In the Name of God

Ethical Guidance for Research on Gametes & Embryos in the Islamic Republic of Iran

۲۰۱۳

Introduction

Human knowledge on reproduction biotechnology and biology has progressed significantly and extensively in the past decades. This progress entered a new era with the advent of ectopic pregnancy techniques, which promoted reproduction biology and assisted reproductive technologies to new heights. As a result, research on gametes and embryos produced through laboratory fertilization posed special ethical concerns. Human research in this field, due to its association with human beings (and their natural dignity) is entangled with unique ethical considerations and requirements that have been addressed in this guidance.

Clinical trials are recognized to be the most efficient method for collecting evidential data for clinical purposes, and play a crucial and significant role in advancing medical sciences. However, unlike other studies, clinical trials entail intentional interventions in the parameters being tried, and thus involve a greater degree of ethical concerns and considerations than other modes and types of research. Researchers and participants in clinical trials 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. The provisions of this guidance apply to all research on laboratory embryos or gametes (until fertilization).

Chapter ١ – Human Dignity

١ Research on human gametes or embryos shall be allowed unless necessary to safeguard fertility or other aspects of human health, and no suitable substitutes exist for human gametes or embryos.

٢ Any sales of human gametes or embryos, or usage of embryos acquired through commercial channels shall be prohibited.

٣ Creating human embryos for research purposes shall be prohibited. Research on human embryos may be acceptable only when the embryos are created for reproduction and infertility treatment, and the excess embryos remaining are used for research purposes.

Note: For research-treatment cloning, human embryos may be created for treatment purposes, and if an alternative method for creating the desired stem cells is not available.

٤ Inducing ovulation and ovum extraction from human body solely for research purposes shall be prohibited. Ova may be used in this respect that had been induced and extracted for fertilization, and remained unused after the completion of the assisted reproduction process, or else created outside the human body (for instance, from stem cells).

٥ Research necessitating damage to, or destruction of an embryo shall be prohibited on embryos with an age of more than ١٤ days after fertilization (the frozen period of the embryos shall not be considered in this respect).

Note: Manipulation (including biopsy) of an embryo designated for fertilization may be permissible if conducted to treat the same embryo.

٦ The number of embryos under study shall be kept at a minimum that satisfies the trial objective(s).

٧ Research on human gametes or embryos with the following objectives shall be prohibited:

٧.١ Eugenics;

٧.٢ Genetic optimization and enhancement;

٧.٣ Breeding hybrid species, or human-animal chimeras;

٧.٤ Genetic modification of a human gamete or embryo to be placed into the uterus, unless to prevent or treat a disease; and

٧.٥ Human reproductive cloning.

Chapter ٢ – Informed Consent and Confidentiality

١ Since an embryo is created from the couple's gametes, and thus cannot be labeled as an offspring, informed consent documents for participating in the research shall be signed by couples that provide gametes to produce embryos. Such couples shall hereinafter be known as "embryo owners".

٢ Any research on human embryos shall require signature of informed consent documents by embryo owners, and approval of a research ethics committee.

٣ Embryo owners should be informed that the process for their information and signing an informed consent document for participation in the research shall be completely separate from the infertility treatment process, and the mentioned treatment shall not require such consent. This issue shall be clearly mentioned in all research proposals in this respect.

٤ Embryo owners may revoke their consent for usage of their embryo for research at any time. Revoking consent shall be possible until the embryo is placed into the uterus.

٥ Embryo owners shall not be entitled to limit the usage of their donated embryo to particular parties.

٦ Researchers shall accurately record the information regarding the biological origin of gametes and embryos. Validity and confidentiality of the mentioned information shall be ensured.

Chapter ۳ – Cases Where Research on Embryos Leads to Pregnancy

۱ In such research projects, possible risks of participation shall be compensated by the research benefits for the resulting child. In studies executed solely for achieving new information, the possibility of any additional risk shall be unacceptable.

۲ Researchers shall ensure that the probability of any unpredicted impacts on the embryo, or long-term risks for the resulting child's health is kept at a minimum.