Attachment A_Unofficial Reformatted Draft National Institutes of Health Guidelines for Human Stem Cell Research
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NATIONAL INSTITUTES OF HEALTH GUIDELINES FOR HUMAN STEM CELL RESEARCH

I. SCOPE OF GUIDELINES

These Guidelines describe the circumstances under which human embryonic stem cells are eligible for use in extramural NIH-funded research, and they also include a section on uses of human embryonic stem cells or human induced pluripotent stem cells that are ineligible for NIH funding.

For the purpose of these Guidelines, "human embryonic stem cells" are cells that are derived from human embryos, are capable of dividing without differentiating for a prolonged period in culture, and are known to develop into cells and tissues of the three primary germ layers. Although human embryonic stem cells are derived from embryos, such stem cells are not themselves human embryos.

II. GUIDELINES FOR ELIGIBILITY OF HUMAN EMBRYONIC STEM CELLS FOR USE IN RESEARCH

A. The Executive Order: Executive Order 13505, Removing Barriers to Responsible Scientific Research Involving Human Stem Cells, states that the Secretary of the Department of Health and Human Services (DHHS), through the Director of the NIH, may support and conduct responsible, scientifically worthy human stem cell research, including human embryonic stem cell research, to the extent permitted by law.

B. Eligibility of Human Embryonic Stem Cells Derived from Human Embryos: Human embryonic stem cells may be used in research using NIH funds, if the cells were derived from human embryos that were created for reproductive purposes, were no longer needed for this purpose, were donated for research purposes, and for which documentation for all of the following can be assured:

1. All options pertaining to use of embryos no longer needed for reproductive purposes were explained to the potential donor(s).

2. No inducements were offered for the donation.
3. A policy was in place at the health care facility where the embryos were donated that neither consenting nor refusing to donate embryos for research would affect the quality of care provided to potential donor(s).

4. There was a clear separation between the prospective donor(s)'s decision to create human embryos for reproductive purposes and the prospective donor(s)'s decision to donate human embryos for research purposes.

5. At the time of donation, consent for that donation was obtained from the individual(s) who had sought reproductive services. That is, even if potential donor(s) had given prior indication of their intent to donate to research any embryos that remained after reproductive treatment, consent for the donation should have been given at the time of the donation. Donor(s) were informed that they retained the right to withdraw consent until the embryos were actually used for research.

6. Decisions related to the creation of human embryos for reproductive purposes were made free from the influence of researchers proposing to derive or utilize human embryonic stem cells in research. Whenever it was practicable, the attending physician responsible for reproductive clinical care and the researcher deriving and/or proposing to utilize human embryonic stem cells should not have been the same person.

7. Written informed consent was obtained from individual(s) who sought reproductive services and who elected to donate human embryos for research purposes. The following information, which is pertinent to making the decision of whether or not to donate human embryos for research purposes, was in the written consent form for donation and discussed with potential donor(s) in the informed consent process:

   a. A statement that donation of the embryos for research was voluntary;

   b. A statement that donor(s) understood alternative options pertaining to use of the embryos;

   c. A statement that the embryos would be used to derive human embryonic stem cells for research;

   d. Information about what would happen to the embryos in the derivation of human embryonic stem cells for research;

   e. A statement that human embryonic stem cells derived from the embryos might be maintained for many years;

   f. A statement that the donation was made without any restriction or direction regarding the individual(s) who may receive medical benefit from the use of the stem cells;

g. A statement that the research was not intended to provide direct medical benefit to the donor(s);

h. A statement as to whether or not information that could identify the donor(s) would be retained prior to the derivation or the use of the human embryonic stem cells (relevant guidance from the DHHS Office for Human Research Protections (OHRP) should be followed, as applicable; see OHRP's Guidance for Investigators and Institutional Review Boards Regarding Research Involving Human Embryonic Stem Cells, Germ Cells, and Stem Cell-Derived Test Articles and Guidance on Research Involving Coded Private Information or Biological Specimens (37.8 KB PDF; get Adobe Reader), or successor guidances); and

i. A statement that the results of research using the human embryonic stem cells may have commercial potential, and a statement that the donor(s) would not receive financial or any other benefits from any such commercial development.

C. Prior to the use of NIH funds: Funding recipients must ensure that: (1) the human embryonic stem cells were derived consistent with sections II.A and B of these Guidelines; and (2) the grantee institution maintains appropriate documentation demonstrating such consistency in accordance with 45 C.F.R. Part 74.53, which also details rights of access by NIH. The responsible grantee institutional official must provide assurances with respect to (1) and (2) when endorsing applications and progress reports submitted to NIH for projects that utilize these cells.

III. RESEARCH USING HUMAN EMBRYONIC STEM CELLS AND/OR HUMAN INDUCED PLURIPOTENT STEM CELLS THAT, ALTHOUGH THE CELLS MAY COME FROM ALLOWABLE SOURCES, IS NEVERTHELESS INELIGIBLE FOR NIH FUNDING

This section governs research using human embryonic stem cells and human induced pluripotent stem cells, i.e., human cells that are capable of dividing without differentiating for a prolonged period in culture, and are known to develop into cells and tissues of the three primary germ layers. There are some uses of these cells that, although they may come from allowable sources, are nevertheless ineligible for NIH funding, as follows:

A. Research in which human embryonic stem cells (even if derived according to these Guidelines) or human induced pluripotent stem cells are introduced into non-human primate blastocysts.

B. Research involving the breeding of animals where the introduction of human embryonic stem cells (even if derived according to these Guidelines) or human induced pluripotent stem cells may have contributed to the germ line.

IV. OTHER NON-ALLOWABLE RESEARCH

A. NIH funding of the derivation of stem cells from human embryos is prohibited by the annual appropriations ban on funding of human embryo research (Consolidated Appropriations Act, 2009, Pub. L. 110-161, 3/11/09), otherwise known as the Dickey-Wicker Amendment.

B. NIH funding for research using human embryonic stem cells derived from other sources, including somatic cell nuclear transfer, parthenogenesis, and/or IVF embryos created for research purposes, is not allowed under these Guidelines.

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