

Use of Human Embryos for Stem Cell Research

Preamble

The objectives of the Stem Cell Network Policy Development Committee are to provide input in the development of public policy and to promote ethical conduct in stem cell research. The Committee recognizes the existing moral and legal debate concerning the donation and use of frozen versus non-frozen human embryos for stem cell research and stresses the need for a consensus, which is necessary for developing and implementing coherent policies in research ethics. This policy statement seeks to articulate ethical norms and principles¹ relating to human embryonic stem cell (hESC) research, in accordance with fundamental rights and freedoms. The Committee hopes that this policy statement will be a beneficial resource for researchers; it is designed to encourage responsible practices and the highest ethical standards in hESC research.

To achieve its objectives, the Committee surveyed the existing regulatory frameworks of embryo and stem cell research in 50 countries^{2, 3}. Preliminary results indicate that, only 16 countries address the donation of human embryos for research purposes, and then just 3 of them have enacted policy that distinguishes between the donation of frozen and non-frozen embryos for research purposes. It was found that although the issues surrounding

¹ This position statement borrows extensively from the principles and the language established by the Updated Guidelines for Human Pluripotent Stem Cell Research issued by the Canadian Institutes of Health Research (June 28 2006), the Committee on Guidelines for Human Embryonic Stem Cell Research of the National Research Council and Institute of Medicine of the National Academy of Sciences of the USA (April 2004); and the Draft Guidelines for the Conduct of Human Embryonic Stem Cell Research of the International Society for Stem Cell Research (July 2006).

² Australia, Argentina, Austria, Belgium, Brazil, Bulgaria, Canada, China, Colombia, Costa Rica, Cyprus, Denmark, Estonia, Finland, France, Georgia, Germany, Greece, Hungary, Iceland, India, Ireland, Israel, Italy, Japan, Latvia, Lithuania, New Zealand, Norway, Panama, Peru, Poland, Portugal, Singapore, Slovenia, Slovakia, Spain, Romania, Russia, South Africa, South Korea, Sweden, Switzerland, The Netherlands, Tunisia, Turkey, Ukraine, United Kingdom, United States and Vietnam. The criterion for selection was based on the presence of policy and laws on embryo, stem cell and/or cloning research.

³ Isasi RM, Knoppers BM, “*Mind the Gap: Policy Approaches to Embryonic Stem Cell and Cloning Research in 50 Countries*,” (April 2006) 13:1 European Journal of Health Law 9-26. See also, Knoppers BM, Isasi RM, et. al., “*Ethics Issues in Stem Cell Research*” (April 21, 2006) 312 Science 366.

the donation of frozen embryos are mainly discussed,⁴ there remain gaps in policies surrounding the donation and use of non-frozen embryos. Positions include limiting such donations to supernumerary IVF embryos or prohibiting any research on embryos.

Preliminary evidence regarding the fate of frozen human embryos and the process of obtaining consent for embryo donation is mixed if not conflicting⁵. To date, the main concerns regarding the use and donation of embryos have centred on: the need for a reflection period to ensure adequate informed consent;⁶ possible conflict of interests for the treatment team; the prohibition of financial gains or incentives for embryo donation;⁷ and the possibility of therapeutic misconception (or, the donors' misunderstanding between research and therapy⁸).

It is the Committee's position that all research projects must follow applicable and appropriate best practices for donation, procurement, culture, and storage of cells and tissues to ensure, in particular, the informed consent of the donor and the traceability of stem cells lines with respect to their sources.

⁴ See for example, Swedish National Council on Medical Ethics, *Statement of Opinion on Embryonic Stem Cell Research*, Stockholm, (January 17, 2002).

⁵ Choudhary M., Haimes E., et. al., "Demographic, Medical and Treatment Characteristics Associated with Couples Decisions to Donate Fresh Spare Human Embryos," (September 2004) 19:9 Hum Reprod. 2091-6 and Hammarberg K., Tinnery L., "Deciding the Fate of Supernumerary Frozen Embryos: A Survey of Couples' Decisions and the Factors Influencing their Choice", (20 May 2006) 86:1 Fertil Steril. 1-6. See also, Bankowski BJ, Lyerly AD, et. al., "The Social Implications of Embryo Cryopreservation," (October 2005) 84:4 Fert Steril 823-32.

⁶ See for instance, ESHRE Task Force on Ethics and Law, "II. The Cryopreservation of Human Embryos," (2001)16:5 Human Reproduction 1049-1050. See also, ESHRE Task Force on Ethics and Law, "IV. Stem Cells," (2002) 17:5 Human Reproduction 1409-1410. Cf. with Ethics Committee of the American Society for Reproductive Medicine, "Donating Spare Embryos for Embryonic Stem-Cell Research" (September 2004) 82 Fertil. Steril. (Suppl 1) S224-7.

⁷ Lo B, Zettler P, et. al., "A New Era in the Ethics of Human Embryonic Stem Cell Research" (Nov-Dec 2005) 23:10 Stem Cells 1454-9. See also, Greely HT, "Moving Human Embryonic Stem Cells from Legislature to Lab: Remaining Legal and Ethical Questions" (May 2006) PLOS Medicine 1-5, as well as, Magnus D and Cho MK, "Issues in Oocyte Donation for Stem Cell Research. Science," (Jun 2005) 17:308 5729.

⁸ Braude P, Minger SL, et. al., "Stem cell therapy: hope or hype?" Editorial, (May 2005) 21:330 (7501) BMJ 1159-60.

Executive Summary

The policy of the Stem Cell Network is that it is ethically acceptable to derive and use hESC lines from either frozen or non-frozen human embryos for research which aims to: develop cell replacement therapies, further other medical uses, treat human diseases, and prevent suffering. The Stem Cell Network expects that the same strict standards will be applied in approving research using all human embryos, whether frozen or non-frozen.

This policy statement sets out the Stem Cell Network's position on:

- Requirements for the procurement of human embryonic stem cell lines from both frozen and non-frozen human embryos;
- Requirements for ensuring informed consent for the donation and use of human embryos for stem cell research;
- Safeguards for the protection of privacy and confidentiality of donors;
- Safeguards against possible conflict of interests;
- Compliance with the Stem Cell Network policy statement.

Policy Statement:

I. Procurement of hESC Lines from Frozen or Non-Frozen Human Embryos

1. It is ethically acceptable to derive and use hESC lines from either frozen or non-frozen human embryos for research which aims to: develop cell replacement therapies, further other medical uses, treat human diseases, and prevent suffering.
2. Research that derives hESC lines or other cell lines of a pluripotent nature, whether from frozen or non-frozen embryos, should only be conducted on embryos that were originally created for reproductive purposes. Human embryos used for research should therefore be in excess of clinical need or deemed of insufficient quality for clinical use.

3. It is critical that the origin of all cell lines be documented if they are to be widely utilized within the research community. It is the research institution's duty to ensure that documentation exists for the provenance of hESCs
4. The scientific rationale to generate new hESC lines using human embryos, as well as the reason for the number of embryos needed, must be clearly presented and justified. It is required that researchers demonstrate the essential use of embryos for research goals, in addition to the absence of alternatives to such use.
5. A Research Ethics Board, or its equivalent, must review the procurement of gametes or embryos for the purpose of generating new hESC lines, regardless of the source of research funding.

II Informed Consent

6. Informed consent must be obtained from all gamete donors for use in embryo research. Consent to embryo donation for research purposes must be explicitly obtained at the time of donation, regardless of any prior indications or intentions expressed by the donor.
7. Embryo donors must be informed that they retain the right to withdraw their consent only until the embryos are actually used in cell line derivation.
8. The person obtaining the informed consent must have no economic, financial or other vested interests in the research protocol.
9. It is prohibited to give cash, in-kind payments, monetary inducements or promise of therapeutic benefits for donating excess embryos for research purposes.

10. It is prohibited to give cash, in kind payments, monetary inducements or promise of therapeutic benefits for donating gametes from which the embryos were created, in excess of reimbursement for reasonable costs.

11. The informed consent process must disclose, at minimum, the following points:
 - a. The materials will be used in the derivation of totipotent or pluripotent cells for research;

 - b. The embryos will be destroyed during the process of deriving totipotent or pluripotent cells for research;

 - c. The derived cells and/or cell lines may be stored for several years and used for future studies, subject to appropriate subsequent ethical review;

 - d. Donation is made without any restriction or direction regarding who may be the recipient of the cell transplants, except in the case of autologous transplantation;

 - e. The possibility that resulting cells or cell lines may have commercial potential and the donor will not receive financial benefits from any future commercial development;

 - f. The potential health risks for the donor;

 - g. The donor's health information will be retained and specific measures taken to protect privacy and confidentiality;

 - h. Sources of funding for the intended research should be disclosed;

- i. The research is not intended to provide direct medical benefit to a particular person, including the donor, but will rather contribute to research advances that may benefit others;
- j. Neither consenting nor refusing to donate materials for research will affect the quality of care provided to potential donors;
- k. The donated embryos will not be used to produce a pregnancy and will not be allowed to develop in culture (in vitro) for longer than 14 days.
- l. Contact information should the donors wish to find out, so far as possible, the research uses of their donation.

III Privacy and Confidentiality

- 12. Appropriate safeguards must be used to protect the privacy and confidentiality of any personal information obtained from the donor.
- 13. Donor embryos and cell lines must be coded using internationally accepted standards to maintain privacy.

IV Safeguards against Possible Conflict of Interests

- 14. A clear distinction should be made between consent for research donation and consent for clinical treatment in order to facilitate free and voluntary informed consent and to prevent potential conflict of interests. The treating physician or infertility clinician should not be the investigator involved in performing research with the donated materials.

15. Reimbursement to researchers or relevant health care professionals for involvement in the research should not be of such amount to constitute inducement.
16. Consenting or refusing to donate embryos for research must not affect or alter in any way the quality of care provided to prospective donors. Clinical staff must provide appropriate care to patients without prejudice concerning the patient's decision regarding the disposition of their embryos.
17. Researchers must not request that members of the infertility treatment team generate more embryos than necessary for the optimal chance of reproductive success.
18. The infertility clinic and any party responsible for obtaining consent or collecting materials should be reimbursed only for reasonable costs and professional services.

V. Compliance

19. Any submission for funding to the Stem Cell Network involving the use of human embryos for stem cell research must be accompanied by a signed statement by the principal investigators undertaking the research. The signed statement must also be endorsed by the principal investigators' institution, stating that the proposed research protocols are in compliance with this policy statement.