Ethical Issues And Consent Process Pertaining To Stem Cell Research

Policy

Human stem cells can be obtained from various sources

- Aborted (spontaneous or induced) foetal tissue,
- Stored or spare embryos obtained from infertility treatment,
- Embryos produced for research purposes (including somatic cell nuclear transfer)
- Existing cell lines (e.g., haematopoietic or neuronal stem cells)
- Collected from peripheral blood or bone marrow.

General Considerations in the Process of Obtaining Informed Consent for Individuals or Couples Who Will Participate in Stem Cell Research

a) The purposes of the study should be made clear. In particular, the purposes of stem cell research, including the research protocol adopted in the study for which informed consent is being sought, should be fully described. A clinician or the researcher should be available to answer questions.

b) The informed consent process should state, depending on the nature of biological sample to be collected, (i) what is normally done with foetal tissue at the institution at which individuals are undergoing medical termination of pregnancy, (ii) what is normally done with spare embryos or gametes at the infertility clinic or the institution, (iii) the options available for use of spare embryos or gametes (such as cryopreservation, donation to another couple for infertility treatment or fertilization), (iv) that the research will not transfer any spare embryo to another woman's uterus, (v) that the research will result in destruction of the embryo, (vi) what is normally done with gametes at the infertility clinic or the institution, (vii) whether embryos will be produced with donated gametes (e.g., by using in vitro fertilization or somatic cell nuclear transfer).

c) The written informed consent should be obtained by a clinician.

d) It is desirable that a couple (both spouses) be present at the time of obtaining informed consent, and, whenever possible, the written informed consent should be signed by both of them.

e) The creation of embryos solely for the purpose of research should not be undertaken.

f) The informed consent process should disclose (i) possible risks from the procedure to obtain stem cells and how the risks will be minimized, (ii) the actions to be taken to protect privacy and confidentiality of the donors, (iii) the right to withdrawal from the study even after providing

initial consent and the right to order destruction of tissues, cells and their derivatives, provided that the these samples can be linked to the donor at the stage when their destruction is sought.

g) The informed consent process should disclose clearly that the person(s) providing informed consent to participate may not benefit directly. The nature of compensation to be provided in case of injury from the procedure used to obtain biological material should be disclosed. Compensation, if any, to be provided for participation in the research should also be disclosed.

h) The informed consent process should state that genetic or medical information about the gametes, foetal tissue, embryos or stem cells derived from these sources will not be provided to the donor.

i) The informed consent process should explicitly disclose whether the sample obtained from a donor will be solely used for non-commercial scientific research or whether commercial benefits are expected to accrue from the work carried out on the sample. Should there be any commercial potential, the nature of sharing of profits with the donors should be explicitly stated during the process of obtaining informed consent.

CONSENT FORM FOR USE IN COLLECTION OF TISSUE
TO BE USED IN HUMAN STEM CELL RESEARCH

Project Title	
Name and Complete Address of the Project Implementing Agency	
Name, Address and Telephone Number of the Principal Investigator	
I have been explained the purposes of the research being undertaken, and I have understood them	Yes/ No
I have had the opportunity to ask questions and am satisfied with the answers provided to me	Yes/ No
I have been informed of the risks of participation and donation	Yes/ No
I have been informed of the compensations to be provided to me in case of any physical injury to me resulting from the tissue collection	Yes/ No
I have been informed of the steps to be implemented for protecting my privacy and confidentiality and I am satisfied with them	Yes/ No
I have been informed that certain screening tests may be perfomed on the tissue samples donated by me and that I will not be provided with the results of these tests	Yes/ No
I have been informed that no identifiable results pertaining to me that are generated during the	Yes/ No

course of this research will be provided to me	
I have been informed that I will not derive any direct benefits resulting from this research	Yes/ No
I have been informed that I have the right to instruct destruction of my tissue samples at any stage of this research provided that my tissue samples are identifiable at that stage	Yes/ No
I am willingly donating my sample for the purpose of this research study and I confirm that I have not been coerced, directly or indirectly, to donate my sample.	
Donor's Signature	Date
Witnessed by	Date