General Guidelines for Ethics in Medical Research Involving Human Subjects in the Islamic Republic of Iran

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Introduction

In medicine, evidence-based practice must be employed. Such evidence is obtained through research. Therefore, the advancement of medical knowledge depends on research. A large part of research, in order to yield reliable results, must ultimately be conducted on human beings.

This General Guideline on Ethics in Research Involving Human Subjects in the Islamic Republic of Iran contains the ethical principles and regulations that all researchers who conduct research on human subjects (including data or biological materials derived from humans) must adopt as the basis and guide for their work. Likewise, all research managers and ethics committees in the country must use this document as their operational framework and make every effort to ensure its maximum observance in their own research activities and, to the extent possible, in the work of other researchers as well.

This guideline has been formulated based on ethical principles, particularly human dignity, as well as Islamic and national values and foundations. The sequence of the articles does not reflect their order of importance. This guideline must be viewed as a single integrated whole, and no article should be interpreted without due attention to the introduction and other relevant articles. In addition to this guideline, every researcher must be aware of and comply with other relevant laws and guidelines issued by official authorities, such as the specialized ethics guidelines in the country.

Article 1: The primary purpose of every research project must be to promote human health while respecting human dignity and rights.

Article 2: In research involving human subjects, the health and safety of each individual subject take precedence over all other interests throughout the entire period of the research, both during and after its implementation. Any research conducted on human subjects must be designed and executed by individuals possessing the necessary and relevant clinical expertise and skills. In clinical trials involving patients or healthy volunteers, supervision by a physician with appropriate skills and knowledge is mandatory.

Article 3: Research on humans is justifiable only if its potential benefits for each individual subject outweigh its risks. In research of a non-therapeutic nature, the level of harm to which the subject is

exposed must not exceed that which ordinary people encounter in their daily lives. Ensuring this, is the responsibility of the designers, executors, and collaborators of the research, as well as all review or monitoring bodies, including the Research Ethics Committee.

Article 4: Factors such as speed, ease of work, lower cost for the researcher, and/or mere practicality must never justify exposing subjects to increased risk of harm, or imposing any additional restrictions on their autonomy.

Article 5: Before the commencement of any medical research, preliminary measures must be taken to minimize potential harm to subjects and to ensure their safety.

Article 6: In double-blind clinical trials in which the subject is unaware of the nature of the drug or intervention prescribed, the researcher must make necessary provisions to assist the subject if required and in emergency situations.

Article 7: If during the course of research, it becomes clear that the risks of participation for the subjects outweigh its potential benefits, the research must be immediately terminated.

Article 8: The design and execution of research involving human subjects must be consistent with accepted scientific principles based on current knowledge and a comprehensive review of existing scientific literature and prior laboratory research, and, where necessary, appropriate animal studies. Animal studies must be conducted with full observance of ethical principles for working with laboratory animals.

Article 9: In medical research that may cause harm to the environment, necessary precautions must be taken to protect and preserve the environment and to prevent damage to it.

Article 10: Every research project must be conducted based on and in accordance with a proposal (protocol). In clinical trials, in addition to the research proposal, an operational manual (protocol) must also be prepared and submitted. The proposal and manual must include all essential components, including the section on ethical considerations, budget information, sponsors, organizational affiliations, potential conflicts of interest, incentives for participants, and provisions for treatment or compensation of injured individuals. In cases where written informed consent is required, a consent form must be drafted and appended to the proposal. Research must not commence until the proposal has been approved or ratified by an independent Research Ethics Committee.

Article 11: In addition to reviewing and approving the research proposal and protocol, the Research Ethics Committee has the right to monitor research projects during and after implementation for compliance with ethical considerations. Information and documents requested by the Ethics Committee for monitoring purposes must be made available by the researchers.

Article 12: The selection of potential subjects from among patient populations or any other community group must be fair, such that the distribution of burdens (risks or costs) and benefits of research participation within that community and society at large is not discriminatory.

Article 13: Obtaining informed and voluntary consent is mandatory in every research conducted on human subjects. Such consent must be in written form. In cases where obtaining written informed consent is impossible or deemed unnecessary, the matter, with reasons stated, must be referred to the

Ethics Committee. Upon the Ethics Committee's approval, written consent may be waived or replaced by oral or implied consent.

Article 14: If during the research any changes occur in the research procedures or new information becomes available that could affect the subject's decision to continue participation, the matter must be reported to the Ethics Committee. If the Committee agrees to continuation, the subject must be informed and their informed consent must be re-obtained.

Article 15: The researcher must ensure that the consent obtained is indeed informed. To this end, in all medical research , whether therapeutic or non-therapeutic , the researcher is obliged to adequately inform the prospective subject of all information that could influence their decision-making. This information includes: the title and objectives of the research, its duration, the methods to be used (including the possibility of random assignment to intervention or control groups), funding sources, any potential conflicts of interest, the researcher's organizational affiliations, and the expected benefits and harms of the study. Furthermore, each subject must be informed that they may withdraw from the study at any time and must be made aware of the potential risks and harms of early withdrawal and receive support. The researcher must also patiently and thoroughly answer all questions and concerns of these individuals. These matters must be reflected in the informed consent form.

Article 16: The researcher must ensure that the consent obtained is voluntary. Any behavior involving threats, inducements, deception, or coercion in any form invalidates the subject's consent. The individual must be given sufficient time to consider participation and to consult with others, such as family members or a family physician. Moreover, in research where the researcher holds a higher organizational position relative to the subject, the reasons for this method of recruitment must be approved by the Ethics Committee; in such cases, a trusted third party must obtain the consent.

Article 17: The principal investigator is directly responsible for providing sufficient information in understandable language to the subject, ensuring comprehension of the information provided, and obtaining informed consent. In cases where, for some reason (e.g., a large number of subjects), such information is provided by another person, it is the principal investigator who is responsible for selecting a knowledgeable and suitable individual for this task and for ensuring the conditions specified in this article are met.

Article 18: In research using biological materials (including tissues and human body fluids) or data whose owners' identity is known or traceable, informed consent must be obtained for collection, analysis, storage, and/or reuse. In cases where obtaining consent is impossible or would compromise the validity of the research, the use of stored data or biological materials without informed consent is permissible only upon review and approval by the Ethics Committee.

Article 19: Refusal to participate in research, or discontinuation of cooperation, must not affect the medical services provided to the individual at the same institution – such as a hospital. This must be communicated to the subject during the informed consent process.

Article 20: In cases where informing the subject about a certain aspect of the research would compromise the validity of the research, the necessity of incomplete disclosure by the researcher must be approved by the Ethics Committee. After the cause of this limitation has been removed, complete information must be provided to the subject.

Article 21: Certain individuals or groups, such as persons with mental disabilities, children, fetuses, neonates, emergency patients, or prisoners, who may participate as subjects in research, may lack the necessary capacity or freedom to give consent. These individuals or groups are considered vulnerable and must be afforded special protection.

Article 22: Vulnerable groups must never be used as subjects preferentially (e.g., due to ease of access). Medical research involving vulnerable groups or communities is justifiable only if it is designed and conducted to address the health needs and priorities of that particular group or community, and there is a reasonable likelihood that the group or community will benefit from the results.

Article 23: In research on vulnerable groups, the duty to obtain informed consent is not waived. For individuals who have a legal guardian, the researcher is obliged, in addition to obtaining informed consent from the legal guardian, to obtain the informed consent of the individual themselves, to the extent of their capacity. In all cases, the refusal of such individuals to participate in research must be respected.

Article 24: If during the research a subject with capacity loses capacity, or a subject without capacity gains capacity, informed consent for continued participation must be obtained from the legal guardian or the individual themselves, as appropriate, in light of the change in status.

Article 25: The researcher is responsible for respecting the principle of confidentiality and protecting the privacy of subjects, and for taking appropriate measures to prevent its disclosure. The researcher is also obliged to ensure respect for the private sphere of subjects throughout the research. Any dissemination of data or information obtained from patients must be based on informed consent.

Article 26: Any injury or damage resulting from participation in research must be compensated in accordance with applicable laws. This must be considered at the time of research design. The preferred method for fulfilling this is through unconditional insurance coverage.

Article 27: At the conclusion of the research, every individual who participated as a subject has the right to be informed of the study results and to benefit from interventions or methods shown to be beneficial in that study.

Article 28: Researchers are obliged to publish their research findings honestly, accurately, and completely. Results, whether negative or positive, as well as funding sources, organizational affiliations, and conflicts of interest – if any – must be fully disclosed. Researchers must not accept, when entering into a research contract, any condition that would require the omission or non-publication of findings that are unfavorable to the research sponsor.

Article 29: The manner of reporting research findings must ensure the material and intellectual rights of all individuals associated with the research, including the researcher(s), subjects, and the supporting institution.

Article 30: Reports and articles resulting from research that violates the provisions of this guideline should not be accepted for publication.

Article 31: The research methodology must not contradict the social, cultural, and religious values of the community.