

In the Name of God

**Ethical Guidance for Medical Genetic Research
in the Islamic Republic of Iran**

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Introduction

The increasing progress of genetics and the special sensitivity of human genetic data, awareness of the fact that human genetic research always involves significant ethical concerns and considerations, and the importance of genetic research in promoting health and curing diseases, all highlight the need for observing ethical principles and regulations in genetic research.

This guidance addresses gathering, processing, using and storing genetic, proteomic, and other cellular data of human and biological samples, hereinafter known collectively as "genetic data", for research purposes. The provisions of this guidance do not generalize to usage for non-research purposes, such as police or judicial investigations of criminal cases, determining genealogy, or the like. Researchers should know and follow the provisions of this guidance, the "General Ethical Guidance for Medical Research", and any other official regulations, requirements or guidances of the country in regard to research projects.

Provisions

- 1 Genetic research on human participants shall be ethically permissible only when aimed at promoting or advancing at least of the following fields:
 - 1.1 Diagnosing, classifying or screening genetic-based diseases or disabilities;
 - 1.2 Assessing or diagnosing susceptibility for diseases;
 - 1.3 Providing consultation to individuals or couples to determine the susceptibility of their child(ren) to genetic-based diseases or disabilities;
 - 1.4 Preventing, treating or rehabilitating diseases or disabilities;
 - 1.5 Investigating legal, penal, civil, judicial and forensic aspects; or
 - 1.6 Conducting demographic genetic research.
- 2 Research involving or aiming at the following fields shall be ethically unacceptable:
 - 2.1 Eugenics;
 - 2.2 Human reproductive cloning;
 - 2.3 Discrimination or stigmatization against individuals or groups; or
 - 2.4 Violating of human rights, dignity, or fundamental liberties.
- 3 Any study or manipulation of human genomes shall be permissible only after accurately and comprehensively considering possible risks and side effects for the participant(s) and future generations, and ensuring that potential benefits outweigh possible risks involved.
- 4 Any engineering of human genomes that might be transferred to future generations shall be ethically unacceptable, except for treatment purposes (prevention, treatment or rehabilitation).
- 5 The participants – or their legal representatives, if needed – shall express their voluntary and informed consent to cooperating with genetic research teams,

similar to other types of research, and in accordance to the provisions of the "General Ethical Guidance for Medical Research with Human Participants" and other special research ethics guidances of the country.

- ٦ The participants may retract their previous consent to collection of human genetic data or biological samples for research purposes, unless the data is irreversibly anonymized to prevent the information being traceable to the related individuals. Such retraction of consent shall not entail fines or damages for the related participants.
- ٧ In case the research includes tests with predictive results about the participants' health or other life aspects, the participants shall be fully briefed (during the process for signing the informed consent document) about the nature and consequences of the tests, and provided suitable genetic consultation. The consultant shall provide fair guidance commensurate with the participants' cultural and individual conditions, without any prejudgment.
- ٨ In case the research includes tests with predictive results about the health or other life aspects of the participants' family members or relatives, the method for informing them – or confidentiality of the results – shall be discussed with the related participants and mentioned in the informed consent document.
- ٩ Individuals with hereditary diseases or disabilities, high (suspected or proven) disease susceptibility, and asymptomatic carrier conditions shall be properly informed at a suitable time about the available facilities and possibilities regarding their situation. Moreover, if the treatment process dictates the inclusion of a relative or family member of the participant, the related physician shall provide the required information to the appointed relative after seeking the consent of the original participants or their legal representatives.
- ١٠ No participant shall be denied access to their own genetic data.
- ١١ The gathered genetic data or biological samples shall not be utilized for purposes different from, or in contrast with the provisions of the informed consent document.
- ١٢ Irreversibly anonymized human genetic data may be used for research purposes if approved by the related research ethics committee.

- ۱۳ Research results and findings on human genetic data shall be published for general use.
- ۱۴ Research on human genomes in their natural form shall not involve exclusive individual benefits.
- ۱۵ Pre-birth genetic diagnosis shall be permissible only when beneficial for the related mother's or fetus's health.