Guidelines for Using Cells from Established Human Embryonic Stem Cell Lines for Research

2006
Preface

In November 2005, the Ministry of Health released the *Guidelines for Using Cells from Established Human Embryonic Stem Cell Lines for Research: Discussion Document* for public consultation. The discussion document contained information about human embryonic stem cell (hESC) research, outlined the ethical issues raised by hESC research, summarised the policies of a number of countries on hESC research, and invited feedback on the proposed *Guidelines for using Cells from Established Human Embryonic Stem Cell Lines for Research*.

Written submissions closed on 3 March 2006. One hundred and three written submissions were received, and nine oral submissions were heard at a public meeting held in May. A wide range of views were expressed on research using cells from hESC lines. The Ministry has prepared a summary of submissions, which is available on the Ministry’s website, http://www.moh.govt.nz.

The proposed *Guidelines for using Cells from Established Human Embryonic Stem Cell Lines for Research* were reviewed in light of submissions received. The finalised Guidelines are presented in this document, and are also available at http://www.newhealth.govt.nz/ethicscommittees. The Guidelines allow New Zealand researchers to use cells from established hESC lines in research with a number of restrictions, including mandatory ethical review of hESC research applications.

The Guidelines will be reviewed by the Ministry of Health following the outcome of the Advisory Committee on Assisted Reproductive Technology’s consideration and public consultation on the research use of human embryos in New Zealand, including their use to derive stem cell lines, in the second half of 2006.
Guidelines for Using Cells from Established Human Embryonic Stem Cell Lines for Research

Definition

A human embryonic stem cell line is a cell line derived from cells from the inner cell mass of an early embryo (up to 14 days).

Part One: Ethical review and other requirements

Research to be approved by an ethics committee prior to commencement of research

1. It is the responsibility of researchers/investigators to ensure that all research using established human embryonic stem cell lines is ethically reviewed and approved by an appropriate ethics committee before the cell line is imported into New Zealand. Except where legislation requires otherwise, the appropriate ethics committee will be a health and disability ethics committee established under the New Zealand Public Health and Disability Act 2000.¹

2. Where research using established human embryonic stem cell lines involves animals, researchers/investigators must ensure that the research has been ethically reviewed and approved by an animal ethics committee, in addition to any other approvals required, before the cell line is imported into New Zealand.

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¹ For research using established human embryonic stem cell lines that fits the definition of human reproductive research (ie, research that uses or creates a human gamete, a human embryo, or a hybrid embryo) under the Human Assisted Reproductive Technology (HART) Act 2004, the appropriate ethics committee will be the HART Act ethics committee (the Ethics Committee on Assisted Reproductive Technology).
3. Where research using established human embryonic stem cell lines involves genetic modification of cells, researchers/investigators must ensure that the research has been reviewed and approved by the Environmental Risk Management Authority, in addition to any other approvals required, before the cell line is imported into New Zealand.

4. Research using human embryonic stem cell lines must comply with all other standards of ethical research in New Zealand as expressed in the *Operational Standard for Ethics Committees* and other guidance for researchers and ethics committees.

**Part Two: Provisions associated with the way in which the human embryonic stem cell lines have been established**

Embryo(s) to have been created for the purpose of fertility treatment

5. The principal researcher must provide the ethics committee with evidence that the embryo(s) used to create the human embryonic stem cell line in question were created for the purpose of fertility treatment and are no longer required for that purpose.

Consent

6. The principal researcher must provide adequate evidence that the people whose gametes were used in creating the embryo(s) gave free and informed consent to the use of the embryo(s) to derive embryonic stem cell lines. Evidence may include:

- copies of the original donor consent forms
• copies of applications to, and approval documentation from, an ethics committee or institutional review board which conforms to the Declaration of Helsinki and International Ethical Guidelines for Biomedical Research Involving Human Subjects

• details of the requirements of ethical review and other regulations in the country of origin at the time the cells were extracted.

7. The principal researcher must provide evidence that consent to derive embryonic stem cell lines was requested after the embryo(s) in question were determined to be surplus to the requirements of the consenting people.

8. The evidence provided should show that the people who gave consent to the use of the embryo(s) in research were adequately informed that:

(i) their decision on donation would not affect any aspect of their future treatment in any way

(ii) they could withdraw or amend their consent up until the time when the embryos were used

(iii) they would have no control over the use of cells from embryonic stem cell lines derived from the embryo

(iv) their embryos and any resulting cell lines would be anonymous

(v) any stem cell lines created may be able to be cultured indefinitely and used in multiple research projects

(vi) any stem cell lines created may be exported to another country

(vii) they would not benefit financially from any profits made from embryonic stem cell lines or products derived from such lines.
9. If a donor has placed restrictions around the research uses to which their embryonic stem cell line may be used, the principal researcher must clearly identify these restrictions in the consent documentation.

10. The principal researcher must provide evidence to the ethics committee that the consent of the people whose gametes were used in creating the embryo was not given in exchange for any payment or consideration.

**Regulation in the country of origin and third countries**

11. The principal researcher must provide evidence that the human embryonic stem cell lines were obtained in accordance with the laws and regulations of the country of origin and any third country in which they were processed.

**Part Three: Provisions relating to proposed use of the established human embryonic stem cell lines**

**Age and condition of human embryonic stem cell line**

12. The principal researcher must provide documentation that shows the age of the human embryonic stem cell line, describes the various media upon which the cell line has been cultured, and provides information about the condition of the cell line.

**Justification for research**

13. The principal researcher must demonstrate to the ethics committee that the research aims to increase knowledge about either conditions/disorders and their treatment, or the processes of human development.
14. The principal researcher must clearly explain and demonstrate to the ethics committee why this objective is best addressed through research using human embryonic stem cell lines rather than other types of research, including research using other stem cells (such as adult stem cells or animal embryonic stem cells).

Research design and quality

15. The principal researcher must provide evidence to the ethics committee that their research protocol has been favourably peer reviewed in every instance by a suitably qualified and experienced independent person or committee.

16. The Gene Technology Advisory Committee is available to provide advice to ethics committees for research using established human embryonic stem cell lines.

Excess human embryonic stem cells

17. The principal researcher must describe to the ethics committee how any human embryonic stem cell lines left over after the completion of the research project will be securely stored or disposed.

Part Four: Duties of ethics committees

Research using approved human embryonic stem cell lines

18. Where an application involves the use of established human embryonic stem cells from a line that has already been approved for another research project in New Zealand, the ethics committee shall not reconsider issues relating to the origin of that stem cell line. These issues are addressed in Part Two of these guidelines.
Register of hESC research

19. Ethics committees shall co-operate to establish a register of publicly available information on approved research using human embryonic stem cell lines and recognised sources of human embryonic stem cell lines. This register shall include:

(i) the short title of the research project

(ii) an explanation of the goals and methodology of the research project in layman’s terms

(iii) the date the research was approved, audited, and completed

(iii) the full name of the institution at which the research is to be carried out

(iv) the name or identifying code of the cell line from which the human embryonic stem cells were obtained

(v) the name and address of the supplier of the cells

(vi) any restrictions on the uses to which human embryonic stem cells from the cell line may be put due to the nature of the consent obtained from the donors of the embryos used to derive the cell line or for any other reason.

20. This register should be publicly available in electronic form and hard copy.