

Ethical Guidelines for Human Embryonic Stem Cell Research

Preamble

1. Research on the early human embryo has long been recognized as essential to progress in a host of biomedical areas, from reproductive medicine to the treatment of paediatric cancers. Nowadays, with the possibility of stem cell research and cell replacement therapies, embryo research holds out the promise of cures for many serious disease conditions, such as diabetes and Alzheimer's disease. Stem cell has been the focus of discussion in the science circle. It also raises a lot of ethical issues, such as reproductive cloning.

2. In Hong Kong, the Human Reproductive Technology Ordinance (Cap. 561) (the Ordinance), which was enacted in June 2000, is the only piece of legislation governing the use of technologies on assisted reproduction and the use of embryo for research. The Council on Human Reproductive Technology (the Council), a statutory body formed under this ordinance, has recognized the importance of the science and application of stem cell technologies. A Working Group on New Developments in Reproductive Technology, which was formed under the Council to look into the development of advances in reproductive technology, has discussed the issues on human embryonic stem cells research. The Ethics Committee of the Council has also looked into the ethical issues of human embryonic stem cell research.

3. On the basis of the recommendations from the Ethics Committee, the Council adopted the following ethical guidelines for compliance by embryo researchers.

Human Embryonic Stem Cell Research

4. An underlying intermediate position with regard to the moral status of the human embryo is adopted. The intermediate position neither accords the embryo full moral status from the moment of its conception nor considers it void of any moral status. Instead, it accords the embryo moral respect, which increases relative to its biological development.

5. The potential benefits of embryonic stem cell research are sufficient justification of such research. Based on the intermediate position, the use of embryos or fetal tissues as sources for generating stem cells is ethically justified subject to the options as stated in paras. 6-11 below.

Options for Deriving Human Embryonic Stem Cells

6. As the embryo represents human life in its early form, its potential use for research must be commensurate with its moral status. In accordance with the intermediate position, it is ethically permissible to use "excess RT embryos" (see Note) for the derivation of stem cell lines and research.

7. Before "excess RT embryos" are used for deriving embryonic stem cells, it is necessary to first find out, in so far as is practicable, whether at present any stem cell lines exist in Hong Kong and to what extent they would meet present research needs.

8. Alternatively, the possibility of importing stem cell lines should be examined. If human embryonic stem cells are to be imported into Hong Kong, it will be necessary to ensure that the Ordinance, its regulations and other relevant Ordinances are followed and that those stem cells are not derived from cloned embryos or embryos created for research purposes.

9. It is also worthy to consider whether adult stem cells could first be used before resorting to embryonic stem cells, given the fact that greater potential is increasingly being discovered with adult stem cells. Nevertheless, the apparent greater plasticity of embryonic stem cells compared to adult stem cells in developing into various types of cells needs to be taken into consideration as well as the fact that, at present, the yield of adult stem cells is insufficient.

10. Should none of these options meet research needs, it is ethically justified to generate stem cells from “excess RT embryos” in Hong Kong subject to certain restrictions.

11. Only the minimum number of excess RT embryos may be used for research.

Conditions for Human Embryonic Stem Cell Research

12. The purposes and the therapeutic benefits of human embryonic stem cell research must be sufficiently significant, non-trivial and well-founded. They must be commensurate with the respect due to the human embryo. Non-medical research with human embryonic stem cells (including eugenic enhancement and cosmetic research) is considered ethically unjustified.

13. There should be no commercial transactions or benefits with regard to embryo donation.

14. The morality of the process of donation must be ensured. This implies that the roles of persons conducting embryonic stem cell research and the persons providing IVF treatment should be separated and that documented, free and informed consent must be obtained. Due to the specific nature of embryonic stem cells and their virtual “immortality”, such consent should be obtained before donation for embryonic stem cell research. Donors should be protected against inducement, coercion or undue influence. Measures should be taken to provide for the reasonable protection and safeguarding of donor identity.

15. Fair access to and sharing of research results among researchers should be possible so as not to unduly restrict further research and adversely affect the development of therapeutic benefits.

Somatic Cell Nuclear Replacement

16. From both the scientific and ethical point of view, the Council considers that the “embryo” created by somatic cell nuclear replacement (SCNR) should be regarded as an embryo since it has the full potential to develop into a human being, regardless of the means of its creation (i.e. whether it has been formed by fertilization or not).

17. As section 15(1)(a) of the Ordinance prohibits the creation of an embryo for the purposes of embryo research, the creation of an embryo by SCNR for embryo research is therefore prohibited.

Research involving Mixing of Human Embryonic Stem Cells with Non-human Embryos or Vice Versa

18. Regarding research involving the mixing of human embryonic stem cells with non-human embryos or vice versa, the relevant provision is section 15(1)(a)(ii) of the Ordinance.

19. For the purpose of embryo research, combining human and non-human gametes or embryos or any part thereof such as to give rise to a 2 cell zygote is prohibited in section 15(1)(a)(ii) of the Ordinance. Since any embryonic stem cell forms part of the embryo, the mixing of human embryonic stem cells with non-human embryo or vice versa for the purpose of embryo research is not allowed.

Patenting of Embryonic Stem Cell Lines

20. The patenting of inventions involving elements of human origin leads to the question of morality as it tends to devalue human dignity. The bottom line drawn in the Hong Kong Patents Ordinance is that “patenting must not be contrary to public order and morality”. The following principles for patenting of human embryonic stem cell lines should be observed -

- (a) in accordance with the ethical principle of the non-commercialization of the human body, embryos should not be used for commercial or industrial purposes;
- (b) no remuneration should be paid to the persons who donate embryos for research purposes except for the reimbursement of necessary expenses;
- (c) based on the general distinction between discovery (not patentable) and invention (patentable), neither the human body itself, nor knowledge related to the human body or its elements (e.g. unmodified stem cells) are patentable. Embryonic stem cell lines with identified functions may, however, be patentable;
- (d) a just balance should be sought between the interests of the inventors and the interests of society so that access to health care will not be adversely affected; and
- (e) embryo donors should be provided with complete and specific information on how the donated embryo will be used, in particular the potential patenting of the embryonic stem cells extracted from the donated embryos and that they will not participate in the profit made from it. Informed and free consent needs to be obtained when embryos are donated and when the embryos are actually used for research to cultivate stem cell lines.

Use of Human Embryonic Stem Cell Lines

21. In order to minimize the destructive use of human embryos for the generation of embryonic stem cells and avoid unnecessary duplication of research, researchers should obtain information on existing stem cell lines and make best use of the resources available, both locally and from overseas.

Note:

The term “excess RT embryos” is defined as human embryos that-

- (a) were produced, by reproductive technology (RT) procedures, for use in treatment of a woman; and
- (b) are excess to the needs of -
 - (i) the woman for whom they were produced for RT treatment; and
 - (ii) her spouse at the time the embryos were produced by RT procedures.