In the Name of God

Ethical Guidance for Research on Human Tissues and Organs in the Islamic Republic of Iran

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Introduction

Considering scientific and technical advancements resulting from research on human organs and tissues, and highlighting the significance of conducting such research would establish the need to observe relevant ethical principles and considerations as evident and crucial. Any use of human body, tissues or organs for treatment, training and research purposes must be in full compliance with ethical principles, especially human dignity, as well as legal and religious requirements. The present guidance entails fundamental ethical requirements and considerations to be observed and followed in research on human tissues or organs. For the purposes of this guidance, research on human tissues or organs means research projects using human body parts, including organs, tissues, or secretions from living or dead bodies, fetuses or placentae.

Researchers should know and follow the provisions of this guidance, the "General Ethical Guidance for Medical Research", special domestic guidances for research ethics in different disciplines, and any other related regulations or requirements. This guidance entails general and special provisions.

General Provisions

١ Researchers shall pay due attention to the fact that the organs and tissues being used have had human origins, and human dignity dictates their being gathered, stored, utilized and destroyed in compliance with relevant considerations and regulations.

٢ Human body parts may be used only in research projects that seek valuable objectives for combating diseases and promoting human health.

٣ Before being executed, all research projects on human organs and tissues shall be approved by relevant research ethics committees, entitled to supervise the entire stages of the study. Researcher(s) shall fully and effectively cooperate with the research ethics committee in question.

٤ Informed consent of the individuals donating tissues or organs, or their legal representative shall be considered as a pre-requisite for ethical approval of any research on human organs or tissues. The informed consent document shall be prepared in compliance with all applicable requirements, and be appended to the research proposal at the time of submission for approval.

٥ In cases where informed consent cannot be obtained from the individuals donating the stored samples, or their legal representatives, the sample may be used for the research project if approved by the relevant research ethics committee, and if initial general consent had been obtained for research usage. In such cases, only samples may be used that have been irreversibly anonymized.

٦ All information gathered and recorded from the owners of organs or tissues being studied shall be construed as professional secrets, and subject to all principles and considerations related to confidentiality and safeguarding privacy.

٧ The center executing the research project on human organs or tissues shall own the required skills and facilities to guarantee confidentiality. Otherwise,

the information to be used shall be recorded and stored in an anonymous and untraceable manner.

٨ Researcher(s) shall make optimal use of the organs and tissues made available for research purposes, and prevent their being wasted.

٩ Researcher(s) shall predict and take the required safety measures, including screening tests and protective equipment, to prevent transfer of contamination from the body parts being studied to other individuals, including the researcher(s), participants or others involved in the research process.

١٠ Research on human organs or tissues may engender methods or products with possible commercial utilizations. The intellectual property rights resulting from such studies shall be approved and supported. The possibility for commercial use of the research results and their potential beneficiaries shall be mentioned in the informed consent document.

١١ Time, method and extent of informing the participants about the research results shall be mentioned in the informed consent document. In any manner, participants or their legal representatives shall be provided access to all the information obtained in the course of the research about them.

١٢ In cases of shortage of tissues or organs, treatment purposes shall be considered as prior to research purposes.

Special Provisions

Chapter ١: Using Organs and Tissues of Aborted Human Fetuses for Research

The organism resulting from conception up to ٨ weeks shall be known as an embryo, after ٨ weeks until birth as a fetus, and from birth up to ٢٨ days as an infant. In any research on human fetuses, the provisions of this guidance, the principle of human dignity, as well as all legal and religious requirements shall be followed.

١ The necessity of the research project and other parts of the research proposal shall be approved by the relevant research ethics committee.

٢ Human fetuses shall not be subject to sales or other commercial uses.

٣ For studies using the body parts of aborted fetuses (as well as umbilical blood, still considered as fetal blood), the informed consent of both parents shall be obtained.

٤ Apart from the fetus, placenta and other uterine contents shall be construed as maternal tissues, for which the mother's consent shall be necessary and sufficient.

٥ The individual or team deciding on an abortion shall be completely independent from the team designing or executing the research project on that fetus after the abortion.

٦ Before completion of the abortion process, no decisions or negotiations shall be permissible about possible future uses of that fetus in the research project.

٧ Confidentiality and privacy of the individuals related to the fetus shall be guaranteed during the research process and publication of the results.

٨ The research project shall not cause any damage or injury whatsoever for the mother.

Chapter ٢: Taking Organs and Tissues from a Dead Human Body or a Brain-Dead Person

١ In all studies using organs or tissues from a dead human body, the scientific value, necessity of executing research and measures stipulated to respect the dignity of the deceased and rights of the bereaved (such as obtaining appropriate inform consent) shall be reflected in the research proposal and approved by the relevant research ethics committee.

٢ The method and conditions of obtaining consent for using a dead body for research purposes shall be similar to that for treatment purposes, meaning that the informed consent shall be obtained from the legal heirs of the deceased to take and use organs and tissues of the body in question. If before death, the deceased had expressly disagreed with his/her tissues or organs being used for research purposes, the heirs may not agree to such transaction.

٣ For cases involving research samples being taken from brain-dead patients, all conditions and legal requirements of the "Executive Code on Brain Death", and the "Brain Death Confirmation Protocol" shall be closely followed.

٤ Cardio-pulmonary support to brain-dead patients shall not be ceased with the sole aim of using their bodies for research purposes; any organ or tissue may be taken only after confirmation of the patient's cardio-pulmonary death or donation of critical organs for treatment purposes.

٥ Organs or body parts of deceased individuals may be stored in biobanks after obtaining the consent of their legal heirs, and only for the purposes mentioned in the consent document. The heirs may demand the stored items to be removed from the biobank at any time.

٦ After completed use for research, the body parts used should be destroyed or buried in accordance with Islamic rituals, or those of any other religion held by the deceased.

Chapter ٣: Research Including Organ or Tissue Transplant from Living Donors

١ In research including organ or tissue transplants, the living donor's intention and consent shall be held prior to the intention and interests of the receiver. Written informed consent shall be obtained from both the donor and receiver, the document for which shall include the method of project execution, objectives, type and extent of the organ or tissue to be donated and transplanted, and the risks involved in the process.

٢ Research projects may only use renewable organs or tissues of living individuals, such as bone marrow. In cases of dire need for using other organs, paired organs where the absence of one would not pose serious danger for the donors, may be used under the supervision and approval of the research ethics committee of the related university, provided that the donor receive proper insurance coverage for life, and be compensated for the possible damages of donating that organ. Using vital organs, such as heart or brain, or paired organs where the absence of one would seriously compromise the donor's life quality, shall be prohibited.

٣ If after the removal of tissues or organs, the donors require special treatment or follow-up measures within a designated period, the requisite conditions and facilities for follow-up or treatment shall be provided to the donors free of charge. Such research projects shall enjoy sufficient insurance coverage. If during or after the follow-up period, the donor develops a condition that can be attributed to donating that organ or tissue, the expenses resulting from that condition shall be covered by the research team.

٤ The donors may renounce donating tissues or organs before the research has reached the irreversible stage. In that case, that tissue or organ shall be destroyed or returned to the donors upon their request. The donors shall not be inflicted any charges as a result of their renunciation.

٥ Financial incentives and special concessions shall not be used to motivate individuals to donate tissues or organs.

٦ Individuals without the capacity for voluntary and informed consent, such as children, mentally retarded individuals, mental patients and prisoners, may not be chosen to donate tissues or organs for research purposes. The mentioned group may only participate as receivers and only in treatment studies with possible direct treatment benefits for them.

٧ The research project shall not compromise the provision of accessible and standard treatments to the receiver.

Chapter ٤: Biobanks

١ Human organs, tissues or body parts may be stored after obtaining the informed consent of the owner. Type and period of storage, as well as possible future uses shall be mentioned in the consent document.

٢ Individuals shall be entitled to demand their samples to be removed from the biobank, in case the identity of the donors is known or traceable.

٣ In case the identity of the sample donors is known or traceable, the informed consent of the donors or their legal representative(s) shall be obtained again for any further research.

٤ For samples with untraceable donors, further research may be conducted on the basis of the initial consent, without obtaining a new one.

٥ If the samples stored in biobanks could be used for both treatment and research purposes, priority shall be considered for treatment uses. In any case, the research project shall not compromise the extent or quality of treatment uses.