In the Name of God

Ethical Guidance for Research on Stem Cells in the Islamic Republic of Iran

۲۰۱۳

Introduction

Research on stem cells from human embryos or adult cells has presented bright hopes for minimizing pains and curing hard-to-treat diseases, but at the same time involves special ethical considerations and concerns, in critical areas such as the participants' safety and respect for human embryos.

Correct and sustainable exploitation of the benefits and advantages of such research undoubtedly depends on following these special ethical requirements and considerations, the most significant instances of which have been addressed in this guidance. The global experience recorded in the field, the rich Iranian Islamic culture and its particular views about human health and the ethical status of human embryo have all been taken into consideration in the process of developing this guidance.

Researchers and clinical specialists participating in research projects on stem cells 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.

١ Legitimate sources for generating pluripotent stem cells shall include:

١.١ Embryos in excess to the demands of treating infertility through induced pregnancy;

١.٢ Aborted fetuses;

١.٣ Embryos generated for research-treatment simulations;

١.٤ Induced pluripotent stem cells; and

١.٥ Umbilical cord or placenta of a born infant.

٢ Only embryos may be used for research purposes that were created for infertility treatment, but were in excess to that particular demand.

٣ Embryos donated to create stem cells shall not be placed in the uterus of another woman or other animal females.

٤ Ova, sperms, embryos, fetuses or any other human tissues used for creating stem cells shall not be acquired through commercial transactions.

٥ Voluntary and informed consent shall be obtained from both parents of the embryo or fetus being used. In case a third person exists, namely the donor of the gamete, his/her voluntary and informed consent shall also be requisite for using the final resulting embryo.

٦ Infertility treatment specialists, the excess embryos resulting from whose activity is going to be used, shall not be the same as the researchers using stem cells for research or treatment purposes.

٧ Using fetuses to generate stem cells shall not affect the decision to abort the fetus. For this purpose, the individual(s) to decide about abortion shall be completely independent from the research team.

٨ Ova shall not be extracted for the sole purpose of generating stem cells, and the ova used for this respect shall be in excess to the infertility treatment demands.

٩ Induced pluripotent stem cells shall not be:

٩.١ donated to individuals during the research, except in autologous donations;

٩.٢ combined with human or non-human embryos; or

٩.٣ transplanted to human or non-human embryos.

١٠ Voluntary and informed consent shall be obtained from all participants in the research project.

١١ Voluntary and informed consent shall be obtained specially for the type of the research being conducted.

١٢ For obtaining voluntary and informed consent, all information capable of affecting decision-making shall be provided to the stem cell source donor(s), including:

١٢.١ the use(s) of the donated items;

١٢.٢ the possibility of donated items being destroyed through stem cell extraction;

١٢.٣ the possibility of long-term storage of donated items for future use;

١٢.٤ the possible financial profits resulting from the research project (at present or distant future);

١٢.٥ the fact that the treatment and medical findings of the research project shall benefit the entire society, not the donor(s) alone;

١٢.٦ the fact that the donors' refusal of consent or donation shall not jeopardize their treatment process;

١٢.٧ the participants' liberty to stop cooperating with the study, without jeopardizing their normal treatment process;

١٢.٨ in case of embryo donations, the fact that the donated embryos shall not be used to fertilize other couples;

١٢.٩ the need for donors to undergo screening for genetic and infectious diseases;

١٢.١٠ the possibility of genetic changes occurring in donated cells; and

١٢.١١ the possibility for commercialization of donated cells, and the donors' lack of entitlement on this opportunity.

١٣ For full observation of the "confidentiality" principle, the participants' personal information in the research project shall be kept completely confidential.

١٤ Research and treatment centers shall take the required measures (such as codification) to follow the "confidentiality" principle. The information shall otherwise be destroyed.

١٥ The research team shall avoid gathering unnecessary personal information of the participants.

١٦ Sufficient pre-clinical trials shall be conducted on animal models.

١٧ Small animal models shall be used for the following purposes:

١٧.١ trying a transplant of wild-type, mutant or genetically modified stem cells;

١٧.٢ assessing recovery after cell therapy;

١٧.٣ considering biological mechanisms of tissue regeneration; or

١٧.٤ assessing degree and mode of cell therapy, age and disease degree for highest efficiency.

١٨ Large animal models may be required in two cases: in research projects where small animal models would not suffice, and in studies on connective tissues including bones, cartilages or tendons.

١٩ Studies on non-human primates may be conducted to gather the required information not accessible through other means. Such studies shall be directly supervised by a competent veterinarian.