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EDITORIAL

Biomedical research ethics: An Islamic view — part I

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Abstract Most of the currently accepted western basic principles of ethics in research are consistent with the instructions of Islam. This statement may come as a surprise to some western researchers. In this article, I will discuss why Islam rejects secularization and this is not because the ethical principles embedded in Islam's teachings are archaic and out of touch with current realities. In addition, I will point out the agreement between general broad principles of research ethics and Islamic teachings concerning life; this would show clearly that Islam has addressed the regulation of ethics in research more than 14 centuries ago.
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History

The basic principles of ethics were first found in the pyramids texts from approximately 3000 B.C, and they echoed throughout Egyptian history.[1] The three principal sources of Egyptian morality were: man's self-contemplation in search of the human roots of good and evil; the demand that justice be done if harmony and stability were to be established; and religious thoughts that promised heavenly rewards for good deeds on earth.[2] Following the Pharaonic era, different consecutive religions promoted good deeds and morals till Islam, as the prophet Mohamed (peace be upon him) said, I was sent to complete the epitomes of Ethics.[3]

Basics of Islam

Islam is the second most common faith in the world with over a billion adherents.[4] The basics of Islam were summarized beautifully in the hadith narrated on the authority of ('Abdullah) son of Umar Ibn-El-Khatab. The prophet (peace be upon him) was asked by Gabriel the Angel about Al-Islam, Iman and Al-Ihsan. He replied: [Al-Islam implies that you testify that there is no God but Allah and that Muhammad is the messenger of Allah, and you establish prayer, pay Zakat, observe the fast of Ramadan, and perform pilgrimage to the (House) if you are solvent enough (to bear the expense of the journey). Iman (faith) implies that you affirm your faith in Allah, in His angels, in His Books, in His Apostles, in the Day of Judgment, and you affirm your faith in the Divine Decree about good and evil. Al-Ihsan (performance of good deeds) implies that you worship Allah as if you are seeing Him, for though you don't see Him, He, verily, sees you].[5]

The teaching of Islam covers all the fields of human activity. The instructions, which cover everyday activity is called Shari'a. The sources of Shari'a are primary and secondary sources. The primary sources in a chronological orders are: the Holy Quran; The Sunna (Hadith), which are the authentic traditions and sayings of the Prophet Mohamed (peace be upon him); Igma', which is the

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unanimous opinion of Islamic scholars or A'imma; and Analogy (Qias), which is a reasoning used to rule on events not mentioned in the Quran and Sunna by matching procedures of similar or equivalent events. The secondary sources of Shari'a are: Istihsan (the choice of one of several lawful opinions); views of Prophet's companions; current local customs if lawful; public welfare; rulings of previous divine religions if not contradicting the primary sources of Shari'a. The Shari'a is not rigid, it is flexible enough to adapt to emerging situations in different times and places. The hardship rule allows a forbidden action to be undertaken if the alternative would cause harm.[6]

Secularization, Islam, and ethics

Secularization means humans ruling their lives, with no regard or consideration to a higher spiritual authority. Some Secular advocates consider following the divine law would result in misery for the people.[7] This may be the basis as to why some societies have separated the church from every day life and replaced God's rules with man made laws and guidelines. The secular reasoning evolved when societies were faced with ethical and practical dilemmas. This reasoning can be weak and inconsistent if not based on an underlying coherent system of moral values.[8] These secular guidelines, for example, deal paradoxically with some situations, e.g. a man who marries two wives should be punished severely for the crime of bigamy, as the U.S. Supreme Court ruled in 1878. Plurality of wives (polygamy), as originally permitted by the Mormon religion, violated criminal law and was not defensible as an exercise of religious liberty. If on the other hand he co-habits with several women as girlfriends and has children with them, he will not be penalized so long he is paying child support.[9]

Western countries do not understand why Muslims are against implementation of secularization in their countries. We have to understand that Islam is not only a religion; it is a way of life. As mentioned earlier, the Shari'a controls every day activities of Muslims. Once an individual joins Islam, he is bound by Islamic rules and hence he is obliged to follow instructions and rules in the Quran as stated in Ayat: Al-Nisa (4): 65; Al Ma idah (5): 48—49; Al Araf (7): 3; Al Baqarah (2): 85 and Al Nisa (4): 59[10] as shown in Table 1. The rejection of Secularization within Muslim communities does not affect the relationship between Muslim countries and Secular States as Islam respects others believes and choices.

Table 1 List of Ayat of Quran referred to within the article

Islam and secularization	• But no, by thy Lord, they can have no (real) Faith, until they make thee judge in all disputes between them, and find in their souls no resistance against thy decisions, but accept them with the fullest conviction (Al-Nisa (4): 65).
	• And this (He commands): judge thou between them by what God hath revealed, and follow not their vain desires, but beware of them lest they beguile thee from any of that (teaching) which God hath sent down to thee. And if they turn away, be assured that for some of their crimes it is God's purpose to punish them. And truly most men are rebellious (Al Ma idah (5): 49).
	• Follow (O men!) the revelation given unto you from your Lord, and follow not, as friends, or protectors, other than Him. Little it is ye remember of admonition (Al A raf (7): 3).
Broad guidelines for research ethics	• We have honoured the sons of Adam; provided them with transport on land and sea; given them for sustenance things good and pure; and conferred on them special favours, above a great part of Our creation (Al Isra (17): 70).
	• It is not righteousness that ye turn your faces towards East or West; but it is righteousness- to believe in God and the Last Day, and the Angels, and the Book, and the Messengers; to spend of your substance, out of love for Him, for your kin, for orphans, for the needy, for the wayfarer, for those who ask, and for the ransom of slaves; to be steadfast in prayer, and practice regular charity; to fulfill the contracts which ye have made; and to be firm and patient, in pain (or suffering) and adversity, and throughout all periods of panic. Such are the people of truth, the God-fearing (Al Baqarah (2): 177).
Respect for persons	• Let there be no compulsion in religion: Truth stands out clear from error: Whoever rejects Evil and believes in God hath grasped the most trustworthy handhold, that never breaks. And God heareth and knoweth all things (Al Baqarah (2): 256).

One would ask what is the relationship of such rejection of secularization in Muslim communities and biomedical research ethics? The simple answer is that certain research ideas are considered unlawful under Sharia. The purpose of listing the Ayat of Quran is to make it clear to the reader that it is a divine command to follow the rules of Sharia (not Secular laws) in Muslim States. The clear example of such forbidden research ideas is the use of surrogate uterus for the treatment of infertility and the use of tissue cloning and gene manipulation to control the characteristics of an embryo, which is an interference with God's power and will. Also payment for subjects to participate in phase I trials, in which there is no direct benefit to the subject. Some would use the participation in such trials as a profession, such as modeling, which is unlawful and forbidden under Islamic law.

Broad guidelines for research ethics

The teaching of the prophet (peace be upon him) inspires to conduct medical research. He stated that [there is a cure for every disease and we should search for it]. Islam puts emphasis on seeking knowledge and benefits from it. There is no consideration for knowledge that provides no utility. Islam encourages precision in conducting research, which should add value. In addition, Islam forces dissemination of knowledge and prohibits hiding it; as the Prophet (peace be upon him) said: [Whoever withholds knowledge arrives in the judgment day leashed with a leash from fire].[11]

Islam looks at the problems of human experimentation as a purely legal issue as stated in Al Isra (17): 70 and Al Hijr (15): 28—31. In addition, Islam provides adequate guidelines and safeguards for the protection of human subjects as stated in Al Baqarah (2): 177 (Table 1).

Islamic ethical guidelines of research are derived from the purposes and principles of the Islamic law (Shari'a). Medical research in an Islamic community should be conducted for one of five reasons, which are known as Maqasid Al-Shari'a.[12] These reasons or goals for conducting medical research are: 1) preservation of religion and morality; 2) preservation of life and health; 3) preservation of progeny (curing infertility); 4) preservation of intellect; and 5) preservation of wealth. If any of the five purposes is at risk, permission is then considered granted to undertake human experiments that would be otherwise morally according to Islam prohibited. The principles of the law can be divided into five categories[8]:

1. *Intention of research*: If the purpose of the proposed research is ill intentioned, ill-conceived, or the method used in determining the objective is scientifically invalid, then the research project is not ethically acceptable.
2. *Certainty and doubts*: There must be some empirical evidence of low efficacy of the current standard of care and treatment or potential benefits of the proposed new treatment before an experiment is authorized.
3. *Risks or Injuries*: Human experimentation is associated with potential hazards and risks. These risks have to be balanced against the harm caused by the disease and the potential benefit of the proposed new treatment (risk/benefit ratio).
4. *Hardship*: Necessity legalizes the prohibited. An example of such a situation is participation in a phase I trial. When there is an endemic disease with no available successful standard of care, and there is a promising new drug as proven by experimental studies, it would be permissible to expose healthy volunteers to the potential harm of participation in such trials for the benefit of the community provided that they receive no payment for such a utilitarian attitude.
5. *Custom or precedent*: The principle of custom (or standard of care) is used to define the standards of good clinical practice. The standard of care is when the majority of reasonable physicians consider as reasonable care and which constitutes a professional standard.

The Western foundational principles of research ethics as mentioned in the CIOMS (Council for International Organizations of Medical Sciences) guidelines[13] and other documents[14—16] include: respect for persons, beneficence/non-maleficence and justice.

(1) *Respect for persons* incorporates at least two fundamental ethical considerations, 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. Islam respects autonomy even in the issue of belief as stated in Al Baqarah (2): 256; Yunus (10): 99 and Al Baqarah (2): 272 (Table 1).

The consent process including the documentation of consent usually should create transparency in the research process to augment respect for

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person. In addition, it helps in insuring the protection of the welfare of the research subjects. Consent to participate in an experiment does not remove the duties and obligations of the traditional doctor-patient relationship. In Islam, consent is allowed under the doctrine of the ''human temporary custody of life''. This means that the subject and physician or researcher are accountable before God for any decision made, such as consenting to a highly risky experiment that has no potential direct benefit. This is why Islam would object to phase I trials in healthy subjects unless under unique and compelling circumstances with every effort made to protect the participants and detect complications as early as possible and take the necessary steps to treat it.

The event of unintentional death or injury to a human subject due to participation in an experiment could trigger a criminal charge, for which compensatory and not punitive damages are awarded. Having the subject's signature on an informed consent document does not relieve the investigator from financial liability and thus not admissible as a defense in this case. The strictness of the Islamic law in this matter is intended more as a deterrent to the investigator to use great care during the study protocol.

The protection of subjects participating in research includes the protection of the decisionally impaired subjects by allowing a guardian to make the decision in their behalf. Furthermore, the subject's confidentiality should be protected as stated in Yusuf (12): 5 (Table 2).

The Prophet (peace be upon him) stated that [all my nation is forgiven except those who reveal secrets], also he stated [that whoever protects the secret of a Muslim his secrets would be protected by God in life and hereafter].[17]

(2) *Beneficence* refers to the ethical obligations to maximize benefits and to minimize harms. This principle indicates that the risks of research should be reasonable in the light of the expected direct benefits, that the research design is sound, and that the investigators are competent both to conduct the research and to safeguard the welfare of the research subjects. Beneficence further means avoidance of the deliberate infliction of harm on persons. This aspect of beneficence is sometimes expressed as a separate principle, *non-maleficence* or ''do no harm'' as advised by the Prophet (peace be upon him). Also the Quran prohibits us from inflicting harm to people as stated in Al Ahzab (33): 58 (Table 2).

(3) *Justice* refers to the ethical obligation to treat each person in accordance with what is morally right and proper to give each person what is due to him or her. In the ethics of research involving human subjects, the principle refers primarily

Table 2 List of Ayat of Quran referred to within the article

Confidentiality protection	• Said (the father): My (dear) little son! Relate not thy vision to thy brothers, lest they concoct a plot against thee: for Satan is to man an avowed enemy (Yusuf (12): 5).
Non-maleficence	• And those who annoy believing men and women undeservedly, bear (on themselves) a calumny and a glaring sin (Al Ahzab (33): 58).
Justice	• God doth command you to render back your trusts to those to whom they are due; And when ye judge between man and man, that ye judge with justice: Verily how excellent is the teaching which He giveth you! For God is He Who heareth and seeth all things (Al Nisa (4): 58).
	• O ye who believe! Stand out firmly for justice, as witnesses to God, even as against yourselves, or your parents, or your kin, and whether it be (against) rich or poor: for God can best protect both. Follow not the lusts (of your hearts), lest ye swerve, and if ye distort (justice) or decline to do justice, verily God is well-acquainted with all that ye do (Al Nisa (4): 135).
	• O ye who believe! Stand out firmly for God, as witnesses to fair dealing, and let not the hatred of others to you make you swerve to wrong and depart from justice. Be just: that is next to piety: and fear God. For God is well-acquainted with all that ye do (Al Ma idah (5): 8).
	• If thou judge, judge in equity between them. For God loveth those who judge in equity (Al Ma idah (5): 42).
	• Say: My Lord hath commanded justice; and that ye set your whole selves (to Him) at every time and place of prayer, and call upon Him, making your devotion sincere as in His sight: such as He created you in the beginning, so shall ye return (Al Araf (7): 29).
	• God commands justice, the doing of good, and liberality to kith and kin, and He forbids all shameful deeds, and injustice and rebellion: He instructs you, that ye may receive admonition (Al Nahl (16): 90).

to *distributive justice*, which requires the equitable distribution of both the burdens and the benefits of participation in research. Other forms of justice include: the respect of people's rights (*right based justice*), *legal justice* (respect of morally acceptable laws) and *justice as reciprocity* (post-trial benefit). Justice in Islam is the basic of ruling between people and relations in different aspects of life as stated in Ayat: Al Nisa (4): 58; Al Nisa (4): 135; Al Ma idah (5): 8; Al Ma idah (5): 42; Al A raf (7): 29 and Al Nahl (16): 90 (Table 2).

The Prophet Mohamed (peace be upon him) said: [There is no special merit of an Arab over a non-Arab except by righteousness and piety and you are all from Adam and Adam is from dust]. Also he said: [People are as equal as the teeth in the toothcomb, and superiority comes only through good deeds and piety].[18]

Conclusion

Islamic law is based on a complete system of morality that can provide a moral context in medicine from a legal perspective. Muslim teaching is also very flexible and adaptable to many new and novel situations. Strictly speaking, Muslims need not have ethical teachings as a separate discipline because it is already included in their law. Morality and ethics in Islam are absolute and are of divine origin. Islamic law automatically bans all immoral actions as ''Haram'' and automatically permits all what is moral as Mubaah. Ethical guidelines are both fixed and variable. The fixed moral and legal principles are broad enough to encompass the needs of all times and places. However, there may be some differences among religious scholars in the interpretation of the flexible part of morality and ethics application. Each Scholar is accountable to his opinion and carries the consequences of benefits or sins for those who follow his decision. Islam rejects secularization. Accordingly, in a Muslim community a researcher should observe that research and the procedures followed are within the context of Shari'a.

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