

The Islamic Viewpoint on the International ethical Guidelines for  
Biomedical Research Involving human Subjects

By

Hossam E. Fadel, MD, PhD, FACOG

Islam encourages the pursuit of learning. There are several Quranic verses and traditions of the Prophet to that effect. The first revealed verses of the Quran state "Recite in the name of your Lord, Who created. He created man from a clot of blood. Recite, and your Lord is Most Generous, Who has taught by the pen. He taught Man that what he knew not" (Al-'alaq 96:1 - 5). Allah also says, addressing the Prophet, "Say, "My Lord, increase my knowledge"" (Taaha 20:114). The Prophet said "God, let me benefit from what You have taught me, teach me what benefits me, and increase my knowledge."

Learning in Islam is not limited to religious studies. Early Muslim scholars used to acquire an extensive knowledge, not only in jurisprudence (fiqh), Quran and linguistic studies, but also in medicine, chemistry, and natural sciences.

Scientific research is a religious duty. Allah asks us to look inside ourselves and at the universe to discover God's laws. "Let man consider from what he is created. (AL-Tariq 86:5-7). And: "Will they not reflect on camels, how they are created; the sky, how it is raised; the mountains, how they are

erected; and the Earth, how it is leveled." (Al-Ghashiah 88:17-20).

Research involving human subjects creates a lot of potential pitfalls that unfortunately led to tragedies in the last century. The most well known of which is the experimentation by Nazis on the prisoners and the Tuskegee syphilis experiment in the USA. This led to the establishment of ethical principles to guide research involving humans. These are:

1. Respect of persons.
2. Beneficence
3. Non malficence
4. Justice

These four principles are clearly in agreement with Islamic rules. Allah says "we have honored Adam's children" (Al-Israa 17:70). Respect of the person is a major aspect of the dignity of a human being. Respect of the person gives him the right to make his own choices and decisions. In the context of research it means that, no one should be involved in a research project without his free and voluntary consent. The Islamic principle that applies

here is "No one is entitled to dispose of the right of human being without his permission".

A basic purpose of Islamic law is to "secure benefits for people and to protect them from harm." This is termed "beneficence" in our lexicon at present. Another Islamic law states that "every action that leads to harm or that prevents a benefit is forbidden" i.e. That what is now called "non-maleficence." In cases where benefit and harm are not absolute which is the usual case in biomedical research, the rule that applies is that if a less substantial instance of harm and an outweighing benefit are in conflict, the harm is forgiven for the sake of the benefit.

Justice is an established principle in Islamic law Allah says "God enjoins justice and charity" (Al-Nahl 16:90). Justice means equity and fairness and charity is either the acquisition of benefit or the prevention of harm.

The CIOMS guidelines are meant to apply these ethical principles into actual

practice. Therefore, in general, they are in agreement with Islamic principles.

The performance of research on human subjects is Islamically acceptable. However, it should be useful and responsive to the purposes of Islamic Law, including the safeguarding of one's religion, life, intellect, progeny, and property, and that it should cause harm to none of God's creatures. On the other hand, a person who pursues scientific knowledge to cause harm is subject to God's wrath. God says, "And they learn what causes them harm and brings them no benefit, and they already know that whoever purchases it has no share in the hereafter." (2:102) The Prophet asked God's refuge from learning that brings no benefit. The research should by no means lead to something prohibited. A researcher should comply with the framework of Islamic Law in any research he undertakes. Moreover, a researcher should observe the rules and ethics of the profession especially as they relate to the ethics of biomedical research. To be more specific, the research is Islamically acceptable under the following conditions:

- 1) The purpose of the study is to secure an absolute benefit i.e., enhancing human health, or to prevent an instance of absolute harm which impairs health or to give priority to securing an outweighing benefit over preventing a less substantial instance of harm.
- 2) The benefit does not violate a legal stipulation nor contradict any absolute ruling of Islamic jurisprudence.
- 3) The research itself should be legitimate i.e. both the means and end must be legally permissible.
- 4) Further the design of study should be scientifically sound so that it should be more likely to achieve the purpose it is expected to accomplish that is in accordance with the rule that "every action that ceases to pursue its objective is unacceptable."
- 5) That the research team is qualified and competent to conduct the research as consistent with the Quanic guidance "God enjoins you to deliver your trust to their rightful owners" (4:58) and the prophetic saying "Allah loves the person who is performing a job, to do it in the best possible way".

I will then discuss some of the CIOMS ethical guidelines.

A Universally accepted standard is the establishment of Ethical review committees to evaluate biomedical research and to ensure that its purpose and methodology are in accordance with the ethical guidelines. Usually the committees consist of scientists, physicians, lay people and legal personnel.

In an Islamic country it is recommended that the ethical review committee gets the opinion of an Islamic jurisprudence (fiqh) committee to be certain that the proposed study is within the guidelines of Islam. An Islamic rule is "A responsible adult is not to embark on any undertaking before he finds out how it is regarded by God".

The guideline that ethical review committees should be independent of the research teams and sponsors is in agreement with Islamic principles. The ethical review committee is in effect giving a testimony. For such to be Islamically acceptable it must be made by a neutral party. To satisfy this

requirement (validity of testimony) any material or nonmaterial rewards for the committees should not be contingent on the outcome of the review (testimony).

In case the research is externally sponsored i.e. by an institution, industrial/drug company from another country, 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 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. Equity for all people is a basic tenet of Islam and Allah says "God enjoins justice" (*Al-Nahl* 16: 90).

and "O mankind reverence your Guardian Lord who created you from a single person." (4:1)

In addition, another ethical review should be conducted in the host country

to make sure that the proposed research meets the health needs and priorities of that country. One of the purposes of Islamic law is "To place everything in its right place [on the list of priorities]."

On the basis of the Islamic Law 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. This is stipulated in Islamic jurisprudence (fiqh) rule, "No one is entitled to dispose of the rights of a human being without his permission" and "no right of a human being can be canceled without his consent."

It is a prerequisite for the validity of informed consent that it should be given with full knowledge and correct understanding, on the part of the subject, of what he is consenting to. Jurisprudence stipulations confirm this in saying that "mutual agreement can not be reached under conditions of ignorance," and that "consent to an unknown thing and acquittal from an unknown thing are not valid."

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.

There is no objection in Islamic Law to the compensation of research subjects for lost earnings and for transport and other expenses that might be incurred as a result of participating 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.

Additional financial or in-kind payments, made to induce participation in research may imply undue inducement. However if such payment does tempt the subject and he gives his consent, with his free will, his consent in Islamic jurisprudence, is valid.

However, there should be - in my view - some restriction because the additional payments given to a poor person, or the promise or even the provision of medical care to a person who does not have access to that care in less developed countries or uninsured individuals in Western societies, could be a significant inducement that may cloud the ability of the person to make a true informed decision. The person' may be willing to participate and expose himself to certain risks that if he was not in need of such incentives he may not have consented to the study.

The need to strike a balance between potential benefits and risks in research involving human subjects - with the prospective benefits being more likely and the need to minimize risks are both included in a basic principle of Islamic Law, "if a less substantial instance of harm and an outweighing benefit are in conflict, the harm is forgiven for the sake of the benefit.

It is acceptable from a religious perspective to use the expected, significant benefits to society, as a justification of the risks of interventions for an individual that do not hold out the prospect of direct diagnostic, therapeutic, or preventive benefit for him. This is based on a rule of jurisprudence: "Public interests take precedence over private ones.

This is different from the Helsinki Declaration and the CIOMS guidelines which emphasize that individual benefit precedes social benefits.

I would like Muslim scholars to clarify this point and to discuss to what extent this is acceptable.

The guideline about research in populations and communities with limited resources is consistent with the Islamic principle of justice and charity.

The guideline about the choice of controls in clinical trials can also be endorsed from an Islamic point of view as it requires the researchers to observe, in dealing with human subjects, the obligation of trust when choosing the method of intervention to protect their human rights fully and ensure their safety "God enjoins you to deliver your trust to their rightful owners " (4:58) and in accordance with the rule of prevention the greater of two instances of harm when neither is avoidable.

The guideline "Equitable distribution of burdens and benefits is again in harmony with the Islamic law that calls for justice in all affairs of life. "God enjoins Justice". So it is unfair that participants in a study share in the burdens i.e. the potential side effects or other hardships but they do not share in the benefits when a successful intervention is achieved but is not made available to them.

Islamic ruling is stricter in the matter of involving vulnerable persons than the current guidelines. There are two groups of vulnerable persons:

- A. Those who are mentally incompetent and children: A guardian can not authorize the involvement of such person in biomedical research except 1) if the research involves an absolute or weightier benefit.  
2) If the risks involved do not exceed what is associated with a normal medical or psychological examination of such people, or when the increase in risk level is slight and approved by an ethical review committee in cases when there is an urgent need to treat or diagnose diseases or health problems characteristic of, or unique to, the vulnerable class. This special need falls, in Islamic Law, "necessities which render permissible what is usually prohibited."
- B. Emergency room patients, residents of nursing homes and similar establishments, prisoners, refugees, displaced people, and the like cannot be forced, pressured, deceived, or 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. In a Divine tradition, the Prophet, blessings and peace be upon him, quotes his Lord, 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."

Thus, a special justification of recruiting vulnerable individuals to serve as research subjects is required in Islamic Law, and, as stipulated in the CIOMS guideline, strict measures to protect their personal rights and interests should be taken.

Islamic jurisprudence considers the exclusion of women of reproductive age from biomedical research as unjust because it deprives them from potential benefit. Her participation is conditional on her voluntary informed consent, including information on the precautions taken to spare her and her fetus if she becomes pregnant from any hazards. In Islamic law it is unacceptable for the permission of a husband to replace that of his wife.

However, I would ask Islamic scholars to comment on whether in the case of a married woman does she need to ask the permission of her husband to participate in such studies and if so under which circumstances.

Also, Islamically there is no objection to the participation of pregnant women in biomedical research because of the potential benefit to her and to the fetus that can be derived from such research. While ideally before enrolling pregnant women in biomedical research, the investigators should rule out any harm to the fetus, that is almost impossible to achieve. The safety of new medications can not be assumed from animal experiments or from the study of the pharmacology of the used medication. There will always be some risk. Islamically, it will still be OK if the mother or the fetus is likely to gain an absolute or outweighing benefit, to accept the possibility of such harm.

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.

In some instances, the clinical trials are meant for the treatment of the fetus and not the mother. In these cases there are more risks to the mother without any benefit to her. The most obvious example is maternal fetal surgery to correct a fetal birth defect. In these cases, the maternal instinct may unduly influence her to agree to such trials. Ethically and Islamically, the investigators should make an extra effort to explain the trial, the potential benefit to the fetus and the potential complications in the neonatal management, the short and long term prognosis for the fetus/neonate/child and specially the short and long term complications for the mother before she agrees to participate in the trial.

Safeguarding the confidentiality is a basic tenent of Islamic law. This is the "trust" between an individual and the physician/investigator. 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. Also there are cases where

revealing confidential information is permitted, because it brings a social benefit, or prevents public harm.

Research subjects are entitled to free medical treatment when they incur any disease as a result of their involvement in the research. They are also entitled to equitable compensation for any impairment, disability, or handicap that result from their participation. Their entitlement is based on the principal of justice and by 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.

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.

When a subject dies as a result of his participation in research, his heirs are entitled to monetary compensation, which is the blood money stipulated in Islamic Legislation for accidental homicide.

An exception is cases when the investigators or sponsors obtained in advance, the subjects' informed consent to waive the investigators' responsibility, including their entitlement to compensation for disability and handicaps, when they are not deliberately caused. While Islamically, a competent individual is entitled to waive voluntarily any right of his, there is danger of it being abused. I would think that waiving of the right to reparation better not be permitted.