's eye to another's. The Islamic Jurisprudence (*Fiqh*) Academy in Jeddah issued, in its fourth session in the year 1408 H., resolution no. (1)d4/08/88, which permits organ autografts and transports from a living individual, provided that it is willingly donated and the donor, who should be fully competent, is not harmed by the donation. The Academy permits transplants from dead people, provided that their consent has been given while still alive or permission is obtained from their heirs or from the ruler of Muslims in the case of a dead person whose identity is unknown or who has no heirs. This permission is on condition that no sale of organs takes place.

In Kuwait, the Legal Opinion (*Fatwa*) Authority at the Kuwaiti Ministry of Endowments (*Waqfs*) issued decision no. 455 of 1985, which states that the transplantation of some organs is permissible, subject to certain controls.

In Algeria, the Opinion Giving (*Iftaa*) Committee of the Supreme Islamic Council gave an opinion that permits organ transplantation. See Dr. Muhammad Ali Al-Baaz, "Transplanting Genital Glands and Organs," *The Seminar of an Islamic Perspective of Transplanting Some Human Organs*, 1989, p. 645.

to introduce or replace a missing organ, reshape an organ, restore its normal function, treat a defect, or remove a deformity that causes him psychological or physical harm.

Second: It is permissible to transplant an organ from the body of a human being to the body of another, if it is an auto-regenerating organ, such as blood and skin, provided that the donor is fully competent and that the relevant conditions of Islamic Law are observed.

Third: It is permissible to use a part of an organ that has been removed from another person due to a pathological failing, such as using the cornea of an individual's eye which is removed for such a reason.

Fourth: It is forbidden to transplant a vital organ, such as the heart, from one living person to another.

Fifth: It is forbidden to transplant an organ from a living person, when its removal stops a basic function in the life of that person, even when his life is not dependent on it, such as transplanting the cornea of both eyes. If the removal only affects a basic function partially, the case should be subject to consideration, as explained in the eighth paragraph.

Sixth: It is permissible to transplant an organ from a dead individual to a living one when the latter's life or a basic function of his depends on it, provided that the consent of the deseased person has been given or permission is obtained from his heirs or from the ruler of Muslims in the case of a dead person whose identity is unknown or who has no heirs.

The Legal Position Chosen by the IOMS and Its Argument

On the question of "the sale and donation of human organs," the IOMS supported the viewpoint of the majority, which forbids organ sale and permits the donation of organs and using the organs of dead people with the permission of their guardians. The recommendations of the third seminar, the Islamic View Concerning Certain Medical Practices, in 1987 include the following:

> The ideal way of obtaining organs is that which is the outcome of mutual compassion among people in the form of

organs from dead people donated in their wills or obtained with the consent of heirs, or from dead people whose families are unknown.

The majority also believe that it is also lawful to obtain organs through the donation of a living person to another, subject to the approved conditions and restrictions, which include that the donor suffers no harm and is not subjected to any coercion.

It is not lawful to sell organs. If, however, they cannot be obtained through free donation and can only be acquired in return for money, it is permissible to do so according to the majority of participants, who consider this a case of a prohibited thing rendered permissible due to necessity. Some scholars, however, find it unlawful. Yet, under no circumstances should the acquisition of organs, particularly when injury is involved, be allowed to become the object of competition between the rich and the poor. The state should set up a commission to control such acquisition, prevent the risks involved, and manage it in accordance with a detailed law issued for this purpose.

The Position of the Jurisprudence (fiqh) Academy

Resolution no.(1)d4/08/88, of the council of the Islamic Jurisprudence (*fiqh*) Academy in its fourth session expresses the same position as that of the IOMS, i.e. prohibition of any dealing in human organs that involves a conditional transaction and permission of forms that involve no such conditions. The seventh recommendations of the resolution says:

> It should be understood that endorsing the permission to transplant organs under the circumstances already stated is made under the condition that it involves no organ sale, because a human being should never be subjected to a sale transaction. As for the payment of money by the beneficiary when necessary in his effort to get the needed organ or as a reward and expression of gratitude, this has to be looked into and decided upon.

Topic Seventeen
Transplanting and Implanting Cells of the Brain and Nervous System[93]

Definition

With the progress it has achieved, medicine has succeeded in implanting almost all human organs, other than the brain and its cells, whether they are external organs, such as arms and legs, or internal ones, such as the heart and the liver. This has been achieved after the increasing success of administering the drug cyclosporine, which has to a great extent helped in overcoming the problem of the body's rejection of foreign organs.

In spite of the failure of physicians up till now to implant a brain, although they still entertain the hope, some indications of success have occurred in implanting some brain cells or tissues to replace damaged ones, in a procedure similar to skin grafts.[94]

The gist of the matter is that certain diseases cause damage to some brain cells, due to some chemical or hormone secretions. Is it then lawful to replace such damaged cells with healthy ones taken

(93) The word "transplanting" is added to the title because the topic includes the two rulings on transplanting and implanting.

This subject was discussed at a late stage in IOMS history, in 1989, as one of the subjects of its sixth seminar, following many other subjects. I placed it at this point, however, because it is connected with the previous topic, the donation and sale of human organs, discussed by the IOMS in its third seminar in 1987. This is due to a desire on my part to have some harmony in the arrangement of subjects. In the chronological order the subject of the donation and sale of human organs is followed by the subject of "plastic surgery."

(94) Dr. Mukhtaar Al-Mahdi's paper, *The Sixth Seminar*, pp. 55, 61, and 73.

from the same person, as in the case of transplanting adrenal gland cells, or from somebody else, as in the case of transplanting cells from an early fetus in its tenth or eleventh week of pregnancy?(95)

This shows the connection between this topic and some aspects of the subject of "abortion," but what is intended here is to determine the Islamic ruling on the principle of implanting cells of the brain and nervous system.

The Legal Position Chosen by the IOMS and Its Argument

On the subject of "Transplanting and Implanting Cells of the Brain and Nervous System," The IOMS - in its sixth seminar held in 1989 under the title, "An Islamic Perspective of the Implanting of Certain Human Organs" - supported the point of view of participant jurists, or at least most of them, which finds it lawful to transplant brain cells taken from the adrenal gland of the same person, from cultured stem cells, or from animals and considers it unlawful to transplant stem cells from embryos while in their mother's uterus, even before the breathing in of the spirit. The seminar stated in its recommendation the following:

> The seminar considered the subject of implanting cells of the brain and nervous system (which is not intended to mean the transplanting of cells from one human being to another). The purpose of such implanting is either to treat the failure of certain brain cells to secrete their chemical or hormone substances in sufficient quantities, where the failure is made up for by replacing these with similar cells from another source, or to bridge a gap in the nervous system caused by some injury, in a manner similar to the replacement of a damaged piece of wire with another.

(95) Dr. Hassaan Hathoot in his contribution to the discussions of the sixth seminar, p. 157; Dr. Mukhtaar Al-Mahdi's paper, *ibid.*, p. 70.

The first source for the desired tissues is the adrenal gland of the patient himself. The seminar sees nothing wrong in such a case, which has the advantage of immunological acceptance, because the cells are from the same body.

The second source of the tissue is the living cells of an early fetus (in its tenth or eleventh week). There are various methods of getting such cells.

The first method is taking them from an animal fetus. This method has succeeded with various animal species, and it is hoped to be successful when the necessary precautions are taken to avoid immunological rejection. The seminar finds nothing legally objectionable in this method if its success is possible.

The second method is taking them directly from a human fetus in its mother's uterus by surgically opening the uterus. The method causes the fetus to die as soon as the cells are removed from its brain. The seminar finds this legally forbidden, unless it is carried out after a legitimate abortion to save the mother's life and under the conditions listed in discussing the subject of making use of fetuses.

The third method is one that may be introduced in the near future. It is that of using cultures to cultivate generation after generation of brain cells. The seminar finds that legally acceptable if the source of the cultivated cells is legitimate.

The Position of the Islamic Jurisprudence (*fiqh*) Academy

In its seventeenth session, held in Mecca in 2004, the council of the Islamic Jurisprudence (*fiqh*) Academy discussed the subject of "Transplanting and Implanting Stem Cells." It pointed out the sources of such cells in accordance with the recommendations of the earlier mentioned IOMS sixth seminar of 1989. The third resolution of the council, dated December 17, 2003, says:

Stem cells, the cells of origin from which a fetus is created, have the potential, by God's will, to form all kinds

of body cells. Scientists have recently been able to identify, isolate, and cultivate these cells, for therapeutic purposes and various scientific experimentation. These cells can be used to treat some diseases. They are expected to have in the future a great impact in treating many diseases and congenital deformities, including some types of cancer, diabetic urine, kidney and liver failure, and others.

These cells can be acquired from several sources, such as:

1 - An early embryo in the stage of the bacterial ball (blastula), which is a ball of productive cells from which all body cells generate. The surplus zygotes in test-tube baby procedures are the main source. A donor's ovum may deliberately be inseminated by the sperm of another donor to produce a zygote, let it grow into a blastula, and then extract brain cells from it.

2 - Aborted fetuses at any stage of the pregnancy.

3 - A placenta or chorda umbilicalis.

4 - Children and adults.

5 - Therapeutic cloning by taking a body cell from an adult, extracting its nucleus, and implanting it into an ovum whose nucleus is already removed, in order to reach the blastula stage, from which stem cells can be obtained.

After listening to the submitted papers and the opinions of members, experts, and specialists and getting to know this type of cells, their sources, and ways of using them, the council reached the following decision:

First: it is lawful to acquire and cultivate stem cells and to use them for the purpose of treatment or for conducting permissible research, if their sources are legitimate. The following are examples of such sources:

1 - adults, if they give their consent and the procedure involves no risk for them;

2 - children, if their guardians give permission for a legitimate benefit and without involving any risk for the children;

3 - a placenta or chorda umbilicalis, with the permission of the parents;

4 - a fetus aborted spontaneously or for a therapeutic reason allowed by Islamic Law, with the permission of the parents, calling to mind here what the seventh resolution of the Academy's twelfth session stipulates concerning the cases in which abortion is allowed; and

5 - surplus zygotes in a test-tube baby procedure, if there are any and they are donated by the parents, emphasizing, however, that such cells may not be used for an unlawful pregnancy.

Second: It is unlawful to acquire and use stem cells when their source is

1 - a deliberately-aborted fetus, for no medical reason that is considered valid in Islamic Law;

2 - the deliberate fertilization of an ovum of a donor and a sperm of another donor; or

3 - "therapeutic cloning."

Topic Eighteen
The Extent of Making Use of Aborted Fetuses, Surplus Zygotes, and Anencephalic Babies[96]

Definition

This topic is related to the previous one, Transplanting and Implanting Cells of the Brain, since both deal basically with stem cells. It is also related to the subject of Transplanting and Implanting Human Organs.

Following the recent medical discovery of the therapeutic benefits of stem cells and embryonic tissues, the idea of acquiring such cells and tissues from illegitimate sources started to spread. Physicians suggest to officials some sources that do not violate religious teachings, ethics, or the law. All these are sources related to the early formation of a human being,[97] the stem cells being the early elements from which a fetus forms, with all its cell types that are characterized by activity, adaptability, and freedom from stimulating reactions of immunological rejection.

(96) The IOMS discussed one of these questions, "The Fate of Inseminated Ova," in its third seminar, entitled "The Islamic View Concerning Certain Medical Practices," in 1987.

(97) Until early in 1998, the common belief in medicine was that brain stem cells form when a fetus was ten weeks old and matured by its twelfth week, then each took its own course and became more specialized, and that they never regressed to their more general state and abilities. Discoveries, however, have demonstrated that stem cells that have started on the course of specialization may regress to their more general condition and to their ability to form and transform to any type of body cells. See Muhammad Ali Al-Baar, *Stem Cells and Moral and Jurisprudence Issues*, First Edition (Jeddah: The Saudi House of Publication and Distribution, 1423 H./2002, p. 25.

These suggested sources are aborted fetuses, surplus zygotes, and anencephalic babies, all of which are practically or actually dead. The following defines these sources:

1 - *Aborted Fetuses* are fetuses that are ejected from the uterus before their time. They are not fully formed and have no spirit, although their organs live for a short period.

2 - *Surplus Zygotes* in the test-tube baby (embryo implant) procedure: A physician uses a number of a husband's sperm to inseminate an equal number of his wife's ova, and then implants one to three zygotes onto the wife's uterus wall to complete a pregnancy that can only start in this method. In most cases, when the implant succeeds only one of the three embryos grows.(98)

The implanting procedure begins only after the physician has made sure that the insemination is successful, keeping the embryo in the laboratory for few days. Later, the doctor disposes of the surplus zygotes by burying or killing them; they certainly have no spirit, but they are alive and able to grow.(99)

3 - *Anencephalic Babies*: An anencephalic baby is a human being born without a head cavity and without brain lobes. It has only a brain stem that controls the basic, vital functions, such as respiration and blood circulation, when the baby is born alive. Its life, however, is short; it usually dies within a week after birth, and the longest time lived by such a baby was two months.(100)

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(98) Experiments have shown that one inseminated ovum has a 15% chance of success, which goes up to 23% with two re-planted ova and 30.7% with three. The percentage does not go any higher. The several chances of conception, and the risk involved, increase in proportion with the increase in the number of restored inseminated ova. Dr. Mamoon Al-Haaj Ali Ibraheem's paper, *The Third Seminar on the Islamic View Concerning Certain Medical Practices*, p. 451; his paper, *The Sixth Seminar on an Islamic Perspective of the Implanting of Certain Human Organs*, p.196; Dr. Abdullah Ba Salaamah's paper, *The Sixth Seminar*, p.445.

(99) I wrote the definition of Aborted Embryos and Surplus Zygote on the basis of what is mentioned in the papers and discussions dealing with these subjects.

(100) Dr. Hassaan Hathoot, "The Anencephalic Baby," *The Sixth Seminar on an* =

These three sources (aborted fetuses, surplus zygotes, and anencephalic babies) will be discussed separately in the following three cases, since there is some difference in the way of using them and in the rulings of some scholars concerning them.

The First Case: Medical Use of Aborted Fetuses

The Legal Position Chosen by the IOMS and Its Argument

The position adopted by the IOMS in its sixth seminar, An Islamic Perspective of the Implanting of Certain Human Organs, in 1989 was close to the opinion of the majority of scholars which finds making medical use of aborted fetuses lawful when it is subject to special controls and criteria. The recommendations of the seminar say:

The seminar finds that fetuses can be used as a source for organs wanted to be implanted in other human beings only when certain controls are applied as in the following cases:

- No abortion should be effected in order for the fetus to be used as a source of organs to be implanted in another human being. Only fetuses from spontaneous or legally justified abortions can be used.

- If the fetus has the potential to survive, medical treatment should focus on keeping it alive rather than on exploiting its organs.

- The procedures of organ implants should never be used for commercial purposes.

- Supervision of such matters should be entrusted to a recognized, trustworthy authority.

- Under all circumstances, the human body should be respected and honored.

Islamic Perspective of the Implanting of Certain Human Organs, p. 178. Also see Dr. George Aboona *et. al.*, "The Anencephalic Condition and Organ Transplants," *The Sixth Seminar*, pp. 201-02.

Remarks Concerning the IOMS Recommendations on Making Use of Aborted Fetuses

The IOMS limited its recommendation to the area of organ implants and relevant research. There are two other aspects of medical use of aborted fetuses, mentioned by physicians in detail, but the IOMS only referred to these.

I suggest that the phrase of "making use of aborted fetuses," at the opening of the recommendation, replace the phrase "organ implants." The same observation applies to the resolution of the Islamic Jurisprudence (*fiqh*) Academy in 1990, as it was influenced, on this subject, by the IOMS.

The Position of the Islamic Jurisprudence (*fiqh*) Academy

The Islamic Jurisprudence (*fiqh*) Academy discussed one aspect of the issue under consideration (Making Medical Use of Aborted Fetuses). That aspect was "Using Fetuses as a Source of Organ Implants," which is one aspect of making use of aborted fetuses.

The academy's resolution 58/5/6 says:

In its sixth conference, held in Jeddah in the period of 17 - 23 Shaaban 1410 H. (14 - 20 March 1990), the council of the Islamic Jurisprudence (*fiqh*) Academy - after reviewing the papers and recommendations related to this subject, being one of the subjects of the sixth jurisprudence (*fiqh*) seminar in Kuwait in 23 - 26 Rabee' I, 1410 H. (23 - 26 October 1989), held in collaboration between this Academy and the Islamic Organization of Medical Sciences - decides the following:

1 - Fetuses can be used as a source for organs wanted to be implanted in other human beings only when certain controls are applied.

   a - No abortion should be effected in order for the fetus to be used as a source of organs to be implanted in another human beings. Only fetuses from natural, accidental, or legally justified abortions can be used. No surgical operation may be performed to get the fetus out except when saving the life of its mother is involved.

b - If the fetus has the potential to survive, medical treatment should focus on keeping it alive rather than on exploiting its organs. If it has no potential to survive, it can be made use of only after it dies and in accordance with the conditions set in resolution 1 of the fourth session of this Academy.

2 - The procedures of organ implants should never be used for commercial purposes.

3 - Supervision of such matters should be entrusted to a recognized, trustworthy authority.

The Second Case: Making Use of Surplus Zygotes (Embryos) in Test-Tube Baby Procedures

The Legal Position Chosen by the IOMS and Its Argument

The position adopted by the IOMS in its third seminar, the Islamic View Concerning Certain Medical Practices, in 1987 on the question of surplus zygotes was also close to the opinion of the majority of scholars which finds making medical use of such inseminated ova lawful, subject to the controls that prevent any confusion of lineage and any aggression against human dignity. The recommendations of the seminar say:

> The ideal situation in the case of surplus inseminated ova is to have no surplus to start with. Scientists should go on with their research so that a method could be found to store the unfertilized ova, maintaining their ability to be positively inseminated later.
>
> The seminar recommends that scientists refrain from inseminating more than the number of ova needed, thus no surplus is left. When this is complied with, there would be no need for concern about the fate of unneeded inseminated ova.
>
> If there is a surplus, the majority hold that inseminated ova have no legal sanctity of any kind, and no respect is due to them before they are planted onto the uterus membrane. Therefore, there is no prohibition against destroying such ova in any manner.

Some scholars, however, believe that such an inseminated ovum is the first phase in the creation of a human being, who has received the blessings of God. Therefore, of the options of destroying it, using it in further research, or allowing it to have a natural death, the last, they say, seems to be the least unlawful since it involves no active aggression against human life.

Scholars have agreed to reaffirm the fifth recommendation of the seminar on Reproduction in Islam of 1983, concerning the surrogate uterus, which considers it unlawful to implant a zygote in another woman. Sufficient precautions should be taken to prevent using a zygote for an illegitimate pregnancy. It is also agreed to reaffirm the fourth recommendation of the Reproduction seminar, which warns against experimentation aimed at changing the inborn qualities bestowed by God and against exploiting science for evil, corruption, and destruction. The seminar recommends that Islamic legal controls should be set to enforce that warning.

The sixth seminar, held in 1989, said in its recommendations:

The seminar reviewed the thirteenth and fourteenth recommendations made in the third IOMS seminar - held in Kuwait from 20-23 Shaaban 1407 (18-21 April, 1987) - which dealt with "The Fate of Inseminated Ova."

The seminar endorsed those two recommendations and added to them the following:

A - In reference to the statement at the opening of recommendation thirteen that the ideal situation is to have no surplus to start with, with unfertilized ova being kept to be used later, the seminar takes note that this has become technologically possible, and some Western countries, West Germany in particular, is following this method.

B - To the majority's opinion, opposed by some scholars, that inseminated ova may be killed in any manner before they are

implanted in the uterus, it is added that there is no objection to use such ova in scientific experimentation, but not to foster their growth. Some scholars are completely against this view.

The seminar recommends that a committee should be set up to determine the controls of legitimacy.

The Position of the Islamic Jurisprudence (*fiqh*) Academy

The Islamic Jurisprudence (*fiqh*) Academy concurs with the opinion of the Islamic Organization of Medical Sciences on the subject of "The Fate of Surplus Zygotes." Its resolution 57/5/6 says:

In its sixth conference - held in Jeddah in the period of 17 - 23 Shaaban 1410 H. (14 - 20 March 1990) - the council of the Islamic Jurisprudence (*fiqh*) Academy:

> after reviewing the papers and recommendations related to this subject, being one of the subjects of the sixth jurisprudence (*fiqh*) seminar in Kuwait on 23 - 26 Rabee' I, 1410 H. (23 - 26 October, 1989), held in collaboration between this academy and the Islamic Organization of Medical Sciences (IOMS); and
>
> after reviewing the thirteenth and fourteenth recommendations made at the third IOMS seminar, held in Kuwait on 23 - 26 Rabee' I, 1410 H. (23 - 26 October, 1989), in collaboration between this academy and the IOMS, as well as the fifth recommendation of the first IOMS seminar, held in Kuwait on 11 - 14 Sha'ban, 1403 H. (24 - 27 May 1983), on the same subject - decides:
>
> 1 - In light of the achievement that allows the storing of unfertilized ova to be used later, the insemination of ova should be limited to the number required to be implanted every time, to avoid having a surplus of inseminated ova.
>
> 2 - When, for any reason, there is a surplus of zygotes, they should be left without any medical care until their life comes to a natural end.

3 - It is forbidden to implant an inseminated ovum in a woman other than the one who has produced it, and sufficient precaution should be taken to guard against using a zygote in an illegitimate pregnancy.(101)

The Third Case: Anencephalic Babies

The Legal Position Chosen by the IOMS and Its Argument

The position adopted by the IOMS in its sixth seminar, An Islamic Perspective of the Implanting of Certain Human Organs, in 1989 was the one reached by the majority of scholars which prohibits making any medical use of an anencephalic baby until its brain stem is dead. It was regarded as lawful to use life-sustaining equipment to keep the vital organs of such a baby functioning after its death, in order to use them in human organ transplantation procedures. The recommendations of the seminar say:

> An Anencephalic Baby: As long as such a baby remains alive through the life of its brain stem, it must not be tampered with by removing any of its organs, until its death becomes certain. In this respect, such a baby does not differ from normal people.
>
> When it dies, any removal of its organs should be subject to the valid rulings and conditions concerning transplanting the organs of the dead, such as valid permission, the absence of an alternative, the determining of necessity, and the other controls listed in resolution 1 of the the Islamic Jurisprudence (*fiqh*) Academy in its fourth session.
>
> The seminar believes that there is no objection to keep such an anencephalic baby attached to life-sustaining equipment after the death of the brain stem, which can be diagnosed, to keep the vital organs of such a baby functioning, in order to transplant them to another human being, subject to the conditions listed in resolution 1 of the Islamic Jurisprudence (*fiqh*) Academy in its fourth session.

(101) *The Sixth Seminar*, IOMS publications, p. 656.

The position of the Islamic Jurisprudence (*fiqh*) Academy

The Islamic Jurisprudence (*fiqh*) Academy shares the opinion of the IOMS, which forbids transplanting the organs of an anencephalic baby before its death. The Academy's resolution 56/5/6 on transplanting brain cells says:

> An Anencephalic Baby: Since it is alive at birth, it must not be tampered with by removing any of its organs until its brain stem dies. In this respect, it does not differ from normal people. When it dies, any removal of its organs should be subject to the valid rulings and conditions concerning transplanting the organs of the dead, such as valid permission, the absence of an alternative, the determining of necessity, and the other controls listed in resolution 1 of the fourth session of this Academy. There is no objection in Islamic Law to keep such an anencephalic baby attached to life-sustaining equipment after the death of the brain stem, which can be diagnosed, to keep the vital organs of such a baby functioning, in order to transplant them to another human being, subject to the conditions referred to.

Topic Nineteen
Genital Gland and Organ Transplants(102)

Definition

This topic includes two categories: genital glands and genital organs, details of which are as follows.

First: genital glands (the testicles in the case of men and the ovaries in the case of women) have two functions:

1 - production of sperms in men and ova in women, and

2 - secretion of hormones, which in the case of females affect all body systems, while in the case of males, they affect secondary characteristics such as the growth of facial hair, voice change, bone structure, and the beginning of sexual desire.

Testicle and ovary transplants are still in the stage of experimentation in developed countries.

Second: genital organs are the penis, vulva, and uterus. Transplanting these organs is still a scientific fantasy, but artificial vulvas and vaginas have been devised. Moreover, mechanical devices are used to replace a cut-off organ and perform its functions.

The question here is the ruling on the performance of such operations, if they prove successful, for people who need these glands and organs to function normally, due to some disorder in their sexual functions?.

The Legal Position Chosen by the IOMS and Its Argument

The recommendations of the sixth seminar, An Islamic Perspective of the Implanting of Certain Human Organs, in 1989 include the following:

(102) The IOMS discussed this question in its first seminar, the Seminar on Reproduction in Islam, in May 26, 1983.

First: The seminar concludes that since a testicle and an ovary continue to have and produce the genetic code of the donor even after they are implanted in the recipient, their transplantation is categorically prohibited, because it leads to the confusion of lineage and a born infant will not be the offspring to a husband and a wife legitimately bound by marriage.

Second: The seminar, by majority of opinion, finds that organ transplants of the genital system that carry no genetic characteristics, excluding the external organs, is lawful when it is done to meet a legitimate necessity and in accordance with the legal criteria and controls listed in the previously referred to resolution 1 of the fourth session of the Islamic Jurisprudence (*fiqh*) Academy in 1408 H.

The Position of the Islamic Jurisprudence (*fiqh*) Academy

The position of the Academy is the same as that of the IOMS. On genital organ transplants, resolution 59/8/6 says:

> The Council of the Islamic Jurisprudence (*fiqh*) Academy - in its sixth conference held in Jeddah, Saudi Arabia, in the period 17 - 23 Sha'baan 1410 H. (14 - 20 March, 1990) - having reviewed the papers and recommendations on this subject, which was one of the topics of the sixth jurisprudence (*fiqh*)/medical seminar held in Kuwait from 23 - 26 Rabee' I, 1410 H. (23 - 26 October 1989) in collaboration between this academy and the Islamic Organization of Medical Sciences (IOMS) - decides the following:
>
> 1 - Genital Gland Transplants:
>
> Since a testicle and an ovary continue to have and produce genetic characteristics (the genetic code) of the donor even after they are implanted in the recipient, their transplantation is prohibited in Islamic Law.
>
> 2 - Organ Transplants of the Genital System:
>
> Transplants of some genital system organs that carry no genetic characteristics, excluding the external organs, is

lawful when it is done to meet a legitimate necessity and in accordance with the legal criteria and controls listed in resolution 1 of the fourth session of this Academy.

3 - The procedures of organ transplants should never be subject to commercial purposes.

4 - Supervision of organ transplants should be entrusted to a specialized, trustworthy authority.

Topic Twenty
Sex Change Procedures for Normal People and Intersexes[103]

Definition

Sex change operations for a normal person, whether male or female, are performed at big centers in European countries.

A male is changed to a female by removing his genital organ, constructing a vagina, performing an emasculation operation, and enlarging the breasts.

A female is changed to a male by removing her breasts, constructing an artificial penis, and eliminating, to various extents, the feminine genital canals.

Such an operation is accompanied by intensive psychological and hormone therapy.

A sex change operation for an intersex are made to determine the sexual status of such a person, who has two organs, male and female, or may have neither, only a urine-discharging opening.[104]

The Legal Position Chosen by the IOMS and Its Argument

The recommendations of the third seminar say:

> The seminar addressed the question of plastic surgery and concluded that the surgical procedures called sex change

(103) This was one of the questions discussed by the IOMS in its third seminar, the Islamic View Concerning Certain Medical Practices, in 1987, as part of its discussion of plastic surgery.

(104) Dr. Maajed Abd Al-Majeed's paper, *The Third Seminar*, p. 424.

operations, performed to satisfy decadent desires, are absolutely forbidden. Meanwhile, operations aimed at determining the real sexual status of intersexes are permissible.

I would like to add that the basis of this sound ruling is to safeguard normal human nature and not to change what is created by God, the Most Sublime.

Topic Twenty One
Hymen Patching Surgeries[105]

Definition

What is meant by hymen patching is repairing its lacerations or forming a new hymen. The hymen is a membrane that partially covers the external vaginal opening. It consists of two layers of thin skin with a loose tissue between them, which has an abundance of blood vessels.

The hymen opening comes in various shapes: circular, crescent-like, sieve-like, and divided long-wise. In rare cases, it is solid, and it blocks the exit of ministration blood, causing it to accumulate in the vagina and then in the uterus.

The hymen may break before marriage due to various reasons, foremost among which are (1) an illicit sexual relationship and (2) an accident that causes injury in that location.[106]

The Legal Position Chosen by the IOMS and Its Argument

A recommendation of the third seminar in 1987 says:

> The seminar discussed the subject of plastic surgery and came to the conclusion that it is unlawful to perform surgeries that alter the fundamental nature of the body or of an organ or that are meant to allow the patient to escape justice or engage in fraud, or that are motivated by a whim.

I would like to add that this indicates the ruling over hymen patching surgeries, depending on whether it involves fraud or not.

(105) The IOMS discussed this question, as part of the general topic of Plastic Surgery, in its third seminar, the Seminar on the Islamic View Concerning Certain Medical Practices, in 1987.

(106) Dr. Kamaal Fahmi's paper, *The Third Seminar*, pp. 419-22.

Topic Twenty Two
Plastic Surgery[107]

Definition

Plastic surgery is a branch of general surgery. Plastic surgery operations has become more complicated since the end of World War I. Its most important fields include the treatment of burns and inborn deformations, facial and skull surgery, hand surgery, and general plastic surgery, such as jaw fracture rectification and tattoo removal, as well as the surgery desired by a patient to give one of his organs an acceptable appearance, usually performed on the nose, breasts, eyelids, and other organs.[108]

The Legal Position Chosen by the IOMS and Its Argument

One of the recommendations of the third seminar in 1987 says:

> The seminar discussed the subject of plastic surgery and came to the conclusion that surgeries performed to treat a congenital anomaly or a postnatal deformity and restore the normal and familiar shape and/or function of an organ is legally permissible.
>
> For the majority of scholars, this ruling also covers the elimination of a defect or blemish that causes the person concerned physical or pasychological suffering.
>
> It is unlawful to perform surgeries which alter the fundamental nature of the body or of an organ, which are meant to allow the patient to escape justice or engage in fraud, or which are motivated by a whim.

(107) The IOMS discussed this question in its third seminar, the Islamic View Concerning Certain Medical Practices, 1987.

(108) Dr. Maajed Abd Al-Majeed's paper, *The Third Seminar*, pp. 419-22.

Topic Twenty Three
Minimum and Maximum Menses and Menstrual Cycle Estimation[109]

Definition

Menses is menstruation or the menstrual period, and its first occurrence signifies coming of age for the girl concerned. The period between the beginning and stop of menses is looked at as the period of fertility. The period that includes one instance of menses and the following freedom from menses is called menstrual cycle.

When a girl comes of age, many complex changes occur in all her physical systems, particularly the nervous and the genital, and more specifically in the uterus and ovaries. With these changes, a girl is no longer a child; she is a full-fledged female.

With menopause, many changes also occur, one of which is the permanent ending of menstruation. This ending is usually gradual, with menses occurring once every two or three months and then every six months, and then it ends altogether. Bleeding between two menstruation periods is either a hemorrhage or false menstruation.

It is well known that when menses occurs early in a girl's life, menopause is late to come, and the opposite is true.[110]

The Legal Position Chosen by the IOMS and Its Argument

The recommendations of the third seminar, held in 1987, include the following:

(109) This was one of the subjects addressed by the Islamic Organization of Medical Sciences (IOMS) in its third seminar, the Seminar on the Islamic View Concerning Certain Medical Practices in 1987.

(110) A paper by Dr. Nabeehah Al-Jayyaar, *The Seminar on the Islamic View Concerning Certain Medical Practices*, pp. 433 - 435. 3

The Minimum Menstrual Period and the Maximum Menstrual Cycle

Physicians endorsed one of the viewpoints of Islamic jurisprudence (*fiqh*), the one which holds that the minimum menstruation is a single drop, while the maximum has to be determined in reference to each individual case.

Medically, false menstruation is abnormal bleeding that signifies illness. Its medical causes are diverse. The dividing line between normal bleeding, i.e. menstruation, and abnormal bleeding, i.e. false menstruation, is not clear cut; there is a one-to-three day margin. One must take into account other signs of illness, such as heavy bleeding and the presence of other symptoms, and the results of clinical examination or laboratory tests.

The seminar recommends that Muslim physicians address the questions of the distinction between menstruation and false menstruation and of the maximum duration of menstruation, through conducting the necessary research.

As for the duration of a menstrual cycle, which is from the beginning of a period of menses to the beginning of the following one - when the cycle is normal, that is when the ovaries release ova, in the case of most women the cycle is twenty eight days. The minimum cycle duration is three weeks, and the maximum is indeterminate.

Topic Twenty Four
Minimum and Maximum Duration of Puerperium(111)

Definition

Puerperium is the period that follows childbirth. Certain physical changes occur in this period, restoring the genital system to its normal, pre-pregnancy condition.

The puerperal liquid is the secretions of the uterus that follow childbirth. In the first four days, it is blood, then it gradually turns lighter in color and less in quantity. Within ten days, it becomes a colorless mucus that might continue to be secreted for as long as four weeks.(112)

The Legal Position Chosen by the IOMS and Its Argument

One of the recommendations of the third seminar, held in 1987, is as follows:

> *The Minimum and Maximum Duration of the Puerperal Period*
>
> The medical input at the seminar tends to agree with certain views of jurisprudence (*fiqh*) scholars, which hold that puerperium is what a woman discharges after childbirth or abortion until the location where the placenta exists before it is expelled out of the uterus cavity heals. It begins as blood, then turns into a yellowish liquid, and finally stops.

(111) This also was one of the subjects addressed by the IOMS in its third seminar, the Seminar on the Islamic View Concerning Certain Medical Practices, in 1987.

(112) A paper by Dr. Nabeehah Al-Jayyaar, the the Seminar on the Islamic View Concerning Certain Medical Practices, p. 439.

It has no minimal limit, and, normally, its maximum duration is six weeks. If it exceeds that, it is abnormal and is classified as false menstruation. This abnormal condition might be caused by remains of the placenta in the uterus, by the uterus being too weak for adequate contractions to withhold the blood, or by some other cause that needs to be diagnosed and treated. The puerperal period may end in menstruation or in a long or short free-from-menstruation period.

Topic Twenty Five
Minimum and Maximum Duration of Pregnancy[113]

Definition

Pregnancy results from the union of a mature sperm with a mature ovum produced by one of the ovaries during ovulation (around the midpoint of the menstrual cycle). When the matured ovum escapes from its follicle, or pocket, it is picked up in the far end of one of the Fallopian tubes, and the cilia at the upper lining of the tube carry it down the tube, where it is ready for fertilization within the next twenty-four hours. Soon after it is fertilized, an ovum divides into smaller cells, and within three to four days the blastocyst is formed. The embryo travels down the tubes and implants itself in the uterus lining. The inner layer of the uterus grows, nourishes the embryo and forms the placenta, causing monthly menstruation to stop. Until now, scientists have not specifically determined the key factor that begins labor. It is attributed to the fetus, to the endocrine glands, or to the uterus muscle itself, which reaches its maximum size.[114]

The Legal Position Chosen by the IOMS and Its Argument

A recommendations of the third seminar, held in 1987, is the followsing:

The Minimum Duration of Pregnancy

The uterus may discharge the embryo or fetus it has at any point of the pregnancy, but unless the fetus has matured

(113) This also was one of the subjects addressed by IOMS in its third seminar, the Seminar on the Islamic View Concerning Certain Medical Practices in 1987.

(114) A paper by Dr. Nabeehah Al-Jayyaar, *The Seminar on the Islamic View Concerning Certain Medical Practices*, pp. 436 - 437.

sufficiently to survive, this discharge is called abortion. If the fetus is developed adequately to survive, the discharge is called childbirth. The baby is premature if the pregnancy period is less than thirty-seven weeks.

The dividing line between abortion and birth used to be the end of the twenty-eighth week. Progress in medicine, however, has improved the chance of survival for a fetus discharged even before the end of that period, reducing the dividing line to only twenty-four weeks, which coincides with the Islamic Law ruling which considers the minimum period between conception and delivery to be six months.

The Maximum Duration of Pregnancy

Physicians say that the growth of an embryo progresses from fertilization till delivery, it is nourished by the placenta. Originally, the duration of pregnancy is about 280 days, beginning with the first day of ordinary menses prior to conception.

The delay of delivery beyond that period means the placenta still has sufficient nourishment for the fetus for two additional weeks. After that, the fetus begins to starve, which increases fetus mortality rate in the forty-third and forty-fourth weeks. It is rare for a fetus to survive if it remains in the uterus for forty five weeks.

To allow for rare and abnormal cases, this period is extended to 330 days. No case is known where the placenta could supply a fetus with the means to survive that long. Islamic Law takes further precaution and, on the evidence of some jurisprudence (*fiqh*) viewpoints along with the scientific evidence, maximum pregnancy is ruled to be one year.

Topic Twenty Six
Patterns of Islamic Life and Their Effects on Health Development and Human Development in General[115]

The Islamic Organization of Medical Sciences held its fifth seminar under the above title in Amman, Jordan, during the period 22 - 26 June, 1989.

I have learned that when the papers and the minutes were made ready for publication, Iraq's outrageous invasion of Kuwait took place, with its consequent tampering with the Kuwaiti culture. The original documents of this seminar have not been found so far. The purpose of the seminar was to file detailed scholarly and scientific material to highlight two things. *The first* is the positive, virtuous life style promoted by Islam, a style that maintains and enhances the health of those who embrace it, as when they observe, for example, cleanliness and avoid any excess. *The second* is negative, unwholesome styles of life which are forbidden by the Islamic religion, the avoidance of which saves a person from the calamities of illness and diseases, as when one avoids leaving something harmful on a road or a street.

(115) This was a subject to which the IOMS devoted its fifth seminar, which was held in 1989 under the same title.

Topic Twenty Seven
Problems of Old Age and the Rights of the Elderly(116)

Definition

One of the achievements of the contemporary progress in medicine is the increase of the number of old people, which draws both attention and apprehension. In the last two decades, the world witnessed an unprecedented interest in human old age. This began with the decision of the United Nations Organization to devote the year of 1982 to study the issue of old people in the world. In 1983, the committee formed by the World Heath Organization to address that subject held a meeting with the motto, "Let life be fair to the elderly." The United Nations passed a decision to make 1999 the International Year of the Elderly.

In 1950, the number of old people in the world was not higher than 200 million persons. By 1975, it has increased to 350 million, and in the year 2000 it was almost 590 million out of a total world population of 6 billion people. It is expected that by the year 2025, the number of old people will be over one billion and 100 million people, which will mean one old person out of each eleven people. This is the phenomenon of flourishing in number for the elderly.

What draws attention is that two thirds of those old people live in the developing world, particularly in Asian countries. Naturally, the old, who have claims of gratitude, also have their health, social, and

(116) The IOMS addressed this subject twice. The first was in its fourth seminar, Health Policy: Human Ethics and Values, which was held in 1988 and included this among the topics on its agenda. The second time was in the thirteenth seminar, devoted wholly to this subject and held in 1999 under the title: The Rights of the Elderly from an Islamic Perspective.

psychological needs which exhaust available care resources. The more convincing argument chooses the age of sixty-five as the beginning of old age.(117)

The IOMS Discussion of, and Legal Position on, This Issue

The Islamic Organization of Medical Sciences (IOMS) examined this issue in its fourth seminar, "Health Policy: Human Ethics and Values," held in 1988, and then devoted its thirteenth seminar, "The Rights of the Elderly from an Islamic Perspective," wholly to this subject.

In spite of having several important items on its agenda, the fourth seminar made no recommendations. The following recommendations, however, were made at the conclusion of the seminar on the rights of the elderly.

1 - Various measures should be taken to maintain people's health in their old age. These measures should begin with embryonic life and continue through childhood, adolescence, and adulthood. The network of social relations within the family, school, neighborhood, and community should be enhanced. The relationship between the elderly and their God has to be strengthened and their observance of religious teachings, encouraged. They should be protected from harmful practices and habits, such as smoking, drug addiction, and alcoholism. Moreover, anti-pollution measures should be taken.

2 - The elderly should be taught health-enhancing habits, particularly balanced nutrition, moderate physical exercise, the pursuit of appropriate hobbies, maintaining social relations as much as possible, and spiritual chastening which gives one stronger faith and provides his soul with greater comfort and closeness to his Lord.

3 - The elderly should be provided with appropriate care at all health care levels, including primary care and clinics. Health services

(117) The papers presented at the thirteenth IOMS seminar, which was held in October, 1999 and devoted to the study of the rights of the elderly.

should be adapted to be suitable to meet the special needs of old people. General practitioners should be trained to recognize and treat physical and psychological ailments which may have symptoms among old people different from their symptoms in younger patients.

4 - Equity and fairness should be observed in the provision of health care to the elderly, whether male or female. Efforts should be made to set up a comprehensive health insurance and social security system that covers old people from all sectors - including farmers, professionals, and low-income individuals - who are not covered by existing insurance systems.

5 - Objective and field research dealing with the physical and psychological health of the elderly should be encouraged and funded. All data that relates to their health practices and problems should be gathered, analyzed, and submitted to policy makers to help them make decisions and enact appropriate laws of care for the elderly.

6 - Attention should be devoted to the health welfare of old people in printed, auditory, and visual media. These media should contribute to the education of the elderly and their families as regards their nutrition and physical activity, taking precautions against risks and accidents, and taking their medications regularly. The media should also have special columns or programs to entertain old people.

7 - Courses that deal with health in old age, geriatrics, and care for the elderly should be introduced into the curricula of medical and nursing schools and other medical colleges. Geriatrics and nursing old people should be established as fields of specialization in various establishments of health education.

8 - Religious values and teachings that promote filial piety and devotion, and respect for elders should be emphasized and consolidated, particularly through introducing into the syllabi of the various stages of general education accounts of old people, explaining their conditions, highlighting their family status and rights, and stressing the need to be dutiful to them, treat them

with kindness and compassion, and visit them at their gathering locations. Meanwhile, students should be urged to adopt the kind of healthy behavior that guarantees for them to be healthy in their old age, and encouraged to stay away from smoking, drugs, and all other harmful practices. They should, likewise, be made aware of how to care for the elderly.

9 - Steps should be taken to benefit from the treasury of experience and knowledge that old people possess, by allowing them to participate, as much as possible, in the education of new generations. moreover, decision-makers should consult old people with experience on public issues.

10 - The role of the family in caring for its old members should be supported, and special facilities and aid should be offered to families that provide care to old people. Serious efforts should be made to have an old person live, on a permanent basis, with his own family or enjoy the care offered by another family or at a nursing home that keeps him in contact with his family and which has a family atmosphere, as well as all other conditions which are necessary for the old to maintain their dignity. Thus, they can be provided with the physical, psychological, and social care they need. Nursing homes should be located at various neighborhoods, so that each of them would serve as a nucleus that guarantees the participation of its occupants in the social, cultural, and religious activities of their communities.

11 - Volunteer and non-governmental organization and all other civil social institutes should be encouraged to play a role in extending health and social care to the elderly of both genders, particularly those who receive reduced care from their families.

12 - The attention of authorities and decision-makers should be drawn to the importance and special needs of the elderly. Efforts should be made to enact or supplement the legislation concerning care for the elderly in the light of Islamic Law. This includes raising retirement age, imposing a penalty for filial ingratitude, offering assistance to individuals who are unable to support the old people

in their families, and setting up a higher council for elderly care in which all concerned parties are represented and which enjoys adequate jurisdiction and sufficient resources.

13 - All kind of privileges and facilities should be offered to old people. These include in particular giving them preference in public places; having seats and places reserved for them in public transport vehicles, parks, theatres, and social and cultural clubs; providing means that facilitate their movement if they are handicapped or helpless; offering them appropriate discounts on fees; the fares for land, sea, and air travel; membership fees of clubs and all other establishments of social, recreational, and sports services; and the like.

14 - Old people should be enabled to determine their own needs and given the chance to exploit fully the skills and experience they have gained throughout their lives in ways beneficial to themselves and to society. They should be encouraged to take initiatives, trained to be self sufficient, and assisted in carrying out activities suitable to their abilities and potential. They should also be helped to set up societies which they run themselves and in which they have the chance to prove themselves through active participation in social affairs.

15 - Governments should assess the consequences of demographic changes on a regular basis and should take them into consideration when making overall social development plans. They should pay special attention to the expected great rise in the number of old people, particularly old women, and take the appropriate measures to deal with this expected change.

16 - Respectful terms should be used in addressing, or referring to, the elderly.

17 - An old person should be prepared psychologically before he reaches the day of retirement to spare him any psychological trauma that he may suffer as a result of isolation and unemployment.

18 - Philanthropists should be encouraged to devote endowments for elderly care.

19 - The Islamic Organization of Medical Sciences (IOMS) is called upon to sponsor the publication of a book on "Rulings for the Elderly," which explains worship practices, transactions, and all other rulings related to old people.

20 - The Islamic Conference Organization and the Islamic Organization for Education, Sciences, and Culture are called upon to issue and publish, in collaboration with the IOMS, a document on the rights of the Elderly from an Islamic perspective.

Topic Twenty Eight
Mercy Killing of the Aged, Encouraging Them to End Their Lives, and Denying Them Intensive Care and Expensive Medicines[118]

Definition

Some people with a materialistic way of thinking have voiced their views on the problem of the increase in number of aging people and their consumption of provided services. Those people's argument call for killing aged people, for, the argument goes, they have already performed their roles and had their shares. They compare an aged person to a machine whose life expectancy is completed. The argument calls for giving physicians the right to relieve the aged from the pain of illness or the suffering caused by ingratitude, and to relieve their families from the burden of supporting them and the obligation of keeping in touch with, and being dutiful to, them.

According to this argument, a physician should advise the aged to the best and quickest methods to achieve that goal.

Advocates of the argument also demand depriving the age of intensive care equipment and expensive medications, so that these may be available for young people, who are capable of serving their communities.[119]

The Discussion of the IOMS and Its Legal Position

The IOMS addressed these questions in the seminar on "Rights of the Elderly" in 1999. It had already tackled the question of "Mercy Killing" in the medical and jurisprudence (*fiqh*) papers and discussions of its fourth seminar in 1988.

(118) The IOMS discussed this question in its thirteenth seminar, the Rights of the Elderly from an Islamic Perspective, in 1999. The subject of "Mercy Killing" had already been addressed in the papers and discussions, but not the recommendations, of the fourth seminar, Health Policy: Ethics and Human Values.

(119) The papers and discussions of the seminar on the Rights of the Elderly in 1999.

The recommendations of the Rights of the Elderly seminar in 1999 are clear in their prohibition of mercy killing and suicide. As for the question of intensive care equipment and expensive medications, the recommendations leave it to affordability and the absence of any party that needs them more urgently.

The seminar's recommendations include the following:

> Although the IOMS had already discussed this subject in a former seminar, it has devoted to it a special session in this seminar, in which scholars Yusuf Al-Qaradhaawi, Muhammad Mukhtaar Al-Salaami, MuhamAl-Mahdi Al-Taskheeri, John Brynt, and Jamaal Zaki have spoken. The time allowed for arguments and discussion has been quite liberal. This is due to the fact that promotion of the notion of mercy killing is increasing in the West, in a world where distance is no longer a hindrance for communication and where our scholars who study in the West are exposed to a new cultural preaching. Moreover, the medical workforce in some Islamic countries includes an increasing number of people who do not believe in or observe divine creeds.
>
> The seminar reaffirms that mercy killing is inconsistent with Islamic belief, regardless of the different names given to the procedure (such as death with dignity, for example), and whether it takes the form of a direct medical intervention or of a physician paving the way for a patient to take his own life.
>
> This ruling applies to active intervention as well as passive intervention by withholding the patient's medication with the intention of causing his death, even if it is done at the request of the patient himself or his family.
>
> However, it is not obligatory to administer a medical treatment which is ruled to be definitely useless; a treatment procedure may be withheld or stopped, as long as the patient retains his general human rights, which include being provided with food, drink, nursing care, and relief from pain.

Topic Twenty Nine
Alcohol and Drug Dependence (Addiction)[120]

Definition

Genetic studies have established beyond any doubt that genetic susceptibility plays the major role in increasing the consumption of alcoholic drinks, i.e. addiction, although the main factors of social drinking are the cultural environment, the profession, and the early educational experience. As for drug dependence, acknowledging social factors, specialists differ on identifying the major factor of drug addiction, advancing two theories.

The first theory is that drug addiction depends on a psychological factor. Basically an addictive personality is one that seeks to satisfy a desire to escape from reality and find pleasure in a world of fantasy.

The second theory is that drug addiction depends on metabolic effects, which are the chemical reactions in human cells due to nutrient absorption. A neural susceptibility is connected to the change in response to narcotics.[121]

The Legal Position Chosen by the IOMS

The only paper submitted to the fourth seminar, held in 1988 under the title of "Health Policy: Ethics and Human Values," was "Alcohol and Narcotic Dependence" by Dr. Zaki Hassan. It says:

(120) This question was one of the topics of the fourth seminar, Health Policy: Ethics and Human Values, in 1988, which did not issue any recommendation. It was also a subject on the agenda of the agenda of the ICAA conference of 1997, in which the Islamic Organization of Medical Sciences participated with papers on narcotics and the rulings related to analgesics, but with no recommendation on the effect of addiction on behavior and crime.

(121) Dr. Zaki Hasan (Pakistan), "Depends on Alcoholic Drinks and Narcotics," *Minutes of the Fourth Seminar in 1988*, p. 588.

> Islam focused in particular on alcohol, being the only drug that was habit forming and that led to dependence in the early Islamic society. We should take this into consideration when we look into the consumption of narcotics in the Islamic World, since the prohibition of alcohol was gradual(122)

The discussion of that paper included no comments on how addiction affects the ruling of Islamic Law.

The fourth session was concluded without any recommendations.

(122) *Ibid.*, p. 591.

Topic Thirty
The Rulings Arising from the Discovery of AIDS[123]

Definition and Division

A recently discovered disease is AIDS, which is a name used for the final stage of a chronic infection with the human immunodeficiency virus, which is characterized by clear disease symptoms, together with opportunistic infections and malignant tumors, due to the destruction, caused by that virus, of immune system cells, which resist bacteria and cancer cells.[124]

A person's discovery that he has AIDS gives rise to many rulings, which are elaborated in the nine following points.

The First Point: AIDS as Regarded in Islamic Law
The Medical Viewpoint

AIDS is the acronym of a fatal disease known as Acquired Immunodeficiency Syndrome. It is a syndrome in the sense that it results when a number of symptoms correlate and coincide, and it is acquired because it is transmitted by infection and causes a serious deficiency in the immunity mechanisms created by God in all human beings. This deficiency makes an infected person vulnerable to bacteria, including those that do not usually cause human diseases and are, therefore, called opportunistic bacteria.

After infection with the human immunodeficiency virus (HIV) occurs, the virus penetrates into certain cells, multiplies gradually, and

(123) The IOMS devoted its seventh seminar, entitled "An Islamic Perspectives of the Social Problems of AIDS," held in Kuwait in 1993.

(124) Dr. Muhammad Haytham Al-Khayyaat and Dr. Muhammad Hilmi Wahraan, "Basic Facts about AIDS," *The Minutes of the Seventh Seminar in 1993*, p. 63.

steadily destroys these cells. In most cases, within a short period of no more than two years after the detection of AIDS symptoms, the patient dies.

The infection goes through stages, one of the most important of which is the stage of latency, which ranges from few months to a few years. In children under two years, this stage is relatively small, while in adults it lasts 7-10 years, but it is reduced by the incidence of other, accompanying diseases; malnutrition; and pregnancy in the case of women.

A variety of neurological disorders are common in some stage of AIDS, and they may cause senility, which is common in the later stages in about one third of AIDS patients.(125)

The Legal Position Chosen by the IOMS and Its Argument

In its seventh seminar in 1993, the IOMS chose to consider AIDS similar to other, familiar diseases, except in its later stages. The seventh recommendation of the seminar says, "Legally AIDS is not regarded as a fatal disease until all its symptoms appear, it keeps the patient from practicing his daily life activities, and it is expected to end in death."

The Second Point: The Ruling in Regards to Isolating an AIDS Patient

The Medical Viewpoint

Isolation means keeping the patient from transmitting the infection to others, and this a basic procedure in fighting infectious diseases in general.

Basically, HIV is transmitted through sexual intercourse, and the purpose of isolating a patient is to prevent the genital system secretion of an infected woman or the semen of an infected man from reaching the genital mucous membrane of a non-infected person.

(125) *Ibid.*, pp. 60-63 and 69.

Often, isolation serves the interest of the patient, who is protected against being infected with diseases transmitted by others while he is in a state of exhaustion. Isolation also allows intensive care to be provided to the patient.(126)

The Legal Position Chosen by the IOMS and Its Argument

In its seventh seminar in 1993, the IOMS chose to declare that there is nothing to justify isolating the patient. The recommendations included the following:

> **First**: Patient Isolation. Available medical information at present affirms that no AIDS virus is transmitted through cohabitation, touch, breathing, insects, or shared food, drink, lavatories, swimming pools, seats, or utensils. Nor is it transmitted through any other aspect of interaction in normal daily life. Mainly, the HIV is transmitted in one of the following manners:
>
> 1 - any type of sexual intercourse;
>
> 2 - transfusion of contaminated blood or its components;
>
> 3 - using a contaminated syringe, particularly among drug users; and
>
> 4 - transmission from an infected mother to her child.
>
> On the basis of the above, there is no justification for isolating infected students, workers, or others from their healthy colleagues.

The Third Point: The Ruling on Deliberate Transmission of the Infection

The Medical Viewpoint

Man-made laws throughout the world have no penalty for a person when it is proved that he has deliberately infected others with HIV, after it has been established that he carries the virus or is infected with the disease, except in Federal Russia, where such a person is fined or imprisoned.(127)

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(126) *Ibid.*, pp. 64 and 65.

(127) *Ibid.*, p. 67.

The Legal Position Chosen by the IOMS and Its Argument

The IOMS decided, in its seventh seminar in 1993, that the deliberate transmission of AIDS infection is forbidden, and its punishment ranges from discretionary punishment and retribution to the prescribed punishment of a terror campaign, in proportion to the seriousness of the crime. One of the seminar's recommendations is:

> **Second**. The Deliberate Transmission of AIDS from an Infected Person to a Healthy One in Any Method. Such a deliberate action is forbidden and is regarded as a cardinal sin and a serious crime. It deserves secular punishment, which ranges in accordance with the seriousness of the crime and its effect on individuals and on society.
>
> If the intention of the person committing this deliberate action is to spread this malignant disease in society, his action amounts to a campaign of terror and corruption in the land and deserves one of the penalties prescribed in the verse on terror campaigns: "The repayment of those who wage a war against God and His Messenger, and endeavor to cause corruption in the land is to be killed or crucified, have their hands and feet amputated on alternate sides, or be banished from the land" (*Al-Maaedah* V: 33).
>
> If, however, the intention of the person who deliberately transmits the infection is to pass the disease on to a particular person, using a method of transmission most likely to succeed, and the virus does pass on and the infection kills the recipient - the culprit should be killed in retribution.
>
> If, on the other hand, the intention of the person who deliberately transmits the infection is to pass the disease on to a particular person, and the virus does pass on but the recipient survives - the culprit should be given the appropriate discretionary punishment. When the recipient dies, his heirs are entitled to blood money.

Discretionary punishment should also be given to a person with the intention of deliberately transmitting the infection to a particular person, but the latter does not get infected.

The Fourth Point: The Ruling on Aborting the Fetus of an HIV Patient

The Medical Viewpoint

So far, scientists have not been able to detect whether a fetus is infected while still inside the uterus. Some studies conclude that the percentage of transmitting the infection to a fetus during pregnancy does not exceed 10%, and it is believed that the infection takes place only in the late months of pregnancy.

Had science been able to diagnose the disease in a fetus at an early stage, that would probably be a justification of aborting that fetus in accordance with relevant rulings of Islamic Law, particularly since no remedy for this disease has been discovered yet.

A physician may recommend abortion as being in the mother's interest, because pregnancy reduces the latency period of the disease and hastens its maturity.(128)

The Legal Position Chosen by the IOMS and Its Argument

The IOMS adopted the general ruling which prohibits abortion, particularly after the spirit is breathed into a fetus, except in cases of great medical urgency. One of the recommendations of the seventh seminar, held in 1993, says:

> **Third**: Abortion in the Case of a Pregnant Woman Infected with HIV: The IOMS held a seminar on Reproduction in Islam in 1983, and in regards to the ruling on abortion, it came to the following conclusion:
>
> An embryo is a living organism from the moment of conception, and its life is to be respected in all its stages, especially after the spirit is breathed in. Aggression against it, in the form of abortion, is unlawful except in cases of

(128) *Ibid.*, p. 66.

maximum medical necessity. Some participants, however, disagree and believe abortion before the fortieth day, particularly when there is justification, is lawful.

The current seminar believes that that ruling is valid in the case of a pregnant woman with HIV infection.

The Fifth Point: The Ruling on Custody and Nursing When a Mother is Infected with HIV

The Medical Viewpoint

Only in very few cases throughout the world, it was established that HIV infection was transmitted through a mother's milk. Since no infection takes place through the digestive systems, it is believed that, in the rare cases in which AIDS is transmitted through nursing, it is the sucking of the infant, with the great pressure on the mouth mucous membrane that goes along with it, may cause the infection to be transmitted when the nipple is chapped and bleeding.(129)

The Legal Position Chosen by the IOMS and Its Argument

In its seventh seminar, held in 1993, the IOMS decided to uphold a mother's right to the custody of her child even if she is infected with AIDS. The seminar says in one of its recommendations:

A - Since current medical information indicates that, as the case is with ordinary contact and cohabitation, there is no certain risk in the custody of a healthy infant by his HIV infected mother, the seminar sees no legal objection to such a custody.

B - Since the probability of a healthy child getting infected with AIDS through its mother while she nurses him is very slim - although this may happen due to the virus contained in the mother's milk or to the blood that gets into the infant's mouth when she has a chapped nipple - and since nursing has several benefits, the mother may nurse her child. She should, however, take all precautions to reduce the probability of the infant getting

(129) *Ibid.*, pp. 62 and 65.

infected. The mother may also abstain from nursing her infant if a wet nurse is available to do the job or alternatives, other than the mother's milk, can give the infant sufficient nutrition.

The Sixth Point: The Right of a Free-from-Infection Spouse to Ask for Separation from His/Her HIV-infected Partner

The Medical Viewpoint

The probability of HIV infection being transmitted from a sick spouse to a healthy one cannot be ruled out, particularly when no condom is used. Transmission of the disease from the male to the female is much more probable than the other way around.

Three issues should be noted because they help in reaching the legal ruling:

The first issue is the reduced sexual power of an infected husband.

The second issue is the probability of children being born with the disease when one of the parents in infected.

The third issue is that the correct usage of a condom, when the husband has no other venereal disease, make the possibility of transmitting the infection to the wife almost nil.(130)

The Legal Position Chosen by the IOMS and Its Argument

The IOMS ruled in its seventh seminar in 1993 that a healthy spouse may request to be separated from his/her diseased partner, since this is a fatal disease. A recommendaof the seminar is:

> **Fifth**: The Right of the Healthy Spouse of a Married Couple to Appeal for Separation from the Partner Infected with AIDS: The seminar finds that either spouse can file for separation from his/her diseased partner, the disease being fatal and mainly transmitted through sexual intercourse.

(130) *Ibid.*, pp. 65 and 70.

The Seventh Point: The Ruling on Sexual Intercourse When a Spouse Is an AIDS Patient

The Medical Viewpoint

Experiments have demonstrated that using a condom considerably reduces the likelihood of HIV infection. The probability of infection in the case of one intercourse does not exceed 0.5%, which means one case in every two hundred, unless the other spouse is already infected with another venereal disease, in which case the percentage goes up to 2%.(131)

The Legal Position Chosen by the IOMS and Its Argument

In its seventh seminar in 1993, the IOMS upheld the right of a healthy spouse to abstain from sexual intercourse with his/her diseased partner. One of the seminar's recommendations says:

> **Sixth**: The Right of Sexual Intimacy. If one of the spouses is infected with AIDS, the non-infected partner may abstain from sexual intimacy, because of the above-mentioned fact that sexual intercourse is the main channel of HIV infection.
>
> If, however, the healthy spouse is willing to engage in sexual intercourse, precaution calls for using a condom, which, if used properly, reduces the probability of infection and pregnancy.

The Eighth Point: The Rights of an AIDS Patient

The Medical Viewpoint

It is not necessarily true that an AIDS patient must have been infected through having sex. Some patients get the disease through contact with contaminated blood. An AIDS patient does not transmit the infection to his colleague at work or to anyone else he deals with in the normal contacts of everyday life, except in very limited cases in

(131) *Ibid.*, p. 65.

which blood gets mixed up as a result of wounds or something similar. The HIV infection is not transmitted by insect bites or through touching the perspiration or urine of an infected person, inhaling droplets of his saliva, or sharing his food utensil or anything related to the digestive system.(132)

The Legal Position Chosen by the IOMS and Its Argument

The IOMS, in its seventh seminar in 1993, called for treating an AIDS patient in society the same way as any other person and for giving him some priority in receiving treatment. The general recommendations of the seminar include the following:

> An AIDS patient has the right to receive the treatment and health care that his condition calls for, regardless of the method in which the disease has been transmitted to him.
>
> He should report his infection to his physician to protect the latter and his other patients from the probability of being infected. The physician has to treat such a patient, taking the necessary precautions to protect himself and others.
>
> An AIDS patient should be taught how to keep his condition from getting worse. It is not admissible to be unjust to such a patient, or to fail or taunt him on account of his disease.

The Ninth Point: Prevention of HIV Infection

The Medical Viewpoint

Because so far, no adequate remedies or preventive vaccines are available for AIDS, protection from the disease can only be by avoiding what causes it. Its causes are of two types:

1 - Major causes: These include sexual intercourse, the transfusion of blood or its components, and transmission from an infected mother to her baby, most often during childbirth, when the baby is contaminated by infected genital discharges.

(132) *Ibid.*, pp. 62 and 68.

2 - A minor cause: Transmission through the mother's milk in very limited cases.(133)

The Legal Position Chosen by the IOMS and Its Argument

In its seventh seminar in 1993, the IOMS called for proper education and advice to enable people to avoid being infected with HIV. The general recommendations of the seminar include the following:

1 - Official and public agencies should endeavor to educate society members, alerting them to the threat of AIDS and teaching them how the infection is transmitted and how to protect themselves from it, with a stress on chastity and virtue.

2 - Islamic education should be introduced into the curricula of all education levels, so that it complements other items in the curricula and contributes to building the personality of each individual in a manner that serves the best interests of individuals and society and guarantee protection from this calamity.

(133) *Ibid.*, pp. 61 and 62.

Topic Thirty One
Skin Grafts[134]

Definition

Skin grafting is resorted to for the treatment of disfigurations caused by accidents, burns, and surgical operations which require skin removal.

Skin grafting is a procedure by which skin is transplanted from a healthy area to an injured one. The body supplies the graft with blood after forming a network of blood vessels and capillaries.

The transplanted graft may be taken from a healthy area of the patient's own skin, from another person, or from an animal.[135]

Skin cells can be cultivated by taking a small piece of the patient's skin. Cultivation is achieved by using nutritious and chemical agents and preservatives in a gradual manner. The procedure may take about two weeks, at the end of which a skin patch is formed that can be as big as 75 cm^2. This very recent method is not commonly used because it is highly expensive and requires training that is available in few centers only.[136]

The Legal Position Chosen by the IOMS and Its Argument

The IOMS, in its eighth seminar in 1995, permitted skin grafting procedures under the same conditions set for human organ transplants. The recommendations of the seminar say:

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(134) This subject was on the agenda of the eighth IOMS seminar, An Islamic View of Certain Health Problems, in 1995.

(135) Dr. Abd Al-Ridhaa Laari, "Skin Grafting," *The Minutes of the Eighth seminar*, pp. 73 - 79.

(136) Dr. Salaah Abd Al-Ghani, "Human Skin Banks," *The Minutes of the Eighth seminar*, pp. 85 - 86.

1 - A human being, whether Muslim or non-Muslim enjoys personal sanctity. Honoring a human being and maintaining his sanctity is one of the purposes of Islamic Law. Therefore, skin grafting surgery is permissible under certain conditions which will be listed later and which are not in conflict with that purpose, but rather support and affirm it.

2 - The skin is a living organ, and what applies to the transfer and transplantation of other organs, as decided by jurisprudence (*fiqh*) academies, applies to it.

5 - Operations of skin grafting, where the source of the graft is human, is a necessity in the eyes of Islamic Law, and rulings that concern it are subject to the general rules that govern necessities.

4 - A skin graft from a human source, whether an autograft, taken from the patient himself, or an allograft, taken from an alive or dead human being, is legally free from ritual impurity.

5 - The permissibility of skin grafting operations are contingent upon the following conditions:

   a - Skin grafting should be the only available method to treat the patient.

   b - In the case of a living donor, skin removal should not cause an injury equal to or greater than the injury suffered by the recipient.

   c - Success of the grafting procedure should be expected.

   d - The acquisition of the human graft should not be through purchase, coercion, or beguilement. Still, when the patient who needs the graft cannot find a donor, he may use money to get it.

6 - Skin grafts from a properly slaughtered animal, whose flesh is permitted to Muslims, are a source permitted by Islamic Law.

7 - Skin grafts from a dead or an impure living animal are unlawful to use except in cases of necessity.

8 - Skin grafts from a pig are unlawful to use except in cases of necessity and when no legally permitted alternative is available.

Topic Thirty Two
Human Skin Banks[137]

Definition

The success of skin graft operations created a need to set up skin banks, where skin of all types is stored until needed for medical purposes, as the case is with milk banks. Skin is stored in these banks in three ways:

1 - refrigeration at a degree of 4º, in which case the skin can be kept for three weeks;

2 - freezing, of which the most advanced method uses liquid nitrogen, and in this case the skin can be kept for as long as six months, or even longer, depending on the freezing degree, the normal degree being -90º; and

3 - freeze-drying, which keeps the skin in the form of a powder for a period of eighteen months at room temperature. The freeze-dried skin can be re-liquidized by mixing it with a normal salt solution and covering the injured areas with it.[138]

The Legal Position Chosen by the IOMS and Its Argument

The IOMS has admitted the establishment of human skin banks under legal conditions and controls. In covering the topic of skin grafts, the recommendations of the IOMS eighth seminar say:

> It is permissible to establish a bank to store human skin, taking into consideration the following:

(137) The IOMS discussed this question in its eighth seminar, An Islamic View of Certain Health Problems, in May 26, 1983.

(138) Dr. Salaah Abd Al-Ghani, "Human Skin Banks," *The Minutes of the Eighth seminar*, pp. 83 - 99, 100.

a - The bank should be under the control of the state or a trustworthy authority supervised by the state.

b - The storage of human skin should not exceed actual and projected needs.

c - The pieces of skin which are discarded should be respected by getting them buried and should never be thrown in the garbage.

Topic Thirty Three
Forbidden and Unclean Ingredients Used in the Food and Pharmaceutical Industries[139]

Definition and Categorization

One of the regretted facts of this age is that Arab and Islamic countries are dependent in their food and medications on imports from non-Islamic countries. Another well-known fact is the constant growth of Islamic communities in non-Islamic countries, which fail to observe even the minimum requirements of Islamic food and pharmaceuticals.

At present, chemistry has become an integral element in the food and pharmaceutical industries, and even in manufacturing clothes and in housing. Genetic engineering has managed to increase the production of protein and fatty materials by mammals. It is unfortunate that pigs are the only animals that have given positive results in experimentation in the form of a great increase in weight. European countries now have great supplies of swine fat, which is processed and turned into preservative, artificial flavors, and other ingredients.

In addition, there are many other ways of introducing unclean and forbidden ingredients in food and pharmaceuticals.[140]

The IOMS has divided this topic into two parts, as follows:

The first part is the addition of unclean and forbidden ingredients to food and drugs without transformation or assimilation.

(139) The IOMS discussed this question twice, the first time as one of the subjects of its eighth seminar, An Islamic View of Certain Health Problems, held in Kuwait in 1995, and the second as one of the subjects of its tenth seminar, An Islamic View of Certain Contemporary Medical Problems, held in Morocco in 1997.

(140) Dr. Ahmad Rajaai Al-Jundi "Unclean and Forbidden Substances in Food and Drugs," *Minutes of the Eighth Seminar*, pp. 420-21.

Definition

Transformation (*istihaalah* in Arabic) means alteration, and scholars of Islamic Jurisprudence (*fiqh*) use this term to refer to a change in the essence of something, turning its form into another, different form, so that it stops being what it is and turns into something else.

Scholars may use the term "assimilation" instead of "transformation," because some forms of transformation are actually cases of absorption of something by something else, so that the former material is assimilated into the latter.(141)

The Legal Position Chosen by the IOMS and Its Argument

The IOMS chose three themes in determining the ruling of such additions of unclean and forbidden ingredients, without transformation or assimilation, to food and drugs. These themes are as follows.

The first theme is establishing a general principle that explains the aspects of avoiding transgression in Islamic Law.

The recommendations of the eighth seminar, reaffirmed at the tenth, include the following:

> Every Muslim must observe the rulings of Islamic Law, particularly those relating to food and drugs. By doing so, he guarantees for himself wholesome food, drink, and medicine. It is out of the mercy that God extends to His creatures and of His way to make things easier for those who follow His Law that He takes cases of essential and necessary needs into consideration. Such cases are covered by legal principles, such as "necessity recognizes no prohibition," and "an urgent need, when recognized, is regarded as an absolute necessity." Another principle is that basically a thing is permissible, unless there is recognized evidence that it is prohibited, and it

(141) Al-Bazoodi, *Kashf Al-Asraar (The Revelation of Secrets)*, 2: 2364 and Al-Aamidi, *Al-Ihkaam (Precision)*, 1: 191, as quoted in Dr. Abd Al-Sattaar Abu Ghuddah, "Transformation and Its Controls and Effects, Minutes of the Eighth Seminar, p. 238.

is basically clean, unless there is recognized evidence that it is unclean. In Islamic Law, the prohibition of eating or drinking something does not necessarily imply that it is unclean.

The second theme is pointing out the ruling on adding alcohol, wine, or pig fat without transformation or assimilation.

In dealing with this theme, the IOMS chose to give the ruling for every case separately, rather than to give a general regulation for all of them. The following is an account of the various forms and the choices of the IOMS.

First: Using Alcohol as Skin Disinfectant and Adding It to Perfumes and Creams

The recommendations of the eighth seminar, reaffirmed at the tenth, include the following:

> In Islamic Law, on the basis of what has already been stated that originally things are clean, alcohol is not an unclean substance, whether it is pure or diluted in water. In stating this, the argument that the uncleanness of wine and all intoxicants is abstract rather than material.
>
> Therefore, there is nothing in Islamic Law against using alcohol as a disinfectant for the skin, cuts and wounds, and tools, and as an antiseptic; against using perfumed liquids (eau de cologne) in which alcohol is used as a solvent for volatile elements; or against creams in which alcohol is an ingredient. This does not apply to wine, because it is forbidden to make any use of it.

Second: Using Alcohol in Making Pharmaceuticals

The recommendations of the eighth seminar, reaffirmed at the tenth, include the following:

> As alcohol is an intoxicant, it is forbidden to drink it. Until the ambition of Muslims to manufacture drugs in which alcohol is not an ingredient, particularly medications for children and pregnant women, is realized, there is no legal objection to take the pharmaceuticals that are manufactured at present and have, in its ingredients, a small percentage of alcohol as a preservative or a solvent for some pharmaceuti-

cal ingredients that do not solve in water, as long as alcohol does not function in these drugs as a tranquilizer. This applies when no alternative for such medicines is available.

Third: Food Items That Have a Percentage of Alcoholic Drinks

The recommendations of the eighth seminar, reaffirmed at the tenth, include the following:

> It is unlawful to use food items that contain alcoholic ingredients, regardless of how small their percentage is. This applies in particular to food items common in the West, like some chocolates, ice creams, and soft drinks. This rule is based on the basic principle in Islamic Law that it is forbidden to take even a little of a material that intoxicates when taken in a large quantity, and also on the absence of any legal justification to make an exception and allow such food items.

Fourth: Food Items That Use a Small Percentage of Alcohol to Solve Artificial Colors and Preservatives

The eighth seminar made the following recommendation, which was reaffirmed at the tenth:

> It is permissible to partake of food items that use a small percentage of alcohol to solve some ingredients that do not solve in water, such as artificial colors and preservatives, because the practice is too wide spread and most of the alcohol evaporates in the food-manufacturing process.

Fifth: Food Items That Contain Pig Fat without a Transformation of Its Essence

The eighth seminar made the following recommendation, reaffirmed at the tenth:

> Food items that contain pig fat without a transformation of its essence - such as certain cheeses, and some kinds of oil, lard, ghee, butter, biscuits, chocolate, and ice cream - are categorically forbidden and should never be eaten. Learned scholars are unanimous in considering pigs as unclean and their meat as forbidden. On the other hand no necessity calls for eating such items.

Sixth: Medications That Contain Pig Fat without a Transformation of Its Essence

The recommendations of the eighth seminar, reaffirmed at the tenth, include the following: "Pig-derived insulin is permissible as a treatment for diabetic patients, subject to the legal controls of necessity."

Moreover, a recommendation of the tenth seminar says, "Using heart valves that are taken from pigs are legally permissible, due to necessity."

The third theme is pointing out the ruling on narcotics and relaxants.

The IOMS is of the opinion that narcotics and relaxants, being of clean essence, are forbidden except when used for purposes of treatment. A recommendation of the eighth seminar says:

> Narcotics are forbidden and can be used only for indispensable medical treatment and only in the dosages prescribed by physicians. The essence of narcotics is clean. It is all right to use nutmeg to enhance the flavor of food in small quantities that cause neither muscle relaxations nor narcotization.

The seminar recommends that a special seminar on smoking should be organized, because of its threats to society.

The second part is the addition of unclean and forbidden ingredients in food and drugs resulting in their transformation or assimilation.

The IOMS ruled that it was permissible to consume food items and drugs to which were added unclean and forbidden ingredients that transformed or were assimilated in the manufacturing process. This ruling was made at the eighth seminar, and it was later elaborated at the tenth. A recommendation of the eighth seminar says:

> Transformation means the conversion of one essence into another, different in characteristics, thus transforming unclean or tarnished matters into clean ones, and legally forbidden matters into acceptable ones.
>
> Consequently:
>
> A - Gelatin - which is made from the transformation of the bones, skin, and ligaments of unclean animals - is pure and eating it is permissible.

B - The soap that is produced through the transformation of pig fat or the fat of dead animals becomes pure through that transformation and using it is permissible.

C - The cheese formed by using the rennet of a dead animal whose meat is legally eatable is clean and may be eaten.

D - Ointments, creams, and cosmetics which have pig fat as an ingredient are unclean, and it is unlawful to use them unless it is established that the fat is transformed and its essence converted.

The seminar reaffirms all the stipulations in the second article of the recommendations of the eighth seminar, which relate to unclean and forbidden ingredients in food and drugs. Adding to the subjects studied in that seminar, this one has considered the medical and jurisprudence (*fiqh*) aspects relevant to this question and concludes that ingredients added to food and drugs which are of unclean or forbidden origin convert into legally permissible substances in one of two ways:

A. Transformation

In jurisprudence (*fiqh*) terminology, transformation means the change in the nature of an unclean matter or a matter which is forbidden to eat or drink, and the conversion of its essence into another matter, different in name and characteristics. This is expressed in common scientific terms as the chemical reaction that changes a substance into a different compound, like the conversion of oils and fats of various origins into soap, and as the breakdown of a substance into its various components, such as the decomposition of oils and fats into fatty acids and glycerin. As a chemical reaction takes place when it is intentionally arranged through technical and scientific procedures, it also takes place in an unperceived manner, in ways cited by jurisprudence (*fiqh*) scholars, such as acetification, tanning, and burning.

Based on the above, when a compound ingredient of forbidden or unclean animal origin is transformed, as explained above, it is regarded as clean and taking it in food and medications is permissible.

It is forbidden to use in food or drugs chemical compounds produced from unclean or forbidden origins, such as shed blood and sewage water, which has not been transformed in the sense explained above. Examples of those are food items to which shed blood is added, such as blood-stuffed sausages, blood-containing gruels (black puddings) and hamburger, baby foods with blood ingredients, blood-containing dough and soups, and similar things. All these are unclean food items and eating them is forbidden, since the shed blood they contain is not transformed.

Meanwhile, blood plasma - which is an inexpensive alternative for egg white and is added to flour and used in making pies, soup, sausages, hamburger, various kinds of dough as rusk and biscuit, gruels (puddings), bread, dairy products, and children medicines and food - is regarded by the seminar as a substance different from blood in name and characteristics, and therefore the ruling on blood does not apply to it. Some participants, however, have a different opinion.

B. Assimilation

Assimilation takes place when a forbidden or unclean substance mixes with a clean and permissible one, and the latter is dominant. The mixture is no longer unclean or forbidden if the minor ingredient loses its characteristics - which include taste, color, and smell - and is assimilated in the dominant ingredient. The same ruling that applies to the dominant ingredient applies to the mixture. Examples are

1 - Added ingredients that are solved in alcohol may be used in very small amounts in food items and drugs, such as artificial color, preservatives, emulsions, and anti-rancidity agents.

2 - Lecithin and cholesterol extracted from unclean sources without their being transformed may be used in food items and drugs in very small quantities that are assimilated in mixtures where a clean, permissible substance is dominant.

3 - Used in small quantities, pig-originated enzymes, such as pepsin and all other digestive and similar enzymes, are assimilated in the food item or drug which is the dominant ingredient.

The seminar holds the opinion that:

1 - In consideration of the purposes and ends of actions, solvents, carrier substances, and the propellants of active substances in pressure containers are legally permissible when used for a legitimate purpose or benefit. However, when they are inhaled for their narcotic or hallucinating effect, they are legally prohibited.

2 - There is no objection in Islamic Law to gold being used for medical treatment of male patients in the field of prosthodontics, such as in crowns, braces, and the like. If such gold, however, is used only as an adornment, the ruling on gold being worn by men applies to it. This means that it is legally forbidden.

3 - Originally, Islamic Law forbids men to wear natural silk materials. An exception is made when such a material is worn for therapeutic purposes, such as in the case of allergy, scabies, itching, and similar conditions, in which case it is permissible.

4 - Using heart valves that are taken from pigs is legally permissible, due to necessity.

Topic Thirty Four
The Ruling on Fast Breaking through Current Medical Applications, Other than Food and Drink[142]

Definition

God, the Most Glorious and Sublime, specifies the things that break the fasting of a Muslim; they are food, drink, and sexual intercourse. God says, "So now approach them and seek what God has ordained for you, and eat and drink until you can distinguish a white thread from a black one at dawn. Then go on with your fasting until nightfall" (*Al-Baqarah* II: 187). In a divine tradition cited by the Two Masters and quoted by Abu Hurrairah, God says that a Muslim "abstains from his food and drink for Me." In another version, it is "his food and desire."

There has been a controversy over breakers of fasting other than food, drink, and sexual intercourse. Some scholars tend to be strict, others flexible.

With the emerging need of people for certain controversial applications that have become common due to current medical progress, there is a need for those to be examined at academies of jurisprudence (*fiqh*).

The Legal Position Chosen by the IOMS and Its Argument

The IOMS holds that what breaks the fasting of a Muslim, other than sexual intercourse, is everything that goes into his body beyond

(142) The IOMS discussed this as one of the subjects of its tenth seminar, held in Morocco in 1997, under the title, "An Islamic View of Certain Contemporary Medical Problems."

the throat and to which the denotation of "food" or "drink" applies in quantity and quality. Therefore, medical applications that are not included in that category are not fast breakers.

The recommendations of the tenth seminar, held in 1997, include the following:

Third: Fast Breakers

In the Divine Book of God, the Most Glorious and Sublime, and in verified traditions of the Prophet, fast breakers are three: food, drink, and sexual intercourse. Everything that goes beyond the throat and to which the denotation of "food" or "drink" applies in quantity and quality is a fast breaker. Based on that, the participants have agreed that the following items are not fast breakers:

1 - Eye drops and ear wash

2 - A nitroglycerin tablet, or something similar, that is taken sublingually as a treatment for angina pectoris

3 - Any pessary, vaginal suppository, wash, vaginoscope, or the finger of a physician, midwife, or examiner that goes into the vagina

4 - Any catheter, urethroscope, barium, or bladder wash solution that enters the male or female urethra, i.e. outer urinary tract

5 - Tooth drilling, extraction, or cleaning; and tooth brushing with *siwaak* (tooth cleanser) or brush, provided that the person engaged in such a thing avoids swallowing anything

6 - Hypodermic, muscular, articular, or intravenous injections, with the exception of nutritive intravenous liquid

7 - Blood donation and transfusion

8 - Oxygen and other anesthetic gases

9 - Materials that are absorbed by the skin, such as ointments, liniments, and plasters that carry therapeutic or chemical materials

10 - The act of taking a blood sample for a laboratory test

11 - A catheter inserted into blood vessels to take x-ray pictures of the heart vessels or those of other organs

12 - A laparoscope inserted through the abdomen wall to examine a patient's innards or perform a surgical operation

13 - Mouth-rinsing, gargle, and local therapeutic mouth spray, provided that no swallowing takes place

14 - A uteroscope or an IUCD inserted into the uterus

15 - A specimen (biopsy) taken from the liver or some other organ

The majority of participants ruled that also the following are not fast breakers:

1 - Nose drops and spray and asthma spray

2 - An enema, suppository, anoscope, or a physician's examining finger that is inserted in the rectum

3 - A surgical operation with general anesthesia, if the patient starts his fasting the night before

4 - Injections used to treat kidney failure, injected in the peritoneum or artificial kidney

5 - A gastroscope, provided that it injects no liquids or other materials

Topic Thirty Five
The Human Genome Project and Its Legal Ramifications[143]

Definition

The word "genome" is a combined form of the two words "gene" and "chromosome." It is used to refer to the whole set of bodies carrying hereditary characteristics.

The majority of developed countries collaborated on what they call the Human Genome Project. It was an ambitious project for which the United States allocated five billion dollars. It actually began in 1990 and was supposed to be completed in fifteen years, but it was formally declared as completed in an announcement made at the White House in 2001, that is four years ahead of schedule.

The outcome and achievements of the project include determining the location of every gene on every chromosome, find out the relationship between each gene and those which precede and succeed it, and decipher the code of every gene.

Undoubtedly, this is useful in discovering the causes of genetic disorders; learning the genetic composition of every human being, including the potential he has to be afflicted by certain diseases, such as blood pressure, heart attacks, cancer, and other diseases; determining the gene therapy for genetic disorders; and producing biochemical substances and hormones that the human body needs for growth.[144] Questions have been raised, voicing apprehensions of the consequences of reading a human genome.

(143) The IOMS addressed this question in its twelfth seminar - Heredity, Genetic Engineering, the Human Genome, and Genetic Therapy - held in Kuwait in 1998.

(144) Dr. Hassaan Hathoot, "Reading a Human Genome," and Dr. Omar Al-Alfi, "The Human Genome," *The Minutes of the Twelfth Seminar*, pp. 273-94.

Some of these questions are: Is it in the interest of man to know things about himself which we now consider to be things for the future to reveal? How does one feel if he learns that he will die when he is about forty? or that he will have myoplegia around the age of fifty? Does an official authority or any employer have the right to ask, as part of the medical requirements for employment, to read a genome of the applicant? To what extent is genetic information kept confidential? Is it part of a person's privacy that is covered by professional confindetiality? If examination reveals a hereditary affliction, will that be a justification to reveal the secret to the person's relatives in order to get them examined?(145)

The Legal Position Chosen by the IOMS and Its Argument

In its twelfth seminar in 1998, the IOMS ruled that the Human Genome Project is a community obligation,(146) being a useful scientific undertaking that helps in curing patients. The IOMS worked out the legal controls for the protection of human rights in the actual performance of human genome tests.

The twelfth seminar's recommendations included the following:

Second: The Human Genome

The Human Genome Project that aims at understanding the entire genetic blueprint of a human being is part of man's effort to know himself, to explore God's laws of creation, and to apply the verse in the Glorious Quran which says, "We will show them Our signs in the horizons and in themselves" (*Fussilat* XLI: 53), and similar verses.

Since reading the human genome is a means to identify some hereditary diseases or the potential to be afflicted with them, it is a valuable addition to health and medical studies and to disease prevention and treatment. As such, this pursuit is a community obligation.

(145) Hathoot, *ibid.*, pp. 280-81.

(146) That is, an obligation for which all people are responsible, but it is met if some people undertake it. (Translator's note)

The first item of the recommendations, which sets general principles, says:

> No research, treatment of a human being, or diagnosis related to the genome of a certain person should be undertaken before a very strict advance assessment of potential risks and benefits associated with such an undertaking is conducted. In the procedure, relevant rulings of Islamic Law must be observed, and voluntary, informed consent must be obtained in advance from the person concerned. When that person does not have the competence to express such consent, the consent or permission of his guardian should be acquired, while the ultimate interest of the person concerned should be sought. When that person does not have the competence to give his consent, no genome of his should be the subject of research, unless that research results in a direct enhancement of his health and the consent of his guardian is obtained.
>
> Every person's right to decide whether he wants to be told the findings or consequences of any genetic test should be respected.
>
> All genetic diagnoses, whether filed or intended to be used in research or for any other purpose, should be totally confidential. It can be revealed only in the cases specified at the third IOMS seminar on April 18, 1987, which dealt with professional confidentiality.
>
> No person should be subject to any form of discrimination which is based on his genetic characteristics and which aims at, or results in, undermining his basic rights and freedom and his dignity.
>
> No research or research application related to the human genome - particularly in the fields of biology, genetics, and medicine - should be beyond the scope of the rulings of Islamic Law and of recognition of the human rights endorsed by Islam. Nor should it reduce the basic freedoms or human dignity of any individual or group.

Islamic countries should enter the field of genetic engineering.

The IOMS should form committees concerned with the ethics of medical practice in every Islamic country, as a step towards establishing an Islamic association of medical ethics related to bio-technology.

Topic Thirty Six
Genetic Engineering and Its Impact on Man and His Food[147]

Definition

1 - The term "genetic engineering" consists of two words:

a - "engineering," which means here manipulating the sequential order of the genetic code and rearrangement of gene chemical formulae through in vitro extraction (separation of genes from each other) and insertion (inserting donated genes into a host organism), using scientific techniques;

b - "genetic," and it refers to genes, the chemical formulae of which a living organism is made.

2 - The roots of genetic engineering go back to the year 1953, when two scientists, Watson and Crick, discovered the formula of DNA, or chromosomes. It was already known that a human cell had twenty three pairs of chromosomes, all of which are similar except the sexual pair, where one of the two chromosomes, X, is long and the other, Y, is short. Each chromosome has two DNA strands, linked to form a chain and arranged in a structure resembling a twisted ladder. Watson and Crick discovered the actual structure of DNA. In every human cell the DNA resembles a cassette tape 2800 km long. DNA is composed of a group of nucleotides, each of which is formed of:

a - phosphates and a five-carbon sugar (deoxyribose)

(147) This was one of the subjects addressed by the IOMS in its twelfth seminar, held in Kuwait in 1998, under the title, Heredity, Genetic Engineering, the Human Genome, and Genetic Therapy.

b - a set of nitrogen bases: adenine, cytosine, guanine, and thymine. The thymine in one of the chains is linked to the adenine in the other, and cytosine is linked to guanine.

It has been established, beyond any doubt, that it is the deoxyribonucleic acid (DNA) that carries genetic information. Next, scientists discovered the method in which bio-genetic information is recorded in the form of a chemical code.

In 1974, Australian scientist Stanley N. Cohen managed to develop a method of genetic grafting, known as a chromosome hybridization procedure, from a frog to colon bacteria. In the same year, the first public debate was held on the experiments of reordering the DNA, i.e. DNA engineering technology. As a consequence, the first commercial laboratory to employ genetic engineering technology, known as Genetech, was set up. The 1980s was a decade of great activity in the field of genetic engineering applications, such as insulin production and gene transplants from one plant to another.

3 - When genetic engineering was first conceived, it was with the idea of serving mankind through genetic modification, which is achieved in one of two ways.

The first way is indirect, and it takes the form of modification of the genetic code of organisms. Examples of this are many, and they include the genetic modification of plants; genetic culture of microorganisms, such as bacteria; and animal genetic engineering or what is known as the production of transgenic animals

The second way is direct, and it takes the form of modification of the genetic code of man himself in an attempt to improve the health conditions of patients with genetic disorders or to conduct an early monitoring of embryos through genetic investigation. All such studies fall within the category of gene therapy.

4 - Actually, the applications of this technology are still somewhat uncertain in regards to future hazards, whether to human beings or to other creatures.

a - The hazards involved in genetic engineering applications in animals, plants and microorganisms, include the absence of scientific controls to guarantee that no genetic tampering that threatens the safety of animals takes place. Some genetically modified animals have an obscure gene that may be hazardous to human and environmental health.

b - The hazards involved in genetic engineering applications in human beings include genetic tampering with bacterial (stem) cells, which will produce later, at the age of puberty, sexual cells (sperms and ova). Such tampering may lead to lineage confusion. Another hazard is the potential damage from gene therapy, which is still in the stage of experimentation, which poses the possibility of death or deformity caused by the viruses used in gene transfer or by error in locating a gene on a chromosome of the patient'.(148)

The Legal Position Chosen by the IOMS and Its Argument

On the subject of genetic engineering, the IOMS twelfth seminar in 1998 made, at its conclusion, a distinction between human beings and other creatures.

1 - Using genetic engineering for human beings is permissible if it is for purposes of disease prevention or therapy, provided that controls are applied to seek benefit, avoid harm, and prevent any confusion of lineage.

2 - As for genetic engineering in the case of plants and animals, it is generally permissible, provided that three points are taken into consideration:

The first point is a warning against the possibility of long-term diseases that are harmful to human beings and the environment.

(148) Dr. Saleh Abd Al-'Azeez Kareem, "Creatures and Genetic Engineering," *Minutes of the Eleventh Seminar*, pp. 107-28.

The second is that it should be declared whether an animal or plant source is natural or produced through genetic engineering, and the genetically engineered percentage should be pointed out, so that consumers may know the facts.

The third point is that it is advisable to follow the recommendations and resolutions of the United States Food and Drug Administration, the World Health Organization, and the UN Food and Agriculture Organization.

The seminar calls for the establishment of consumer protection and awareness organizations.

The recommendations of the twelfth seminar include the following:

The seminar discussed the subject of genetic engineering and the apprehensions that accompanied its birth in the 1970s if no controls were made for its application, as it is a two-edged weapon that can be used for good and for evil purposes.

The seminar reached the conclusion that genetic engineering may be applied to prevent or treat a disease or reduce the suffering caused by illness. The permissibility includes genetic surgery to replace one gene with another, introduce a gene into one of the patient's cells, or transplant a gene from one organism to another to produce large quantities of the matter secreted by that gene. The seminar, however, forbids the employment of genetic engineering with germ cells because of the legal dangers involved in such an application. The seminar stresses that it is imperative that states should subsidize the provision of such services to their modest-income subjects who need them, because they are very expensive.

The seminar holds that it is unlawful to use genetic engineering for evil or aggressive purposes or to cross the genetic lines from one species to another for the purpose of producing transgenic creatures, out of frivolity or scientific curiosity.

The seminar also finds it unlawful to use genetic engineering for changing the genetic blueprint, a pursuit which is known as improve-

ment of the human race. Therefore any genetic tampering with the human personality or intervention in a person's competence for individual responsibility is prohibited by Islamic Law.

The seminar warns against the monopolization of scientific progress and against making profit the major goal of that progress, which would deprive the poor from benefiting from scientific achievements. The seminar endorses the United Nations' decision to set up centers of genetic engineering research in developing countries, train the persons needed to work in these centers, and furnish the centers with what is required.

The seminar can see no legal objection to the employment of genetic engineering in the fields of agriculture and animal husbandry, but, at the same time, the seminar does not ignore the recent warnings against the possibility of long-term harmful consequence for human beings, animals, and plants.

The seminar believes that companies and factories which produce foods of animal or plant origin should inform the public which items offered for sale are produced through genetic engineering and which are one hundred per cent natural, so that consumers may know what they are buying. Moreover, the seminar urges governments to be fully on their guard and watch the outcome of such genetic engineering activities and to follow the recommendations and resolutions of the United States Food and Drug Administration, the World Health Organization, and the UN Food and Agriculture Organization in these regards. The seminar recommends the establishment of organizations for consumer protection and education in Islamic countries.

The same recommendations (those of the twelfth seminar), have General Principles Concerning Genetic Engineering as their first item. Among these principles are:

10 - Islamic countries should enter the field of genetic engineering and set up centers for research in this field, which should be complementary to each other as much as possible. The necessary manpower should be trained to serve as staff for these centers....

12 - Scholars of the Islamic Nation should write works that simplify the scientific details related to heredity and genetic engineering, in order to spread and augment awareness about the subject.

13 - Islamic countries should introduce genetic engineering into the syllabi of the various stages of their educational system, with wider attention to those subjects in the stages of college and post-graduate studies.

14 - Islamic countries should increase public awareness of the developments in the field of genetics and genetic engineering through local media, and should state the ruling of Islamic Law on each question in this field.

15 - The seminar recommends the task of following new scientific developments in this field to be entrusted to the IOMS, with similar seminars organized when something new occurs to make the appropriate recommendations.

Remarks on the recommendations of the twelfth seminar, held in Kuwait in 1983, concerning genetic engineering:

1 - In item 15 of the general principles, the IOMS made the promise of following new scientific developments in the field of genetic engineering and to hold similar seminars in the future, but so far no invitations to such a seminar have been extended.

2 - In item 12 of the general principles, the IOMS recommended the publication of works that simplify the scientific details related to genetic engineering, but this recommendation has not been translated into letters addressed to schools of medicine and colleges of Islamic Jurisprudence (*fiqh*), in order to put the recommendation into effect. I call for awards or appreciation certificates to be offered to encourage writers in the field.

3 - The seminar recommended the establishment of organizations of consumer protection from the hazards of genetically engineered products in Islamic countries. I wonder what steps have been taken to put this into action.

Topic Thirty Seven
The Genetic Imprint and Its Role in Confirming Parentage[149]

Definition

1 - The term "genetic imprint" is a descriptive phrase consisting of two words:

a - Genetic. The Arabic word is an adjective of heredity, a discipline that studies the transmission of biological traits from one generation to another and interprets the phenomena associated with that transmission.

b - Imprint. The Arabic word *basmah* is a colloquial word for "sign," and has been approved by the Academy of Arabic as a word denoting a fingerprint. In origin, the word is derived from a root used to denote something thick.

2 - The first person to use the term "genetic imprint" was Professor Alec Jeffrey in 1985, who discovered that the deoxyribonucleic acid (DNA) of every individual is as unique as his finger prints. Later, Eric Lander called it the ultimate confirmation of identity.

3 - As a scientific term and as a term of Islamic jurisprudence (*fiqh*), the genetic imprint is the test that determines a person's identity and his relationship to those who brought him into being. This is done through testing fragments of the DNA found in any cell. The fragments form bars, each with two chains; each chain takes

(149) The IOMS addressed this question twice. the first time was in the twelfth seminar in 1998, which was on Heredity, Genetic Engineering, the Human Genome, and Genetic Therapy. The second time was in a special discussion session about the Validity of a Genetic Imprint in Confirming Parentage, held in Kuwait in 2000 in response to a recommendation of the twelfth seminar calling for such a session.

the form of cross lines arranged according to the order of amino-acid bases. One of the chains is the hereditary characteristics from the father, and the second, those from the mother. The combination of the two chains gives every human being characteristics that distinguish him from other people. For such a test, equipment with highly sophisticated technology are used, and the test data are easy to be read, saved, and kept in computer files by a trainee. They are stored until they are needed.(150)

The Legal Position Chosen by the IOMS and Its Argument

In its twelfth seminar in 1998, the IOMS acknowledged the value of the genetic imprint and the fact that it is almost error-proof in determining biological parentage and confirming identity, and is as good an evidence as tracing similarities. The seminar, however, was reluctant to recommend it as a proof in confirming parentage and took upon itself to hold a discussion session with the aim of arriving at suitable recommendations on this question.

On May 3 and 4, the IOMS fulfilled its pledge, and a discussion session to look into the validity of genetic imprints as evidence in confirming or refuting parentage was held.

The session was concluded with recommendations that included assigning to genetic imprints the same function as tracing similarities and resorting to it only when there are conflicting claims with equal evidence on both sides. In cases where there are no conflicting claims, the claim of a father is admitted, while decision on a mother's claim is deferred for further consideration. The session came up with controls for using the evidence of the genetic imprint rather than tracing similarities.

One of the recommendations of the twelfth seminar in 1998 is:

(150) Dr. Siddeeqah Al-'Awadhi, "The Genetic Imprint's Role in Fatherhood Tests," and Dr. Sufyaan Al-'Asooli, "The Genetic Imprint and the Extent of Its Validity as Evidence in Confirming Parentage," the minutes of the twelfth seminar held in 1998, pp. 333-386; Dr. Sa'd Al-Hilaali, "The Validity of the Genetic Imprint as Evidence in Confirming or Refuting Parentage," the minutes of the discussion session on the Validity of the Genetic Imprint as Evidence (2000), pp. 26 and 27.

The seminar has discussed the question of the genetic imprint, which is the elaborate genetic structure that establishes the identity of a particular individual. In practice, the genetic imprint is an almost error-proof method of determining biological parentage and confirming identity, particularly in the field of forensic medicine, and is equal to other items of strong evidence that are admitted by most jurists in cases other than those of applying prescribed punishments. It is a great contemporary development in the area of tracing similarities, which the majority of Islamic jurisprudence (*fiqh*) schools rely on in determining a contested parentage. A genetic imprint test, however, should be made at several laboratories.

As regards using this method to confirm parentage, due to the fact that the different opinions of jurists on the subject create a need for a more thorough studies of its various aspect, the seminar calls for a discussion session in which specialized jurists and physicians participate in order to arrive at suitable recommendations on this question.

The recommendations of the discussion session of the year 2000 on the validity of the genetic imprint as evidence include the following:

Having looked into those rulings, the comments of jurists, the explanation of the genetic imprint made by scientists from the Genetics Center, and the detailed discussion and debate on the subject - the participants have arrived at the following:

1 - Every human has his own, unique genetic pattern in every cell in his body, which is not shared by any other individual throughout the world. This pattern is known as the genetic imprint. In practice, the genetic imprint is an almost error-proof method of determining biological parentage and confirming identity, particularly in the field of forensic medicine, and is equal to other items of strong evidence that are admitted by most jurists in cases other than those of applying prescribed punishments. It is a great contemporary development in the area of tracing similarities, which the majority of Islamic jurisprudence (*fiqh*) schools rely on

in determining a contested parentage. Therefore, the seminar decides that, with all the more reason, the genetic imprint evidence should be admitted in all the cases in which tracing similarities is applied.

2 - The discussion session rules that the genetic imprint should be resorted to in cases where, in the absence of other evidence or with both (or all) sides having equal evidence, more than one man claims the fatherhood of a child whose lineage has not been established.

3 - A person who claims to be the parent of a child whose lineage is unknown is entitled to the parentage of that child when his claim satisfies the conditions set by Islamic Law. Consequently, such a person has no right to withdraw his claim, any denial of one of that person's other children of the kinship of the claimed child is not admitted, and the genetic imprint evidence is not applicable in such a case.

4 - The admission of some siblings that a child of unknown lineage is their sibling is not binding to the other siblings, the lineage cannot be confirmed, the consequences of the admission is limited to the inherited share of the siblings making the admission, and the genetic imprint evidence is not admitted in such a case.

5 - In the discussion of this subject, varying points of view were made and the debate went on for a long time on whether a woman's claim of parentage is admissible in the case of a child of unknown lineage. It was therefore decided to allow more time for the consideration and investigation of this question.

6 - The genetic imprint is not accepted as evidence of a "conjugal bed," since the proof of marriage has to follow the procedures set in Islamic Law.

7 - The participants believe that the following controls should be operative when a genetic imprint test is to be made:

a - A test should be made only after permission from the concerned authority is obtained.

b - The test should be made in at least two different accredited laboratories, with proper precaution taken to guarantee that none of the laboratories involved has access to the findings of the other(s).

c - Government owned laboratories are preferable, but if such laboratories are not available, the test can be made at government-supervised laboratories. Whatever the case is, one condition that has to be met is that the applicable local and international conditions and controls are met.

d - Another condition is that the staff of these laboratories must be qualified and trustworthy, and none of them should be on terms of kinship, friendship, enmity or common interest with any of the claimants nor should have a record of a dishonorable offense or an act of dishonesty.

Topic Thirty Eight
Family Genetic Counseling[151]

Definition

Genetic or hereditary counseling is that which aims at supplying its seekers with accurate knowledge to assess the likelihood and the percentage of possibility as regards genetic or hereditary disorders, leaving decisions to be made by the parties concerned, in consultation with their physicians, without any attempt to influence that decision one way or another.[152]

The progress achieved in medicine has demonstrated that many incurable diseases and disorders are caused by hereditary factors. One way of preventing such diseases is to guard against such incidence. This can be done by examining a couple engaged to be married. The physician in charge should point out to the couple the possibilities that their offspring would be exposed to and the method to deal with future risks. The best known diseases suspected to have a genetic basis include thalassemia, which is Mediterranean anemia; Alzheimer's disease, a type of senility that causes loss of memory and ends with various types of paralysis; and sickle-cell anemia, which requires lienectomy and bone surgery.

A hereditary disease is transmitted by a single gene, which may come from one of the parents or both, or a genetic mutation may occur, altering the structure of the gene and changing it from a normal to defective one. Such mutations happen frequently, but the body often resists them, and some mutations do not cause any disorder.

(151) The IOMS discussed this as one of the topics of its twelfth seminar, held in 1998 under the title, Heredity, Genetic Engineering, the Human Genome, and Genetic Therapy.

(152) Item 5 of the Recommendations, *The Minutes of the Twelfth Seminar*, p. 1050.

In 1994, Scientists have been able to figure out the number of hereditary diseases transmitted by a single gene as 6,678, out of which 4,458 are prevalent diseases (a prevalent disease is that which is transmitted by one parent only and therefore affects 50% of the offspring according to Mendel's law) and 1,750 are recessive diseases (where both parents carry the defective gene and they are carriers of the disease but not afflicted with it, and so they transmit it to 25% of their offspring according to Mendel's law). In addition, there are 412 diseases that are transmitted by the X chromosome of the mother. They are transmitted to half the male offspring, but females are not infected by them and only carry it. There are also 59 diseases transmitted by the mitochondria (small DNA cellular structures found in the cytoplasm of eukaryotic cells, outside the nucleus, and responsible for metabolism and cellular respiration). Those were the diseases found out in 1994, and undoubtedly the list grows on a daily basis, with the discovery of more hereditary diseases every few days due to the accelerated pace of scientific research in genetics. In 1998, the number exceeded 8,000 hereditary diseases.(153)

The Legal Position Chosen by the IOMS and Its Argument

The IOMS, in its twelfth seminar in 1998, decided that genetic counseling is not compulsory, but it recommended such counseling to people who intend to marry in secret. It also warned against the marriage of relatives in families where some members are afflicted with a hereditary disease.

The recommendations of the twelfth seminar say:

Fifth: Hereditary (Genetic) Counselling.

The seminar has discussed this subject, and it recommends the following:

A - Family genetic counseling services should be made available on a large scale to families and those who plan to

(153) Dr. Muhammad Ali Al-Baar, "A Scrutinizing Look at Genetic Medical Examinations," and Dr. Muhsen Ibn Ali Faares Al-Haazimi, "Seeking Genetic Counselling," the minutes of the twelfth seminar, pp. 621-95.

get married. These services should be staffed by qualified specialists. In addition, public awareness should be promoted and people should be educated by every possible mean to guarantee benefits to all.

B - Genetic counseling should not be compulsory, and its findings should not result in any compulsory measure.

C - The findings of genetic counseling should be kept completely confidential.

D - Services of genetic counseling should be expanded in medical and health institutes, schools, the media, and mosques after sufficient training is given to counselors to expand their knowledge and make them qualified.

E - Since statistics show that the marriage of relatives (as permitted in Islamic Law) may result in a higher rate of transmission of congenital anomalies, the public should be made aware of this so that choices would be informed, particularly in the case of families where some members are afflicted with a hereditary disease.

Sixth: Diseases for Which the Genetic Test Is Compulsory and Those Where It Is Optional.

1 - The seminar believes that efforts should be made to spread awareness of genetic disorders and diseases and limit their incidence.

2 - The seminar calls for the encouragement of genetic tests before marriage through the promotion of greater awareness in auditory and visual media, symposia, and mosques.

3 - The seminar urges health authorities to increase the number of human genetics units, in order to make physicians available for genetic counseling, and to extend to all pregnant women health services in the field of genetic diagnosis and treatment in order to improve procreative health.

4 - No person should be compelled to have a genetic test.

Topic Thirty Nine
The Rights and Obligations of the Handicapped and Psychological Patients and Outlining the Preventive Fence for Mental and Psychological Diseases[154]

Definition

For a person to be responsible, he has to be able to understand the evidence in Islamic Law on which his obligations are based. Although Islamic Law makes rationality the basic condition of competence and of assigning responsibility, sometimes the infliction of a penalty has other requirements.

In criminal justice, the criminal has to be mature and have free choice. In civil penal law, competence of performance is a condition for legal procedures to be started.

In material occurrences, penalty is imposed by force of law, because the consequences and obligations these occurrences entail are established by the statement that has prescribed the penalty, which makes being human the only condition for the penalty to apply.[155]

From international data, it is clear that legislation related to psychological health is not limited to forensic psychiatry, but also extends to the various legal tools related to people whose conditions are diagnosed as mental disorders. What then are the rights and obligations of such people?[156]

(154) The IOMS discussed this question in its tenth seminar in October, 1997, devoted to "Country-to-Country Consultations Concerning Psychological Health Legislation in Various Laws." The IOMS also addressed certain aspects of this question in its first and third conventions in 1981 and 1984 respectively.

(155) Councilor Muhammad Badr Al-Miniaawi, "The Mentally or Psychologically Handicapped and Their Rights," *Minutes of the Eleventh Seminar* in 1997, p. 339.

(156) Dr. Ahmad Rajaai Al-Jundi in his address at the opening of the eleventh seminar, *Minutes of the Eleventh Seminar*, p. 18.

The Legal Position Chosen by the IOMS and Its Argument

The eleventh seminar, held in 1997, dealt with psychological health legislation and recommended that theories, applications, methods, and instruments of psychotherapy should be applied in accordance with the rulings of Islamic Law. The seminar's recommendations say:

> The seminar concludes that efforts should be made to adopt an Islamic perspective in theories, applications, methods, and instruments of psychotherapy to make it compatible with rulings of Islamic Law and with the values and circumstances of Islamic societies. There are two categories that should be observed:
>
> *The first category: Principles of Extending Care to a Psychological Patient and the Rights of Such a Patient.* This category consists of five principles::
>
> **The First Principle** is that efforts should be augmented and made adequate for the maintenance of psychological health and prevention of psychodisorders.
>
> **The Second Principle** is that every human being has the right to receive basic psychological health care.
>
> **The Third Principle** is that the evaluation of psychological health should be compatible with recognized international medical principles.
>
> **The Fourth Principle** is that when there is any need to restrict the freedom of patients with psychological and physical disorders as a precaution against any threat they may pose, this restriction should be minimal, and the necessary instruments should be provided to the patient to enable him to perform his religious obligations and take care of himself.
>
> **The Fifth Principle** is that a patient should enjoy the freedom to choose for himself, and, therefore, his consent must be obtained for any medical intervention that concerns him.

The second category: Principles of Determining the Responsibilities of a Psychological Patient. This category consists of three principles:

The First Principle is that a psychological disorder affects an individual's civic responsibility if it causes him to lose the ability to distinguish good from evil, impairs his ability to make the right judgment, and results from a mental disorder, inadequate discretion, or a weakness of some self-control faculties.

The Second Principle is that a psychological disorder affects criminal responsibility if the psychological patient suffers, at the time of the crime, a mental disorder affecting his will, awareness, reasoning, or mood, and consequently impairing his ability to make sound judgments.

The Third Principle concerns the legal consequences of a disorder that affects responsibility: When it is established that a disorder affects responsibility, the patient's competence should be limited and he should be placed under a guardian who protects the patient's right to defend himself.

Remarks Concerning the Recommendations of the Twelfth

Seminar on the Rights and Obligations of the Handicapped

The IOMS chose to affirm the effect of psychological disorder on criminal responsibility. I support the position of the majority of scholars, which distinguishes between:

1 - aggressive mental and psychological disorder, due to intoxicant and narcotics, and

2 - non-aggressive mental and psychological disorder.

Topic Forty
Determining the Status of Medical Sciences and Life-Related Disciplines in Islamic Law[157]

Definition

Although Islamic Law encourages the pursuit of disciplines that bring benefit to the Islamic Nation, once in a while voices are raised to claim that Islam does not recognize cosmological sciences to be ones that entitle their specialists to receive any credit, credit for learning being earned only when one pursues disciplines of Islamic studies. Such voices ignore that the strong pillars and firm foundations on which the Islamic civilization was built were firm belief and the useful sciences in all areas, such as medicine, pharmacy, astronomy, marine sciences, engineering, architecture, and other sciences. Therefore, reviving the issue is necessary to serve the interests of future generations.[158]

The Legal Position Chosen by the IOMS and Its Argument

In its fourteenth seminar, held in 2001, the IOMS emphasized the point that credit in Islam goes also to all branches of science and learning that benefit mankind and urged the promotion of this notion by all possible means. The recommendations of the seminar say the following:

1 - The seminar emphasizes that the science and learning which the sources of Islamic Law, particularly the Divine Book and the Prophet's Traditions (*sunna*) commends, together with men of

(157) The IOMS addressed this question in its fourteenth seminar, Science in Islam, held in Kuwait in 2001.

(158) The opening remarks of the recommendations of the fourteenth seminar.

learning, are not limited to disciplines of Islamic studies, but include all disciplines, whether Islamic, cosmological, or natural. The seminar also emphasizes that all disciplines of learning are noble, but the degree of their nobility varies with the difference of their subjects, with the disciplines that deal with God and His attributes being the noblest, because anything related to Him is the most noble of all noble things.

2 - The seminar affirms that the learning of cosmological and natural sciences by Muslims is a community obligation, in the sense that it is waived as a general obligation only when some Muslims undertake it, learning it sufficiently to satisfy the need of Muslims for scientific knowledge, and that all Muslims sin when these sciences are not learned at all or not learned sufficiently. This rule also covers the funding of such learning.

3 - The seminar affirms that the finding of cosmological and natural science should be employed in arriving at the Islamic Law position regarding emerging issues. The seminar also stresses the importance of strengthening the ties between scholars of Islamic Law on the one hand and scientists and cosmologists on the other. This is to be done by an increase of the meetings, seminars, symposia, and conferences that result into increased mutual understanding and allow the arrival at considered opinions based on a strong foundation of Islamic Law and natural laws. Such opinions should by guided by flexibility in investigation and decision, thus following the approach of the Prophet, blessings and peace be upon him, who, whenever he had to choose between two things, chose the less demanding, unless it was sinful.

4 - The seminar holds that monotheism calls for unified knowledge and one truth and denies any discrepancy between the knowledge related to this world and that related to the Hereafter. For this reason, the seminar recommends teaching an introduction to Islamic studies in colleges of physical and natural science and an introduction to physical and natural science in colleges of Islamic studies. The syllabi of these two introductions should be designed in a way that guarantees easy understanding and optimal benefit.

5 - The seminar calls for the coupling of the pursuit of any discipline or specialization with a consolidation of religious and ethical values in a manner that guarantees an orientation of science towards what is useful to mankind.

6 - The seminar urges for provision of the necessary means to keep Muslim scientists in their home countries and for the proper environment in Islamic countries to be created to mobilize emigrant scientists and benefit from their expertise and energies to develop the scientific situation in Islamic countries and remove any obstacles that hinder such development.

7 - The seminar recommends the establishment of channels of communication with the scientists of Muslim communities in the West, in order to maintain strong ties between them and their nation and benefit from their experience.

8 - The seminar recommends putting into action the mechanisms of applying a strategy for the development of science and technology in Muslim countries which were suggested by the Islamic Organization of Education, Science, and Culture and approved by the ninth Islamic summit conference.

9 - The seminar recommends efforts to prepare a data base for all scientists in Islamic countries and Muslim scientists in all other parts of the world, highlighting their qualifications, fields of specialization, and scientific and research work.

10 - The seminar calls for linking specialized scientific studies with the references to them or the statements that motivate them in the Glorious Quran, and linking all studies that deal with Islamic Law with the facts of natural and cosmological science that support them.

11 - The seminar recommends teaching the history of science in Islamic countries and the contribution of Islamic culture scientists, as well as the study of the approach followed by Muslim scientists in their research in the fields of secular science and of studies

related to the Hereafter. This approach should be an inspiration in scientific research and should be adapted to meet the conditions of time and location.

12 - The seminar urges the Islamic Organization of Medical Sciences (IOMS) to pay attention to the expected ethical revolution and to draft a document of research ethics from an Islamic perspective to contribute to the correction of mistaken notions that are spread throughout the world and to the transmission of Islamic ethics through the controls of scientific activity laid down by the IOMS.

13 - The seminar recommends efforts to be made to clarify some basic Islamic concepts, such as the consequences of man being a deputy on earth, the role and status of reason as defined by Islamic Law, the inference of the Creator's existence from what He has created, the meaning of His placing what heavens and the earth contain in the service of Man in accordance with God's laws and purposes, and the role of all these things in urging Muslim scientists to conduct research in the fields of science to answer many of the questions which the Glorious Quran instructs Muslims to find answers for.

14 - The seminar regards the Islamic scientific heritage an integral component of the Islamic Nation's memory and believes that its revival is needed in order to connect contemporary sciences with their roots, amend the history of science, and give justice to the role of Islam in the annals of world civilization. It is for that reason that the seminar calls for introducing the history of science into the curricula of Islamic universities, so that students may be acquainted with the scientific progress in the Islamic civilization. Likewise, the seminar recommends that the Islamic scientific heritage which is still in the form of manuscripts be brought out and the necessary measures be taken to edit and study it.

15 - The seminar urges Islamic countries to use education curricula, the media, and other forms of education to implant in their citizens, particularly the younger generations, the desire, urged by

Islam, to pursue all kinds of useful learning and to engage in the duty of discovering the laws set by God for his creatures, which is known today as scientific research.

16 - The seminar recommends to Islamic countries to pay great attention to the issues of human development as the basic gateway to development and progress, and to take steps towards organizing a group of people capable of effecting the desired scientific change and setting the foundations for excellence in research, particularly in the sciences that have precedence today, such as microelectronics, information, communications, genetic engineering, and space sciences.

STATEMENT OF THE ISLAMIC ORGANIZATION FOR MEDICAL SCIENCES ABOUT THE MEDICAL DEFINITION OF DEATH

1 - INTRODUCTION

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Kuwait.

2 - NAMES OF PARTICIPANTS

Introduction

Dr. Ahmed Rajai El-Gendy, Ph.D.
Secretary General Assistant,
Islamic Organization for Medical Sciences (IOMS),
Kuwait.

This is the first (purely) medical symposium held by The Islamic Organization for Medical Sciences in Kuwait between 17 and 19 December, 1996. It had two goals:

First: To be updated on the international developments in the field of the medical definition of the time of death.

Second: To review and respond to a recent campaign in the lay press and media, challenging the established opinion that the death of the brain together with death of the brain stem as a second basis to diagnose death. Such a basis was endorsed by the symposium on medical jurisprudence held in Kuwait in 1985, and the ruling of the Council of Islamic Fiqh (Jurisprudence) a division of the Muslim League Organization, in Makkah, Saudi Arabia, in 1986. This organization thought it was opportune to redress the issue, and called for this symposium attended by the following medical scholars:

Names of Participants (In Alphabetical Order)

1 - **Dr. Abbas Ramadan**
Chairman of Neurosurgery and Vice-Director, Ibn-Sina Hospital, Kuwait.

2 - **Counsellor Abdallah Al-Issa**
Member of Board of Trustees, IOMS, Vice President, Court of Cassation (Tamyiz), Kuwait.

3 - **Dr. Abdel-Lateef Othman**
Professor of Neurology, Al-Azhar University, Cairo, Egypt.

4 - **Dr. Abdel-Monem Ebeid**
Chairman of Anaesthesia, Moassat Hospital, Kuwait.

5 - **Dr. Abdul Rahman Al-Awadi**
President, IOMS, Kuwait.

6 - **Dr. Abu-Shadi El-Rooby,**
Professor of Medicine, Cairo University, Cairo, Egypt.

7 - **Dr. Adnan Khreibet,**
Department of Neuro-Physiology, Ibn-Sina Hospital, Kuwait.

8 - **Dr. Ahmad Badran**
Professor of Surgery, Ciro University, Cairo, Egypt.

9 - **Dr. Ahmad El-Kadi,**
Member of Board of Trustees, IOMS,
Akbar Clinic, Panama City, Florida, USA.

10 - **Dr. Ahmad Rajai El-Gendy,**
Director of Islamic Medicine Center, and Secretary General Assistant, IOMS, Kuwait.

11 - **Dr. Ali Al-Saif,**
Secretary General, IOMS,
Assistant Under Secretary,
Ministry of Health, Kuwait.

12 - **Dr. Asmahan El-Shebeily,**
Department of Neurology, Ibn-Sina Hospital, Kuwait.

13 - **Dr. Essam al-Sherbini,**
Consultant, Department of Medicine, Al-Sabah Hospital, Kuwait.

14 - **Dr. Faisal Abdel-Raheem Shaheen,**
Director, Organ Transplantation Center, Saudi Arabia.

15 - **Dr. Hamdi el-Sayyid,**
President, Doctor's Syndicate, Egypt; Member, People's Council: Professor of Cardiac Surgery, Ein Shams University, Cairo, Egypt.

16 - **Dr. Hassan Hathout**
Member of Board of Trustees, IOMS
Former Professor of Obstetrics & Gynecology, Kuwait University, Islamic Center of Southern California, L.A., USA.

17 - **Dr. Hassan Hassan Ali,**
Professor of Anesthesiology, Harvard University, Massachussets, USA.

18 - **Dr. Hessein Al-Gazairy,**
Director, EMRO, World Health Organization, Alexandria, Egypt.

19 - **Dr. Hussein Malibari,**
Department of Neurology, King Abdul-Aziz University Hospital, Saudi Arabia.

20 - **Dr. Ibrahim Ali Hassan,**
Counsel and Vice-Chairman, Council of the State, Egypt.

21 - **Dr. Ibrahim Badran,**
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22 - **Dr. Khalid Al-Madhkour,**
Member of Board of Trustees, IOMS,
Professor of Sharia, University of Kuwait, Kuwait.

23 - **Dr. Khairy el-Samra,**
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24 - **Dr. Mahmoud Samhan,**
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25 - **Dr. Mahmoud Creidiyeh,**
Neurologist, Director of Barbir Hospital, Beirut, Lebanon.

26 - **Dr. Mamdouh Gabr,**
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27 - **Dr. Mohammad Ali Al Barr,**
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28 - **Dr. Mohammad al-Sabeel,**
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29 - **Dr. Mohammad Emadel Deen Fahli,**
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30 - **Dr. Mohammad Haitham Al-Khayat,**
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34 - **Dr. Mokhtar al-Mahdi,**
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35 - **Dr. Mustafa Moussawi,**
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36 - **Dr. Rauf Mahmood Sallam,**
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37 - **Dr. Safwat Hassan Lutfi,**
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38 - **Dr. Salah el-Ateeqi,**
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39 - **Dr. Soheil Shammary,**
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40 - **Dr. Youssef Rize Lee,**
Neuro-Surgeon, Turkey.

OPENING SPEECH

Dr. Abdul Rahman Al-Awadi

President,
Islamic Organization for Medical Sciences,
KUWAIT

OPENING SPEECH

Dr. Abdul Rahman Al-Awadi
President,
Islamic Organization for Medical Sciences,
KUWAIT

Dear guests and friends,

It has always been the policy of the Islamic Organization for Medical Sciences to tackle the ethical issues that emerged on the medical scene as an inevitable outcome of scientific progress. Various symposia were held comprising medical scientists and religious jurists for a combined discernment of the problems and their implications, only to find that Islamic jurisprudence never failed to formulate an Islamic ruling on all questions. One such issue was the definition of the onset of death, with its relevance to stopping of artificial life support and even the procurement of vital single organs for transplantation. At the global level, the time honored traditional signs of death were open to review and scientifically a shift from them seemed inevitable. After much debate and research (which are indeed still ongoing), the concept of the death of both the brain and brain stem as evidence of death evolved, even while some external signs of life temporarily persist, usually by artificial means of animation. Various protocols to confirm the essentially clinical diagnosis of death of brain and brain stem were formulated, notably those of Helsinki, Minnesota, a Harward, Nottingham, Havana, Sydney and many others.

Hot debate also erupted in the circles of religion and ethics. For a little while the voice of Islam was absent, until the Islamic Organization for Medical Sciences felt the duty to catch up. A select group of high ranking Islamic jurists and medical scholars were invited to a symposium in Kuwait for mutual discussions. This was perhaps the

most difficult symposium in the history of the Organization. By their nature, jurists are understandably over cautious on this issue, for fear of passing a verdict of death on someone who might be still alive. One of the fruits of that symposium was the realization that the complexity of some modern issues makes it impossible for either side alone to formulate a ruling, especially in our age when such encyclopedic individuals excelling in both medicine and jurisprudence are no more. An example was Ibn Rushd of Andalusia whose works in medicine and in jurisprudence were among the top references. Although the debate was heated sometimes, both sides approached the matter with sincerity and open-mindedness until they reached a consensus and issued a ruling.

It is worthwhile to note that at that symposium (1985) the question of organ transplantation was not an issue; at that time, it was not given any consideration, and it was four years later that the Organization held its symposium on "Organ Transplantation".

With this introduction, I would like to pose to your attention the following seven points:

1 - All of us in this Hall are one team searching for the truth. We might disagree but without resentment. It is not, no shame to change our positions if we should, for our prophet (pbuh) said "all humans fall into error but the best are those who revert to the truth ". As Imam Malik said: "From all of you we might take some and leave some, except the one in this grave (the prophet's grave)".

2 - The priority of the Organization is to seek the common good manifested in the five objectives of the Shariah viz. "the protection and preservation of Religion, Life, Mind, Ownership and Offspring". This only pertains through solid faith and sound knowledge. In Islam the pursuit of knowledge is mandatory, as evidenced by more than 500 verses of the Quran. In this respect, it is interesting to note that Imam Al-Shafei said: "I know no nobler science than medicine except the sciences of religion".

3 - We are required to overcome our health problems through ardent scientific research, which unfortunately still lags behind in our

Muslim countries, denying us many opportunities to development and relegating us to mere parasites on foreign knowledge. The GATT threatens us with further widening of the gap between developed and developing nations.

4 - The fruits of global scientific progress will inevitably face us. We should be keen to timely discern them, so as to adopt what does not conflict with our faith and decline what does.

5 - This subject of defining the beginning of death is obviously of vital importance. Although the Organization already devoted for it a juridico-medical symposium in 1985, it saw fit to cast a second look, in the wake of the international conference at San Francisco on 17-19 November 1996. Three delegates from the Organization attended it, to give an update on any new developments or shifted positions on the subject. Their report has been distributed to you.

6 - We here tackle the issue from a purely professional stand point. We have invited the dissenting opinion and will give it its full opportunity in reasoning and expression, but we trust that our universal aim is seeking that truth transcending any prior or dug-in positions. The responsibility is grave before God, who is everwatching even on our intentions.

7 - This symposium is purely medical, without participation of the jurists. The ruling of lawful and unlawful of course belongs in their domain as scholars of religion. Although their ruling will be based on what we present to them as medical opinion, we should avoid passing religious verdicts, confining ourselves to the scientific and ethical aspects. There has always been ethical and unethical (or outright evil) practices by the necessity of human nature that the Quran comments on:

"CONSIDER THE HUMAN SELF, AND HOW IT IS FORMED IN ACCORDANCE WITH WHAT IT IS MEANT TO BE, AND HOW IT IS IMBUED WITH MORAL FAILINGS AS WELL AS WITH CONSCIOUSNESS OF GOD. TO A HAPPY STATE

SHALL INDEED ATTAIN HE WHO CAUSES THIS (SELF) TO GREW IN PURITY, AND TRULY LOST IS HE WHO BURIES IT (INDARKNESS)." (91: 7-10).

Deviations are not confined to a time or a place, but they should always be sought out and corrected. It is also necessary to emphasize that benefiting from scientific progress is an Islamic obligation, in medicine and otherwise, or else millions of lives would have lost to diseases. The only criterion for accepting what is new is its compliance with the Shariah.

I pray for your success, and thank you for taking the trouble to attend, motivated by your love to Islam, your fellow Muslims and your fellow human beings.

"OUR LORD: LET NOT OUR HEARTS SEVERE FROM THE TRUTH AFTER YOU HAVE GUIDED US; AND BESTOW UPON US THE GIFT OF YOUR GRACE; VERILY YOU ARE THE TRUE GIVER OF GIFTS" (3:8).

And peace be upon you.

STATEMENT OF THE ISLAMIC ORGANIZATION FOR MEDICAL SCIENCES ABOUT THE MEDICAL DEFINITION OF DEATH

In the Name of Allah, the Compassionate, the Merciful

Statement of The Islamic Organization for Medical Sciences About the Medical Definition of Death

In 1985, the Islamic Organization for Medical Sciences held a symposium to study "The End of Human Life", participating in which were a select group of top religious jurists, medical scholars, legal experts and authorities in the humanities. After meticulous discussion, the symposium endorsed the following conclusions:

1 - Usually as in the great majority of cases, when death happens, there is no difficulty in its diagnosis, upon its publicly known features or an external clinical examination delineating the dead from the living.

2 - In some (very few) cases, usually under close observation in the intensive care units or similar specialized hospital wings, the need is intense to establish the diagnosis of death, even at the phase when life-like phenomena persist, either spontaneously or by means of artificial life support machinery.

3 - The time old books of jurisprudence were scrutinised in search of the signs that prove death. These were mainly human interpretations based on available medical knowledge at their time, in view of the absence in the Quran and the Traditions of the prophet (PBUH) of a clear cut definition of death. Since the diagnosis of death and its signs has always been in the medical domain, upon which the jurists based there ruling, the medical side presented to the symposium the current medical opinion on the definition of death.

4 - After the medical scholars presented the case, the following points became clear:

- The death of that part of the brain responsible for the primary vital functions, which is called the brain stem, is a reliable indicator of the occurrence of death.
- That the diagnosis of brain stem death is based on clear cut

and reliable evidence, having excluded well known clinical entities that might give a false if positive diagnosis.

- A vital organ or function like the heart or respiration might stop temporarily but can sometimes be saved with restoration of life: but only if the brain stem is alive. If the brain stem has died, there is no prospect of such rescue, and the person's life has practically come to a conclusion, even if other organs or systems have not died yet, but will inevitably also die after a period of time.

5 - Upon these medical data, the religious jurists based the view that if a person has reached, with certainty, the state of brain stem death, then such a person has departed from his life, and some of the rulings concerning death are applicable to him. This is in analogy -although not similarity -to the juridical ruling about the person that reached the stage of "movement of the slain". Concerning the applicability of the other rulings, the jurists preferred to defer discussing them for a future occasion.

6 - In view of all this, there was a consensus that if death of the brain stem is diagnosed with certainty, then disconnecting the person from artificial life support apparatus may be carried out.

The Islamic Organization for Medical Sciences, keen on pursuing any scientific developments on the matter, and feeling the duty to address a recent campaign in the lay press and public media discrediting the standard universal acceptance of brain death with brain stem death as diagnostic of death, decided to hold this symposium. Some doctors participated to that campaign, which added to the urgency of the situation. Two decisions were taken:

i - In view of the scientific front being essentially mobile, the Organization deputed three of its members to participate in the November 1996 international conference held in San Francisco, U.S.A., by the American Association of Bioethics, the International Association of Bioethics and the network death by brain death together with brain stem death. No case where brain and brain stem death was correctly diagnosed ever came back to life, and none of the cases that came back

to life carried an established diagnosis of brain and brain stem death. Issues of novelty were confined to philosophical views or the relative evaluation of confirmatory procedures after the diagnosis was established.

ii - To hold this symposium in Kuwait from 17 to 19 December 1996, a distinguished group of scholars in the specialties of neurology, neurosurgery, anesthesiology, intensive care, neurophysiology, cardiac surgery, organ transplantation, medicine, pediatrics, obstetrics and gynecology, general surgery, medical jurisprudence; who came from Kuwait, Saudi Arabia, Egypt, Lebanon, Turkey and the United States of America, was invited. It was also attended by the Director of the East Mediterranean Regional Office (EMRO) of the World Health Organization.

The subject was comprehensively discussed over three days, including a meticulous appraisal of the clinical cases presented in support of the dissent no case properly be diagnosed as brain + brain stem death ever regained life, and all the cases that regained life had an obvious and flagrant fault in making such diagnosis, omitting, misreading or violating the standard criteria.

Reviewing the global situation and the regional experiences and safeguards taken (the contribution of the Saudi team was particularly commendable) and in full awareness of the scientific and religious dimensions, the Organization found no reason to discard, modify or alter the recommendations of its previous symposium on "Human Life: Its beginning and its end" held in Kuwait in 1985, or the rulings issued by the Congress of Islamic Jurisprudence (a department of the Organization of the Islamic Congress) in Makkah in 1986, both of which have been reaffirmed.

The following standards, criteria and safeguards were spelt out by the Symposium, and the Organization herewith presents them for the benefit of formulating legislation and by laws regulating this subject.

First -Signs which signify death:

An individual is considered dead in one of the following two situations:

a - Complete irreversible cessation of respiratory and cardiovascular systems.

b - Complete irreversible cessation of the functions of the brain including the brain stem.

This should be confirmed upon by the accepted medical standards.

Second -Guidelines for diagnosing brain and brain stem death:

- The presence of a reliable medical specialist well experienced in the clinical diagnosis of brain and brain stem death and the various implications of such diagnosis.
- Prescribed observation necessitates complete medical coverage in a specialized suitably equipped institution.
- Second opinion should be accessible whenever sought.

Preconditions necessary before considering the diagnosis of brain death:

1 - The person must be in continuous deep uninterrupted coma.

2 - The cause of the coma can be explained by extensive damage to the structure of the brain, such as severe traumatic concussion, massive intracranial hemorrhage, after intracranial surgery, a large intracranial tumor or obstructed blood supply to the brain: confirmed by adequate diagnostic measures.

3 - At least six hours have passed since the onset of coma.

4 - There is absence of any attempt at spontaneous breathing.

The diagnosis of complete irreversible cessation of brain and brain stem function necessitates:

1 - Deep coma with complete unreceptivity and unresponsivity.

2 - The clinical signs of absence of brain stem functions including absence of the pupillocornial reflex, absence of occulocephalic reflex, absence of occulovestibular reflex, absence of the gag reflex and absence of the cough and vomiting reflexes.

3 - Absence of spontaneous breathing as confirmed by the apnea test when the respirator is temporally disconnected. It should be borne in mind that:

- Some spinal reflexes may persist for some time after death. This is not incompatible with the diagnosis of brain death.
- Conclusions ensuing upon "decortication" or "decerebration", and also "epileptic seizures", are incompatible with the diagnosis of brain death.

All cases should be excluded which may be reversible or curable such as:

1 - If the patient is under sedatives, transquilizers, narcotics, poisons or muscle relaxants; or if in hypothermia below 33ºC; or in an untreated cardiovascular shock.

2 - Metabolic or endocrine disturbances that might lead to coma.

3 - There should be certainty of complete cessation of brain function over a period of observation of:

- 12 hours since the onset of irreversible coma.
- 24 hours if the coma is due to cessation of circulation (such as cases of cardiac arrest).
- in children under 2 months of age, the observation period is extended to 72 hours,followed by repetition of electroence phalograpy or tests for cerebral circulation.
- children between 2 and 24 months of age require a longer observation period of 24 hours followed by repeat encephalography.
- children over one year of age are handled like adults.

Specifications of the team authorized to diagnose brain death:

1 - The team comprizes two specialists with experience in diagnosing brain death. A neurologist's opinion is also sought if necessary.

2 - One of the two doctors of the team should be a specialist in neurology, neurosurgery or intensive care.

No member of the team should be --

1 - a member of the organ transplantation team,

2 - a member of the family of the deceased person,

3 - have any special interest in the declaration of death (such as inheritance or bequeath),

4 - blemished by any accusation by the family of the deceased that he had committed any professional misconduct.

Proposed Form For Issuing a Brain Death Certificate by (A space for the signature of every member of the medical team against each item is preferable)

	First Examination at initial diagnosis of brain death	Second Examination six hours after initial diagnosis
A- Preconditions:		
- Extensive noncurable brain damage (mention cause)	.....	.....
- Six hours passed since onset of coma - Absence of spontaneous breathing	.....	.....
B - Exclusion of confusing causes:		
- Is temperature below 33 °C?	.....	.....
- History of sedatives, tranquilizers, poisons, muscle relaxants	.....	.....
- Laboratory assay of above drugs?	.....	.....
- Is this a case of untreated cardiovascular shock?	.....	.....
- Have metabolic and endocrine factors been excluded?	.....	.....

C - Clinical examination:		
- Is there unresponsiveness to external stimuli? -Are the following brain stem reflexes absent?	.....	.....
- pupillary reactivity to light	.....	.....
- response to touching cornea	.....	.....
- cephalo-occular reflex	.....	.....
- vestibulo-occular reflex	.....	.....
- vomiting reflex	.....	.....
- cough reflex	.....	.....
D - Confirmatory tests: (if necessary):	☐ no electrical activity	☐ no cerebral circulation
- standard electroencephalography or		
- imaging for cerebral circulation		
E. After all the above has been fulfilled:	.....	.....
- has the apnea test been done?		
- what was its result	.....	.....

With all this, the Islamic Organization for Medical Sciences, with an immense sense of duty towards the Islamic Shariah and the public welfare which the Shariah aims at, appeals to all concerned to confine the discussion of such a sensitive issue within the relevant medical and scientific circles, instead of taking it out in a sensational way to the lay media shattering the confidence and trust of the public that was not given the complete correct data.

It would also behoove the relevant authorities in Muslim countries to issue legislation defining, regulating and safeguarding the diagnosis of death and the practice of organ donation and transplantation based upon the Islamic Sharia, for a legal vacuum is only conducive of confusion or malpractice.

The creation of a venue enabling the organ transplantation centers in Arabic and Islamic countries to communicate, network and exchange views and experiences, should be given appropriate priority.

May God bless our efforts and guide our footsteps.

PARTICIPANTS IN THE 1985 SYMPOSIUM ON HUMAN LIFE: ITS BEGINNING AND ITS END

Held in Kuwait
By
The Islamic Organization
For Medical Sciences

List of Participants in the 1985 Symposium

1 - **Dr. Abdallah Al-Issa**
Vice-Chairman, Court of Appeal, Kuwait

2 - **Dr. Abdallah Basalamah**
Professor of Obstertrics & Gynecology, Jeddah, Saudi Arabia.

3 - **Dr. Abdallah bin Abdelmohsen al Torky**
Rector, Imam Mohammad bin Saud University,
Riyadh, Saudi Arabia

4 - **Dr. Abdallah Mohd. Abdallah**
Counsel, Court of Appeal, Kuwait

5 - **Dr. Abdel Aziz Kamel**
Counsel, Emiri Office, Kuwait

6 - **Dr. Abdel Aziz Khalaf**
Director, Jahra Health Region, Kuwait

7 - **Dr. Abdel-Hadi Abu-Ridah**
Professor of Philosophy, University of Kuwait, Kuwait

8 - **Dr. Abdel Hafez Hilmi**
Professor of Zoology, Kuwait University, Kuwait

9 - **Dr. Abdelmohaimen Bakr Salem**
Professor of Criminal Law, University of Kuwait, Kuwait

10 - **Sheikh Abdel Qader Al-Emari**
Judge at First Court, Qatar

11 - **Sheikh Abdel Rahman Abdel-Khaliq**
Teacher of Religion, Ministry of Education, Kuwait

12 - **Dr. Abdel Razzaq Al-Bahr**
Director, Central Health Region, Kuwait

13 - **Dr. Abdel Razzaq Al-Samerraie**
Ibn-Sina Hospital, Kuwait

14 - **Dr. Abdel Sattar Abu Ghudah**
Juridical Encyclopedia, Kuwait

15 - **Dr. Abdul Mohsen Khalil**
Cheif of General Medical Board, Kuwait

16 - **Dr. Abdul Rahman Al-Sumeit**
Sabah Hospital, Kuwait

17 - **Dr. Adel al-Tawheed**
Ministry of Health, Kuwait

18 - **Dr. Adel Fattah Othman**
Professor of Social Service, Kuwait University, Kuwait

19 - **Dr. Agil al-Nashmi**
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20 - **Dr. Ahmad Abul Fadl**
The Center for Islamic Medicine, Kuwait

21 - **Dr. Ahmad Al-Shatti**
Ministry of Public Health, Kuwait

22 - **Dr. Ahmad el-Ghandour**
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23 - **Dr. Ahmad el-Kadi**
Chest Surgeon, U.S.A.

24 - **Dr. Ahmad Fouad Khalil**
Chairman, Department of Pediatrics, Farwaaniyah Hospital, Kuwait

25 - **Dr. Ahmad Naim**
Director, Central Technical Health Services, Kuwait

26 - **Dr. Ahmad Sharafel-Deen**
Ass. Prof., Faculty of Law, Kuwait University, Kuwait

27 - **Dr. Ahmad Shawki Ibrahim**
Physician, Sabah Hospital, Kuwait

28 - **Sheikh Ali Abdel Wahab al-Motaweh**
President, Social Reform Association, Kuwait

29 - **Dr. Ali al-Seif**
Director of International Health Relations, Kuwait; Secretary General, Islamic Organization for Medical Sciences, Kuwait

30 - **Dr. Ali el-Tannir**
Director, Maternity Hospital, Kuwait

31 - **Dr. Aref Khalil Abu-Abd**
Faculty of Shariah & Islamic Studies, Kuwait

32 - **Sheikh Badr M. Abdel Bassit**
General Secretary of Islamic Encyclopedia, Awqaf Ministry, Kuwait

33 - **Dr. Enezi al-Enezi**
Director, Hormone Laboratory, Sabah Hospital, Kuwait

34 - **Counsel Fouad Tawfiq**
Counsel, Ministry of Health, Kuwait

35 - **Dr. Gamal Husni**
Orthopedic Consultant, Razi Hospital, Kuwait

36 - **Dr. George Abouna**
Chief of Organ Transplantation, Kuwait

37 - **Dr. Hassan el-Shazily**
Dean, Faculty of Sharia & Islamic Studies, Kuwait

38 - **Dr. Hassan Hathout**
Chairman, Department of Obstetrics & Gynecology, Kuwait University, Kuwait

39 - **Sheikh Hay A. Al-Hay**
Ministry of Awqaf & Islamic Affairs, Kuwait

40 - **Dr. Hussein al-Momen**
Chief of School Health, Kuwait

41 - **Sheikh Ibrahim al-Desouki**
Former Minister of Awqaf, Egypt

42 - **Dr. Issam al-Sherbini**
Consultant Physician, Sabah Hospital, Kuwait

43 - **Dr. Kafia Ramadan**
Faculty of Arts, Kuwait

44 - **Dr. Kamal Zanati**
Technical Director, Office of Minister of Health, Kuwait

45 - **Dr. Khalid Al-Madhkour**
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46 - **Dr. Laila al-Dossari**
Director, Maternity Hospital, Kuwait

47 - **Dr. Mahmoud el-Booz**
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48 - **Dr. Mamoun al-Hajj Ibrahim**
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49 - **Dr. Mohammad al-Ashqar**
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50 - **Dr. Mohd. Fakhr el-Islam**
Chairman of Psychiatry, Kuwait

51 - **Counsel M. Farooq Tawfiq**
Counsel, Ministry of Justice, Kuwait

52 - **Dr. M. Fawzi Feidallah**
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53 - **Dr. Mohd. Naeem Yassin**
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54 - **Mohammad Nasser Al-Hamdhan**
Undersecretary, Ministry of Awqaf, Kuwait

55 - **Dr. Mohd. Othman Shabir**
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56 - **Dr. Mohyiddin Saleem**
Chairman of Dermatology, Sabah Hospital, Kuwait

57 - **Dr. Mokhtar Al-Mahdi**
Chief of Neurosurgery, Ibn Sina Hospital, Kuwait

58 - **Sheikh Mokhtar al-Sallami**
Mufti of the Republic of Tunisia

59 - **Dr. Mostafa Sabri**
Faculty of Theology, Istanbul, Turkey

60 - **Dr. Nasr Ahmad Nasr**
School Health Department, Kuwait

61 - **Dr. Omar al-Ashqar**
Faculty of Shariah & Islamic Studies, Kuwait University, Kuwait

62 - **Sheikh Rashed Al-Hammad**
Counsel, Court of Appeal, Kuwait

63 - **Dr. Saddiqah al-Awadi**
Director of Genetices, Ministry of Health, Kuwait

64 - **Dr. Salah al-Ateeqi**
Director, Adan Health Region, Kuwait

65 - **Dr. Salah el-Dadah**
Kidney Transplant Unit, Kuwait

66 - **Sheikh Saleh Moussa Sharaf**
Professor, Al-Azhar University - Council of Islamic Researches - Cairo, Egypt

67 - **Dr. Sami Matar**
Director, External Health Services, Kuwait

68 - **Dr. Shehab A. Shehab**
Fever Hospital, Kuwait

69 - **Dr. Talaat el-Kassabi**
Consultant, Maternity Hospital, Kuwait

70 - **Dr. Tareq al-Abdelgadir**
Assistant Undersecretary of Health, Kuwait

71 - **Dr. Tawfiq la-Tamimi**
Dean, King Faisal University Medical Faculty, Saudi Arabia

72 - **Dr. Tawfiq al-Waaie**
Faculty of Shariah and Islamic Studies, Kuwait University, Kuwait

73 - **Dr. Youssef al-Qaradawi**
Dean, Faculty of Shariah, Qatar

74 - **Sheikh Youssef el-Hajji**
Former Minister of Awqaf & Islamic Affairs, Kuwait

75 - **Dr. Youness Moftu**
Former Professor of Medicine - Undersecretary of Health, Turkey

76 - **Sheikh Zakiyddin Shaban**
Faculty of Shariah & Islamic Studies, Kuwait

RULINGS OF CONGRESS OF ISLAMIC JURISPRUDENCE, JEDDA, ON LIFE SUPPORT EQUIPMENT

In The Name of Allah, the Compassionate, the Merciful

Congress For Islamic Jurisprudence

Praise be to Allah, and Peace and Prayer upon Prophet Mohammad (saws)

Resolution No. (5) D 3/7/86
On "Life Support Equipment" (Resuscitation)

The Congress For Islamic Jurisprudence, in its third periodic meeting in Amman, Kingdom of Jordan, 11-16 October 1986, after duly considering the various aspects of the issue of "Life support equipment", and carefully listening to the adequate explanation of the specialist doctors, took the following resolution: a person is juridically considered dead and therefore juridically subject to all the rulings of death, if he (or she) bears one of the following two criteria:

1 - Complete cessation of the heart and respiration which is medically deemed to be irreversible.

2 - Complete cessation of all the functions of all parts of the brain that specialist medical expertise deem irreversible and the brain goes on to degeneration.

In this condition, it is permissible to disconnect the life-support equipment even if some organs such as the heart is still functioning by virtue of this connected equipment.

And Allah knows best.

PART FOUR

APPENDIX

APPENDIX (1)

LIST OF PARTICIPANTS IN THE INTERNATIONAL ISLAMIC CODE FOR MEDICAL AND HEALTH ETHICS

International Conference on "Islamic Code for Medical and Health Ethics" 11-14 December 2004 Cairo, Egypt

List of Participant

1 - **Dr. Abdul Hamid Hachicha**
Physicians Association
Tunis
Tunisia

2 - **Dr. Abdul Aziz Bilal**
Dean, Medical College
Alexandria University
Egypt

3 - **Dr. Abdul Aziz Mohamed Abdul Aziz**
Head of Anesthesia and Critical care
Ministry of Health
Jordan

4 - **Dr. Abdul Aziz Saleh**
WHO-EMRO
Egypt

5 - **Dr. Abdul Aziz Sheik Yousif**
Minister of Health
Somalia

6 - **Dr. Abdul Fatah Shawki**
Physicians Association
Egypt

7 - **Dr. Abdul Gaffar Mohamed**
Under Secretary
United Arab Emirates

8 - **Dr. Abdul Hameed Al-Harama**
ISESCO
Morocco

9 - **Dr. Abdul Kaliq Bin Al-Qadi Rajab**
Professor of Pathology
Tunisia

10 - **Dr. Abdul Monem Hasballah**
Physicians Association
Egypt

11 - **Dr. Abdul Muniem Abul Fotuh**
General Secretary of Arabian Physicians Union
Egypt

12 - **Dr. Abdul Rahim Mustafawi**
United Arab Emirates

13 - **Dr. Abdul Rahman Al Mahmoud**
Qatar

14 - **Dr. Abdul Rahman Al-Aqeel**
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Kingdom of Saudi Arabia

15 - **Dr. Abdul Rahman Al-Awadi**
President
Islamic Organization for Medical Sciences (IOMS)
Kuwait

16 - **Dr. Abdul Rahman Al-Toom**
President, Medical Ethics Committee
Sudan

17 - **Dr. Abdul Sabour Marzouk**
Ministry of Awqaf
Egypt

18 - **Dr. Abdul Sattar Abu Ghuddah**
Kingdom of Saudi Arabia

19 - **Dr. Abdulla Saeed Hattab**
Dean, Faculty of Medicine and Health Sciences
University of Aden
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Yemen

20 - **Dr. Abdullah Ahmed Junaid**
Professor, Medical College
Yemen

21 - **Counselor. Abdullah Al-Essa**
Member of Executive Committee
Islamic Organization for Medical Sciences (IOMS)
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22 - **Dr. Abdullah Al-Naseef**
Kingdom of Saudi Arabia

23 - **Dr. Abdullah Al-Sharif**
The Assistant Deputy, Ministry of Health
Riyadh
Kingdom of Saudi Arabia

24 - **Dr. Abdullah Basalamah**
Professor of Obstetrics & Gyanecology
Jeddah
Kingdom of Saudi Arabia

25 - **Mrs. Abeer Ahmed Zaid**
Egypt

26 - **Dr. Abellah Abdul Rahman Ali**
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65 - **Mrs. Asma Ghuniam**
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APPENDIX (2)

LIST OF PARTICIPATING ORGANIZATIONS / AUTHORITIES IN INTERNATIONAL CONFERENCE ON "ISLAMIC CODE FOR MEDICAL AND HEALTH ETHICS" 11-14 DECEMBER 2004 CAIRO, EGYPT

Appendix (2)

LIST OF PARTICIPATING ORGANIZATIONS / AUTHORITIES In International Conference on "Islamic Code for Medical and Health Ethics" 11-14 December 2004 Cairo, Egypt

1 - Islamic Organization for Medical Sciences (IOMS), Kuwait.
2 - WHO (EMRO)
3 - ISESCO, Morocco
4 - CIOMS
5 - Arab Physicians Union, Egypt
6 - Physicians Association of Egypt
7 - Physicians Association of Syria
8 - Physicians Association of Jordan
9 - Physicians Association of Morocco
10 - Physicians Association of Tunisia
11 - Physicians Association of Sudan
12 - Physicians Association of Somalia
13 - Physicians Association of Kuwait
14 - Physicians Association of Bahrain
15 - Physicians Association of Oman
16 - Physicians Association of U.A.E.
17 - Medical Ethics Study Center, Pakistan

18 - King Faisal Bio-Ethics Center
19 - Islamic Center, California, U.S.A.
20 - Ajman Net for Science and Technology
21 - Public Study Center, Al-Azhar, Cairo
22 - Islamic Medical Ethical Committee, Islamic Physicians Association
23 - International Islamic Physicians Association
24 - Counsel of Arab Countries
25 - Counsel of Gulf Health Ministers
26 - Dar of Al Efta, Egypt
27 - European Counsel for Efta
28 - Medical College, Kuwait University
29 - Medical College, Cairo University
30 - Medical College, Ain Shams University
31 - Medical College, Alexandria University
32 - Medical College, Damascus University
33 - Medical College, Aleppo University
34 - Al Azhar University
35 - Asyut University
36 - Islamic High Counsel
37 - Riyadh University
38 - Jeddah University
39 - Sanaa University, Yemen
40 - Red Crescent Society, Egypt
41 - Ministry of Health, Egypt
42 - Ministry of Health, Jordan
43 - Ministry of Health, Syria
44 - Ministry of Health, Kuwait
45 - Ministry of Health, Libya
46 - Ministry of Health, U.A.E.