In the Name of God

General Ethical Guidance
for Medical Research with Human Participants
in the Islamic Republic of Iran

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Introduction

Medicine should revolve around treatment based on evidence acquired through research. In fact, the progress of medical sciences depends on research, a large portion of which needs to be executed on human beings at the final stage to provide valid results.

This guidance comprises ethical principles and regulations, to be followed as a basis and direction by all Iranian researchers that utilize human participants (including data and materials extracted from human bodies), as well as research executives and research ethics committees in the country, who dedicate their efforts to guaranteeing maximal compliance with its provisions in the research performance of their entity and others. The guidance has been prepared in accordance with ethical principles, especially human dignity, and other related national and religious values and recommendations. The presentation order of the sections in this guidance does not represent their comparative importance, and the guidance should be regarded as a uniform volume, with each paragraph or provision interpreted with sufficient attention to the introduction and other related sections of the guidance. In addition to this guidance, researchers should know and follow other related legislations and guidances approved by competent authorities, such as special domestic guidances for research ethics in different disciplines.

Provisions

١ The principal objective of any research shall be promoting human health while observing human dignity and rights.

٢ In research involving human participation, health and safety of participants during and after the research shall be the highest priority. Any such research shall be designed and executed by researchers with sufficient and related clinical expertise and competence. In clinical trials on healthy participants or patients, supervision by a physician with adequate skills and knowledge shall be crucial.

٣ Research on human participants shall be considered as justified only when the potential benefits for the participant(s) outweigh the risks involved. In researches of non-treating natures, the damage level participants are exposed to shall not exceed the level ordinary people confront in their everyday life. The responsibility for ensuring this requirement shall rest with designers, executors and collaborators of the research, as well as all councils considering or monitoring the research, including research ethics committees.

٤ Parameters such as promoting speed, ease of work, researchers' comfort, lowering costs or merely making the research practicable shall under no conditions cause the participants to be exposed to additional risks or damages, or further limit their freedom unduly.

٥ Before commencing any medical research, all initial measures shall be taken to minimize possible damage to the participants and guarantee their health.

٦ In double-blind clinical trials where the participants are unaware of the nature of the drugs or interventions designated for them, the researcher(s) shall take the required measures for assisting participants when needed, and in cases of emergency.

٧ The research should be immediately terminated if at any time during the research, it becomes evident that the risks of participation in the research outweigh its potential benefits.

٨ Research on human participants shall be designed and executed in compliance with established scientific principles emanating from latest advances, based on a comprehensive review of available scientific resources and previous laboratory and animal research, if needed. Research on animals shall fully comply with ethical principles for working with laboratory animals.

٩ Medical research that might damage the environment shall entail necessary precautions to protect and minimize such damages.

١٠ Any research shall be conducted on the basis of a proposal. Clinical trials shall require a protocol to be prepared and submitted in addition to the proposal. The proposal and protocol shall address all crucial elements, including ethical considerations, information regarding research funding, sponsors, professional affiliations, any possible conflict of interests, and designated measures to encourage participation in the research, and treat or compensate problems or damages resulting from the research. In cases, the participants might be required to sign informed consent documents, a template for which shall be prepared and attached to the proposal. A clinical trial may commence only after the consideration and approval of the related proposal by an independent research ethics committee.

١١ In addition to considering and approving the proposal and protocol for a research, the research ethics committee shall be entitled to supervise the research process during and after its execution in terms of compliance with ethical considerations. The researcher shall submit all the information and documents required for such supervision to the related committee.

١٢ Potential participants in a research project shall be fairly chosen from among patients or any other populations, in a manner that burdens (risks or expenses) and benefits of participation are distributed equally and without any discrimination among that population, and the society in general.

١٣ Participants in any human research shall express their voluntary and informed consent in written form. In cases where signing an informed consent document is impossible or dispensable, the issue and the reasons therefor shall be communicated to the related research ethics committee. If approved by the

mentioned committee, signing an informed consent document may be postponed or replaced by oral or tacit consent.

١٤ During the research project, if the execution method of the research is altered, or new information is acquired that might influence the participants' decision to continue participation, the issue shall be communicated to the related research ethics committee. In case the committee agrees with the continuation of the research, the related participants shall be informed and asked to sign another informed consent document.

١٥ The researcher(s) shall ensure that the participants agree to their participation in an informed manner. For this purpose, in all medical research, whether treating or non-treating, the researcher(s) shall properly inform the potential participants of all the information that might influence their decision, such as title and objectives of the research, length of the research, method adopted (including random designation to test or control groups), funding sources, any possible conflict of interests, researchers' institutional affiliations, and expected advantages and disadvantages. Moreover, the participants shall be informed of their right to terminate their cooperation with the research project at any time, and also briefed and supported about the potential risks and damages of such an action. The researcher(s) shall also respond to all concerns and questions of the participants patiently and accurately. All these issues need to be reflected in the informed consent document.

١٦ The researchers shall ensure that the participants agree to their participation in a voluntary manner. Behaviors that threaten, deceive, entice or force participants in any manner shall automatically nullify the consent. The potential participants shall be allowed sufficient time to confer with other parties, such as family members or family physicians. Moreover, in cases where the researchers hold higher institutional rankings than the participants, the reasons for adopting such a method for choosing participants shall be submitted to, and approved by the related research ethics committee. In such cases, a third person trusted by the participant shall obtain the participant's consent.

۱۷ The lead researchers shall hold direct responsibility for providing sufficient and comprehensible information to the participants, ensuring that they comprehended the information, and obtaining their informed consent. In cases where this briefing process is fulfilled by a person other than the lead researcher, due to reasons such as the high number of participants, the lead researcher shall be responsible for choosing a suitable and knowledgeable person for the task, and ensuring full compliance with the requirements stipulated in this paragraph.

۱۸ In researches using bodily materials (such as human tissues or fluids) or data, the identity of whose owners or donors are known or can be discovered or traced, the participants shall sign another informed consent document for collection, analysis, storage and/or re-use of such items. In cases where obtaining another informed consent is impossible or might compromise the validity of the research, the research ethics committee may consider and approve the mentioned items to be used without another informed consent.

۱۹ Refusing participation or terminating cooperation with the research project shall not in any way affect the medical services provided to the participants in the same institute, such as hospital. This issue shall be informed to the participants at the time they sign the informed consent document.

۲۰ In cases where informing the participants about an aspect of the research would compromise the research validity, the necessity of incompletely informing the participants as such shall be approved by the related research ethics committee. Once the limitations for the information process were resolved, the participants shall be informed completely.

۲۱ Certain individuals or groups, such as the mentally disabled, children, fetuses and babies, patients in emergency conditions or prisoners, lack the required awareness or freedom for consent to participation in a research project. Such individuals shall be identified as "vulnerable" and be subject to special protection.

۲۲ Vulnerable groups shall never be used as preferential participants for research (due to factors such as easy availability, etc.). Medical research using vulnerable groups or populations may be justified only when designed and

conducted to address priorities and health demands of the same groups or populations, and reasonable chances existed for them to benefit from the research results.

٢٣ The researchers' responsibility to ensure participants' informed consent shall apply to research on vulnerable groups as well. For participants that have legal guardians, the researcher(s) shall obtain informed consent of not only the guardians, but also the vulnerable participants commensurate to their capacities. In any case, the refusal of such individuals to cooperate with the research project shall be duly respected.

٢٤ If during a research, a capable participant loses capacity, or an incapable participant gains capacity, another informed consent shall be obtained from such participants or related guardians due to their changed conditions.

٢٥ The lead researcher shall be responsible for maintaining confidentiality, protecting participants' information, and taking the required measures to prevent their publication, as well as ensuring sufficient privacy for participants throughout the research project. Any publication of data or information gathered from the participants shall be under their informed consent.

٢٦ Any harm or damage resulting from participation in the research shall be compensated as per related legislations, through measures stipulated in the research proposal. This requirement shall be fulfilled preferably through unconditional insurance coverage.

٢٧ At the end of the research project, any of the participants shall be entitled to know the results, or enjoy the interventions or methods proved beneficial by the project.

٢٨ The researcher(s) shall publish the research results truthfully, completely and accurately. The results (whether positive or negative), sources of funding, institutional affiliation(s), and conflict of interests, if any, shall be highlighted. When concluding the contract for executing the research project, the researcher(s) shall reject any conditions that require the omission or withholding of research findings which the sponsors might find unpleasant.

۲۹ The reporting manner of research results shall guarantee financial and intellectual rights of all parties associated with the research, including the researcher(s), participant(s), and sponsor(s).

۳۰ Reports or articles emanating from studies that violate the provisions of this guidance shall not be accepted for publication.

۳۱ The research method shall not be in contrast with the social, religious and cultural values of the society.