

How Does Iranian's Legal System Protect Human Vulnerability and Personal Integrity in Medical Research?

Mohammad Taghi Karoubi ^{1*}, and Mohammad Mehdi Akhondi ²

1. *University of Science and Culture, ACECR, Tehran, Iran*

2. *Reproductive Biotechnology Research Center, Avicenna Research Institute, ACECR, Tehran, Iran*

Abstract

The astonishing advance of medical science in recent decades has had endless advantages for humans, including improved level of health, prevention of disease and advances in treatment. These advances depend to a great extent on conducting continuous research. However, besides its enormous advantages, the sole interest of medical science undermines the principles of respect for human vulnerability and personal integrity, in both positive and negative approaches. The positive approach refers to the people who participate in research and practice, while the negative approach refers to people who are deprived of research and practice. The authors of this work, based on legal or moral grounds try to analyse the tension between the principle of respect for human vulnerability and personal integrity and the interest of medical science. Undoubtedly, in applying scientific knowledge and medical practice human vulnerability should be taken into account. In this regard, especially vulnerable individuals and groups should be protected and the personal integrity of such individuals respected. In the light of the merits of Islamic law, this paper is designed to examine the significance of the principles of human vulnerability and personal integrity in medical research by studying the international documents as formalised by UNESCO in order to explore the place of these principles in the Iranian legal system.

* **Corresponding author:**
Mohammad Taghi Karoubi,
Ph.D., University of Science
and Culture, ACECR, Tehran,
Iran
Tel: +98 21 44238171
Fax: +98 21 44214750
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Introduction

Despite the great benefits of medical research and practice in recent days, the sole interest of medical science in some societies undermines the principle of respect for human vulnerability and personal integrity in different approaches, positive (among the people who are under research and practice) and negative (among the people who are deprived of research and practice).

In the past, the concept of respect for human vulnerability and personal integrity

referred to unsuitable usage of something which threatened the stability of existence of an entity, but with the conduct of medical researches, studies and practices during recent decades, this concept has undergone fundamental change. This paper, in the light of Islamic law, examines the significance of the principles of human vulnerability and personal integrity in medical research by studying the international documents as formalised by UNESCO in order to explore the place of the

principles in the Iranian legal system.

The Concept of Vulnerability

Medical activities including saving human life, restoring life and health to humans, treatment of diseases, alleviating pain and conducting related research, are mainly based on ethics and conform to ethical values. However, reduced attention or lack of attention to ethical issues in some biomedical experiments and researches causes violation of human dignity and personal integrity, in contradiction with the philosophy of conducting experiment and research in this field ^(1,2).

The word "Vulnerable" comes from Latin, "*vulnerabilis*", meaning 'can be wounded' or capable of being wounded ⁽³⁾. Thus 'the meaning is extended to cover the state of being susceptible to injury in many forms. So, the term 'human vulnerability' refers to the state of human being that is susceptible to harms or injuries ⁽³⁾. Human vulnerability is well expressed in Article 8 of the Universal Declaration on Bioethics and Human Rights 2005 as follows:

In applying and advancing scientific knowledge, medical practice and associated technologies, human vulnerability should be taken into account. Individuals and groups of special vulnerability should be protected and the personal integrity of such individuals respected ⁽⁴⁾.

The above article highlights the special vulnerability of human beings that attends the doctor-patient relationship in the clinical setting, the researcher-subject relationship in human subject research as well as development and application of advances in biomedical science and biotechnology and associated products. Article 8, however, does not deal with vulnerability in general or as a broad philosophical concept ^(4,5). The article instead addresses the special vulnerability of certain individuals and groups. Therefore the article is intended to protect individuals and groups whose vulnerability is over and above that natural to the human condition. In this approach, individuals and groups of individuals who are uniquely at risk, who are vulnerable

to having their dignity or personal integrity disrespected, require special thought and care ^(4,5). Article 1 of the declaration also emphasises the scope of the declaration and addresses ethical issues related to medicine, life sciences and associated technologies as applied to human beings, taking into account their social, legal and environmental dimensions ⁽⁴⁾.

Violation of the principle of respect for human vulnerability and personal integrity of people who participate in medical research in general and of some groups who are widely regarded as vulnerable, such as disabled or children in particular, has either occurred during recent years or there was a risk of its occurrence in recent years ⁽¹⁾. For this reason, the issue has received some attention by policy makers, law makers, human rights activists and international organizations, even though they have different interpretations of the concept of respect for human vulnerability and personal integrity ⁽⁶⁾. A few decades ago the concept was only considered as a philosophical issue, but in the third millennium the ethical meaning of respect for human vulnerability and personal integrity was also raised in the field of bioethical issues in biomedical research. This way some attempts have been made by writers and organizations to define the concept of vulnerability. Therefore, it is either defined too narrowly or too widely.

However, The International Bioethics Committee (IBC) in its final report on the principle of respect for human vulnerability and personal integrity did not define vulnerability and emphasises recognition of vulnerability when it arises ⁽⁵⁾. It also emphasises both its importance and its complexity ^(5,7). Hurst in this regard argues that there is agreement that the vulnerable, including individuals, families, groups and communities, should be offered some kind of special attention or protection ⁽⁸⁾. In this approach groups, different people and special conditions that manifest particular potential for damage and vulnerability receive special attention.

Personal Integrity

The word "Integrity" stems from the Latin adjective "*integer*"⁽³⁾. Integrity is a concept of consistency of actions, values, methods, measures, principles, expectations, and outcomes. In ethics, the concept is regarded as the honestly and truthfulness of one's actions⁽⁹⁾. Ethical meanings of integrity used in medicine refer to a quality of wholeness that must be present in the human body. Integrity in health care ethics is usually taken to mean the whole of the life of a human being – medicine "fundamental aspects of a human life that should be respected". Personal integrity refers here to respect for the patient's understanding of his or her own life and illness, but also for his/her interests and free will⁽¹⁰⁾. Each person's life has coherence, a narrative whole based on important events in his/her life and by his/her interpretations and values. It is clear that personal integrity of human beings in medical research and experiment must be respected and protected.

Human Subject Research

The concept of vulnerability in the field of bioethics refers to human dignity. The notion also in ethics is not just a neutral description of the human condition but instead a normative prescription to take care of the vulnerability that is characteristic for human beings⁽⁵⁾. No doubt, some research populations are vulnerable and need special protection. In this regard the particular needs of the economically and medically disadvantaged must be recognised. Children, the disabled, women and immigrants are more vulnerable and it is necessary to provide legal support for them. Children are unable to make decisions and are under guardianship of their parents. The disabled are those who have special conditions imposed on them and live in a situation in which they are regarded as vulnerable groups in society. Women and immigrants, due to their special circumstances, are more endangered^(2,5,10). In developing countries violence against women for several reasons including economic and cultural reasons is regarded as a serious problem. The vulner-

ability of immigrants is also very high⁽¹¹⁾. Thus, states should try to improve the national level of awareness and public knowledge on the issue and also take more effective measures for legal support. In this regard, many questions are raised including nature of vulnerability in clinical treatment, the cause and context of vulnerability and remedies. Indeed, vulnerable persons are those who are relatively incapable of protecting their own interests and may have insufficient power, intelligence, education, resources, strength, or other needed attributes to protect their own interests.

However, it is true to say that the human condition implies vulnerability and taking account of human vulnerability requires an acknowledgment that we are all vulnerable. Fox in his article "Hotep's Story: Exploring the Wounds of Health Vulnerability in the US" argues that vulnerability is intrinsic to the human condition, as certainly as death⁽¹²⁾. In this field, any kind of activity that affects human dignity should receive attention. Awareness and training in relation to available dangers and preventive solutions may be regarded as greatly reducing the risk of damage to people's physical and spiritual integrity^(8,12). Since the right of individual to make personal decisions was recognised as fundamental value in bioethics, creating a suitable atmosphere and grounds for making wise decisions is very important⁽¹⁰⁾. Meanwhile it should be noted that autonomous and wise behaviour of persons can only be achieved when they are able to make informed decisions.

The reality of human life and the conditions imposed on them in different circumstances indicate that people are not living under equal economic, cultural and social conditions. In some developing countries economic pressure and poverty has resulted in transacting body organs. These regrettable transactions in some third world countries are like contract concluded between seller and buyer. Not only is there no legal impediment but also there is no practical will to terminate it. There is con-

siderable difference both *de jure* and *de facto* on the principle of respect for human vulnerability and personal integrity between developed and developing countries.

Therefore, the important question raised is: what is the place of the principle of respect for human vulnerability and personal integrity in Iranian legal system in the light of merits of Islamic teaching? If there is no contradiction between the principle of respect for human vulnerability and personal integrity and Islamic law what type of activity in this regard should be undertaken by legislators in Islamic countries in general and the Iranian Parliament in particular? The following section of this paper examines the concept of humanity in Islamic teaching very briefly in order to explore and determine the situation of human vulnerability in Islamic law in general and Iranian law in particular.

Humanity in Islamic Religious Law

A human being in Islam has two dimensions, material and spiritual, *i.e.* he or she has two talents and two possibilities in his/her personality, one is earthly talent or natural talent and the other is spiritual talent. Based on teachings of Holy *Qur'an* God has given humans freedom to choose each of these talents. In relation to human dignity in Islam, two points of view based on inherent dignity and valuable dignity are raised. Inherent dignity in relation to human matters means the naturally unchangeable and inherent characteristics from birth of an individual, people, minority or race of the human family. The basis of inherent dignity is an important characteristic when it comes to law and the protection from dehumanisation through discrimination, harassment and victimisation. The inherent dignity of the human beings offers the highest level of protection in any human rights laws, as explained in any human rights law introduction and interpretation preamble.

The inherent dignity of humans on the fundamental basis of humanity has received great attention in the Holy *Qur'an* ^(13,14). Indeed, inherent dignity or unmerited honour is bestowed upon all human beings by God

without any distinction based on sex, colour or religion ⁽¹⁵⁾. This doctrine is referred to in many verses of the *Qur'an* and reliable traditions. In this regard the Holy *Qur'an* says:

"We have honoured the children of Adam and carried them on land and sea, and provided them with good things, and preferred them greatly over many of those we carried (17:70)".

The Holy *Qur'anic* verse also says: "And breathed my spirit in him (15:29)". The inherent dignity of human originates from the beautiful relationship of humans with God. In Islamic teachings it is mentioned that God complimented himself after creating humans and said that human is competent for bow of angels. Islamic philosophers have said that the human is the creature that belongs to earth due to the talent received from God and after passing the herbal and animal stages he will achieve human and divine ruler stage and may achieve the highest stage of world.

Mahalati has correctly referred to some rights of humans including their natural rights and inherent dignity before faith and then discussed that each natural talent is regarded as natural right ⁽¹⁶⁾. He also believes that the creation system has granted will and freedom of thought to humans as creatures of God. Within this freedom the human may either achieve the highest stages of paradise or fall to hell. Again, in Islam, all people are endowed with inherent dignity and share on an equal footing rights and obligations, without any distinctions on the basis of race, colour, sex, religion or language. Jafari argues that Islam as a religion which embodies spiritual beliefs and rules considers that all human beings equally are God's subjects ⁽¹⁷⁾.

With regard to the above-cited verse, he also argues that the verse lays down the principle that God, in his wisdom, has originally bestowed honour on human beings generally without any discrimination and made them superior over all other creatures ^(14,17). Since God is the source of this special status of human beings and has created a special relationship with them, it becomes incumbent

on human beings to treat each other with honour and respect⁽¹⁸⁾. This firm and indisputable fact, *i.e.* that the honour bestowed on human beings comes from the highest source, makes the relationship established between the source and the recipients very valuable.

It is notable that according to Islamic teaching, apart from inherent dignity there is another honour which is considered as value dignity, which is acquired by a person who applies his or her innate aptitudes and talents in accomplishing that which is good and in pursuing the path of truth and justice (or the sensible life), maturity and eventually perfection^(14,19). The person who strives for value honour chooses to do so knowing his or her ultimate reward is a life of perfection. More important than the universally recognized belief in man's inherent dignity is the loftier concept of value honour that uses piety as its criterion. Some Islamic jurists in regard to value dignity refer to the Holy *Qur'anic* verse which says:

"O mankind, we have created you male and female, and appointed you races and tribes, that you may know one another. Surely the noblest among you in the sight of God is the most God fearing of you. God is All-knowing, All-Aware (49:13)".

They argue that since human beings, endowed with special privileges, talents and aptitudes, have often been guilty of deviating from divine and human precepts and have fallen into unjust, ignoble and morally unacceptable behaviour. It becomes clear why God granted for mankind only the capacity to be accorded honour and respect on the basis of reciprocity, *i.e.* people are endowed with all the necessary characteristics that will enable them to accord the same honour and dignity to others^(17,20,21). In other words, man's right to dignity is not an absolute that will allow him to claim the right in all cases. If he uses immoral or illegal means to obtain satisfaction of his desires and seeks power at the expense of his subjects, is guilty of using his talents and aptitudes for ill-objectives. Or to pursue the highest forms of self-centeredness,

he will evidently lose his right to honour, dignity and respect. Further, he will constitute a threat to others and should be punished as a criminal in order to protect others in the enjoyment of their rights to life, dignity and honour⁽²⁰⁾.

In this regard the important question arises: does respect for human being depend on his faith and religious beliefs? Some argue that a human without faith is a human without respect and religious beliefs are the basis of human respect and to lose divine respect means to lose inherent dignity^(17,22). It is to be noted that this argument not only is in contradiction with wisdom, but also is in contradiction with religious assumption. In the aforesaid verse of Holy *Qur'an*, sex, colour and races are not criteria for superiority and privilege of humans. The only thing which may result in achieving to the highest stages by a human is his/her *taqwa* or piety⁽¹⁴⁾. According to Islamic teaching, no one can claim to be superior to another, except based on piety before God. Even this advantage is not for the material world or application of rights, but this is between God and mankind. The present authors believe that these criteria are assessed only by God and humans can not issue orders for human piety with divine status. In this regard, Soroush Mahalati, by referring to religious texts, has criticized the view of some Islamic writers who argue that the inherent dignity of humans depends on their faith⁽¹⁶⁾. It is clear that Islam insists on inherent rights as a fundamental issue and thus, it is necessary to attempt to maintain and recognize these rights.

Regardless of the insistence of Islam in human dignity, *Shari'ah* insists on maintaining the value of human life. Article 2 of the Cairo Declaration on Human Rights in Islam in this regards provides that:

a) Life is a God-given gift and the right to life is guaranteed to every human being. It is the duty of individuals, societies and states to protect this right from any violation, and it is prohibited to take away life except for a *Shari'ah*-prescribed reason.

b) It is forbidden to resort to such means as may result in the genocidal annihilation of mankind.

c) The preservation of human life throughout the term of time willed by God is a duty prescribed by *Shari'ah* ⁽²³⁾.

It is a manifestation of the dignity of man that Islam has placed an infinite value on human life and indeed the protection of human life is seen as among the greatest bounties granted by God. The existence of life itself is a trust for every human being to utilize, and it is the basis of rights and duties. Human life is a right and duty. It is a type of right for each human, which nobody may violate, unless upon legitimate and justified ground such as punishment in accordance with law. It is also a duty because the person himself and others have a duty to protect human personal integrity. The personal integrity of humans has special importance in Islamic thought, because if it is not protected, it is impossible to benefit from other natural rights, such as freedom. That is why life is so much regarded and protected from being interrupted or discontinued by human intervention. Killing, ignoring life and imposing damage on the body is prohibited and counted as among the biggest sins. This is expressed in the Holy *Qur'an* in the following terms:

"Whosoever kills a human being (without any reason, like) manslaughter, or corruption on earth, it is as though he had killed all mankind (5:32)".

The Holy *Qur'an* also lays down:

"Do not kill a soul which Allah has made sacred except through the due process of law (6:151)".

Indeed, the protection of life as denoted by *Qur'anic* verses must not be exclusively understood as it is. Extension of the scope of life should be permitted so as to allow the protection to be granted effectively and in line with the purposes of human life itself. Not only the existence of life but the quality of life and safety is also protected in Islam. Allah says:

"And whosoever saves a life it is as though he had saved the lives of all mankind (5:32)".

Human health as well as other activities in human life are all attended and given concern in Islam. Shi'a dynamic jurisprudence has paid special attention to humans and their personal integrity. Violating human respect and personal integrity is in contradiction with Islamic teaching. Thus, legislators and policy makers in Islamic countries should enact laws to forbid of medical researches which result in violating human personal integrity.

Iranian Legal System

Among Muslim states that apply *Shari'ah* in their legal systems, the Iranian revolution of 1979 came with the idea of Islamization of all laws and regulations and judicial systems, namely the intended revival of pre-modern Islamic law, as a spiritual event in an increasingly secular world. Islamic law, as a sacred law, is the most typical manifestation of the Islamic way of life and is the kernel of political Islam ^(11,24,25). Following the Islamic revolution, which was to a large degree a reaction to the Shah's radical secularization programme, the first step taken by the new government was the preparation of a new constitution to reflect the new revolutionary goals: "freedom, rule of law and Islamic government", or in other words, Islamism and republicanism. The Islamic republic is a system based on belief in:

1. The One God (as stated in the phrase "There is no God except Allah"), His exclusive sovereignty and right to legislate, and the necessity of submission to His commands;
2. Divine revelation and its fundamental role in setting forth the law;
3. The return to God in the Hereafter and the constructive role of this belief in the course of man's ascent towards God;
4. The justice of God in creation and legislation;
5. Continuous leadership and perpetual guidance, and its fundamental role in ensuring the uninterrupted process of the revolution of Islam;

6. The exalted dignity and value of men, and his freedom coupled with responsibility before God; in which equity, justice, political, economic, social, and cultural independence, and national solidarity are secured by recourse to: Continuous *Ijtihad* of *Fuqaha* possessing necessary qualifications, exercised on the basis of the *Qur'an* and *Sunna* of the *Masumun*, upon all of whom be peace; Sciences and arts and the most advanced results of human experience, with the effort to advance them further; Negation of all forms of oppression, both the infliction of and the submission to it, and of dominance, both its imposition and its acceptance.

Making a modern and harmonized composition of those idealistic aspects of the revolution was not an easy task. Article 4 of the Iranian constitution of 1979, however, set the stage for using "Islamization" as a basis for changing substantive and procedural criminal law in post-revolutionary Iran. It states that:

All civil, penal, financial, economic, administrative, cultural, military, political laws and other laws or regulations must be based on Islamic criteria. This principle applies absolutely and generally to all articles of the constitution as well as to all other laws and regulations and the *Fuqaha'* of the Guardian Council are judges in this matter.

In the light of international declarations and documents on human subject research the 26 Codes has been customized by the Ministry of Health and Medical Education, Office of Study for Humanistic and Islamic Science on Medicine and Medical Ethics in accordance to Islamic law ⁽²⁶⁾. The Protection Code of Human Subject in Medical Research or 26 Codes is the most important legislation on the issue which covering new fields of science and technology ⁽²⁶⁾. The Protection Code of Human Subject in Medical Research pays attention to informed consent, human rights during research, certifying research projects according to risks and benefits, privacy of information, compensation of human subjects under investigation, sensitivity to cultural and religious implications, observing the rights of

prisoners and individuals with mental illness, and conducting research on fetuses. Later some guidelines such as the ethical guidelines for genetic research, the ethical guidelines for research on embryo and gamete, the ethical guidelines for transplantation, the ethical guidelines for research on specific groups have been ratified by a competent authority ⁽²⁶⁾.

However, a quick look at Iranian laws and regulations shows that less attention has been paid to the principle of respect for human vulnerability and personal integrity in medical research and practice. Presently, in the case of violation of the principle of respect for human vulnerability, we have to resort to the general principle of penal law or liability law in order to fill the current gap in our legal system. And it is clear that it is not possible to cover and provide a proper response to the most complicated issue in this field. Since there is no contradiction of this principle of respect for human vulnerability and personal integrity with the main source of Iranian law, therefore there is room for legislators of the country to take legal actions in order to achieve the objectives of the principle of respect for human vulnerability and personal integrity in medical research and practice as articulated by international instruments such as the Universal Declaration on Bioethics and Human Rights in particular.

Conclusion

Advancement of medical sciences, besides its endless advantages in prevention and treatment of diseases, on one hand created some dangers for human subjects who undergo experiment, research and treatment and on the other hand deprived persons who do not participate in experiment, research for treatment. Attention has been paid to discussion of the principle of respect for human vulnerability and personal integrity in medical research and experiment with respect to social and ethical issues within framework of national regulations of some countries and international documents. With respect to ethical issues, it is

to be noted that respect for the principle of human vulnerability and personal respect demands awareness of possible vulnerability and use of a variety of tools to take due action in the way of providing social support. Improving culture and observing ethical principles in society may remove grounds for abuse of vulnerable groups.

To present authors, Islam has paid special attention to humans and their personal integrity. Violation of human respect and personal integrity is in contradiction with Islamic teaching. Thus, legislators and policy makers in Islamic societies should enact proper legislation with regard to medical researches and treatment that may result in violating human personal integrity. Little attention has so far been paid to the principle of respect for human vulnerability and personal integrity in medical research and treatment in Iranian laws and regulations. Presently, in the case of violation of the principle of respect for human vulnerability, we have to resort to the general principle of penal law or liability law in order to fill the current gap in our legal system. And it is clear that it is not possible to cover and provide a proper response to the most complicated issues in this field. Since there is no contradiction of this principle of respect for human vulnerability and personal integrity with the main source of Iranian law, therefore there is room for the legislators of the country to take legal actions in order to achieve the objectives of the principle of respect for human vulnerability and personal integrity in medical research and practice as articulated by international documents instruments, such as the Universal Declaration on Bioethics and Human Rights in particular.

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