

University of North Carolina at Chapel Hill

**Policy on the Use of Human Embryonic Stem Cells in
Research**

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Ad hoc Faculty Advisory Committee on Stem Cell Research

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The University of North Carolina at Chapel Hill (“University”) recognizes the potential value of Human Embryonic Stem Cells in research, including clinical research. The University encourages their responsible use as a means of advancing knowledge, with the eventual goal of using these cells in therapeutic practice in hopes of curing disease and ameliorating other disabling or debilitating health conditions. However, the University also recognizes that some potential uses of Human Embryonic Stem Cells are not currently allowed under federal directive, and that other potential uses are ethically and socially controversial. It is the purpose of this policy to lay out the potential uses of Human Embryonic Stem Cells and to differentiate among those uses approved and disapproved by the University. This policy applies to all research uses of Human Embryonic Stem Cells, including research involving human subjects. Setting standards for the use of Human Embryonic Stem Cells in therapeutic practice is premature until research has demonstrated their safety and efficacy.

This policy is consistent with the *Guidelines for Human Embryonic Stem Cell Research* (2005) published by the National Research Council and the Institute of Medicine. One University faculty member was a member of both groups and helped the University committee place its ideas in the larger context of an emerging national scientific consensus.

I. Definitions

- A. A *Human Zygote* is a diploid cell formed by the union of a mature female germ cell (ovum or egg) and a mature male germ cell (sperm). It is sometimes referred to as a fertilized egg.
- B. A *Human Embryo* is a set of rapidly dividing cells in the early stages of development into a human being, usually defined as extending from the time of implantation in the uterus through the end of the first eight weeks after fertilization of a human egg. Cell cleavage, differentiation of cells into tissue types, and the development of primitive organs mark this period.
- C. *Pluripotent Stem Cells* are cells with the capacity to differentiate into the adult cells of all germ layers (endoderm, ectoderm and mesoderm).
- D. A *Human Embryonic Stem Cell* is a type of Pluripotent Stem Cell cultured under conditions that maintain its undifferentiated state. Under these conditions, Human Embryonic Stem Cells can divide for indefinite periods and have the potential to give rise to specialized adult cells.

- E. *Determined Stem Cells* are found in both embryonic and adult tissue. They are lineage-restricted and can give rise to some, but not all, possible adult cell types. They occur in Human Embryos generally after four or more cell divisions of a Human Zygote, or fertilized egg. They also occur in fetal, neonatal and pediatric tissues and to variable extent in tissues from adults. These cells are sometimes inaccurately called “adult stem cells” in the lay press.
- F. *Somatic Cell Nuclear Transfer (“SCNT”)* involves transferring a nucleus from a somatic cell (a cell taken from adult tissue) into an embryonic cell from which the nucleus has been removed. The resulting cell consists of an embryonic cytoplasm and the nucleus of a mature cell.
- G. *Reproductive Cloning* is the implantation of an egg created through SCNT into a pseudopregnant host for the purpose of yielding a live birth.
- H. A *Chimera* is an organism consisting of two or more genetically different cell types from the same or different species. Examples would be an organism created by introducing embryonic stem cells of one species into the developing embryo of another species, or a kidney transplanted into a recipient from an unrelated donor.
- I. An *Embryonic Stem Cell Research Oversight Committee (ESCRO)* is a committee that reviews and approves all proposed uses of human embryonic stem cells. It contains members with expertise in all aspects of the biological and biomedical sciences necessary to understand and evaluate potential uses of human embryonic stem cells. It also contains members of the community and other members who may represent interests such as medical ethics, law, theology, or serve as patient advocates.

II. Prohibited Activities Involving Human Embryonic Stem Cells

- A. *Reproductive Cloning of Human Beings*. The use of Human Embryonic Stem Cells to clone a human being is prohibited. This prohibition specifically includes any use of SCNT to produce a human being.
- B. *Creation of Chimeras Using Human Embryonic Stem Cells*. The introduction of human embryonic stem cells into an embryo of any nonhuman primate is prohibited. The introduction of any embryonic stem cell into a human embryo is prohibited. The breeding of any animal into which human embryonic stem cells has been introduced is prohibited.
- C. No embryonic stem cells may be derived from a Human Embryo that has reached a developmental stage of more than fourteen (14) days. This prohibition also applies to the use of SCNT on cells derived from a Human

Embryo that has reached a developmental stage of more than fourteen (14) days.

- D. The sale of Human Embryonic Stem Cells is prohibited. This prohibition does not limit the University from paying or charging the reasonable costs associated with the transfer of cell lines from one location to another, including license fees justified by such costs.

III. Allowable Activities Involving Human Embryonic Stem Cells

- A. *Use of Human Embryonic Stem Cell Lines or Cultures.* Research with Human Embryonic Stem Cell cultures or stem cell lines is allowed, whether or not they are included on the NIH Embryonic Stem Cell Registry, as long as their creation, acquisition and use are consistent with all other provisions of this policy.
- B. *Creation of New Human Embryonic Stem Cell Lines or Cultures.* The use of SCNT to create new Human Embryonic Stem Cell cultures or stem cell lines from Pluripotent Stem Cells is allowed. The use of SCNT to create new Human Embryonic Stem Cell lines from existing Human Embryonic Stem Cell cultures or lines is allowed, as long as the existing stem cell line was created and acquired consistent with all other provisions of this policy.

IV. Activities Requiring Special Scientific and Ethical Justification

- A. The transfer to human beings of Human Embryonic Stem Cells is only allowable if the ethics, safety and value of the proposed research can be fully justified to the satisfaction of both the cognizant Institutional Review Board and the ESCRO.

There is evidence that Human Embryonic Stem Cell lines may produce aberrant descendant cells or may increase the risk of cancer in recipients, perhaps substantially. Transfer of such cells to human beings requires substantial, credible scientific evidence that the potential benefits of their use clearly outweigh the risks. Such evidence might include research demonstrating that cultured Human Embryonic Stem Cell lines produce normal descendant cells, that the risk of cancer in recipients is not increased by the use Human Embryonic Stem Cell lines, or that effective therapy for resulting cancer mitigates the risk.

- B. *Use of SCNT on Unfertilized Human Eggs.* The use of SCNT to create Human Embryonic Stem Cells from unfertilized human eggs requires special scientific and ethical review and is only allowable if the safety and value of the proposed research can be fully justified to the satisfaction of the cognizant Institutional Review Board and the ESCRO.

- C. *Creation of Human Zygotes.* The creation of human zygotes solely for the purpose of deriving Human Embryonic Stem Cells requires special scientific and ethical review and is only allowable if the safety and value of the proposed research can be fully justified to the satisfaction of the cognizant Institutional Review Board and the ESCRO. Without the special review and approval described in this Section, all stem cells must be derived from sources that have been created for purposes other than research, such as Human Zygotes or Human Embryos created for *in vitro* fertilization.
- V. Required Scientific and Ethical Review Process and Principles
- A. ESCRO Review Process
1. No Human Embryonic Stem Cells may be created, derived, obtained, possessed or used by any person employed by, enrolled at or otherwise associated with the University or its programs unless a scientific protocol describing the proposed use of such embryonic stem cells has been reviewed and approved by the University ESCRO.
 2. The University ESCRO review is specific to the scientific and ethical issues involved in using Human Embryonic Stem Cells in research. This ESCRO review requirement is separate from and in addition to any review otherwise required, such as review by the cognizant Institutional Review Board (for research with human subjects), the Institutional Animal Care and Use Committee (for research with laboratory animals), or the Institutional Biosafety Committee (for research using recombinant DNA).
 3. The ESCRO will coordinate its review activities with those of other University research regulatory review committees. ESCRO policies and procedures will be consistent with this policy. The ESCRO will also be guided in the development of its policies and procedures by federal and state laws and regulations and by the *Guidelines for Human Embryonic Stem Cell Research* (2005) published by the National Research Council and the Institute of Medicine.
- B. Institutional Review Board Process
1. Any University research project involving Human Embryonic Stem Cells must be reviewed and approved by the University's Institutional Review Board designated to have oversight of research with Human Embryonic Stem Cells (currently the Biomedical Institutional Review Board). Such review shall be in accordance with all relevant University policies and federal regulations. Such review is in addition to review by the ESCRO.
 2. The Institutional Review Board shall specifically determine that all Human Embryonic Stem Cells were obtained with the voluntary, informed consent of the donor or the family of the donor (where the donor is

deceased or not capable of providing legally effective, informed consent). In making this determination, the Institutional Review Board shall apply relevant consent principles contained in the *Guidelines for Human Embryonic Stem Cell Research* (2005) published by the National Research Council and the Institute of Medicine.

VI. Additional Requirements

- A. The use of federal funds to create, derive or conduct research using Human Embryonic Stem Cells must be in accordance with applicable federal laws, regulations and executive orders. The conduct of research with Human Embryonic Stem Cells that does not include any use of federal funds is not subject to the restrictions of this paragraph, but is subject to all other provisions of this policy. Investigators must be able to document the sources of funds used for research on Human Embryonic Stem Cells in a manner sufficient to satisfy internal or external audit.
- B. The transfer of Human Embryonic Stem Cells to the University from any other individual or organization or from the University to any other individual or organization must be authorized in a Material Transfer Agreement (“MTA”) signed by authorized representatives of the University and the providing or receiving party. Any such MTA must obligate the recipient to obey the prohibitions and limitations contained in this policy and, in cases of transfer from an outside provider to the University, the provider’s warranty or representation that the cell line was created in accordance with the provisions of this policy and those of relevant state and federal law. If the owner of the Human Embryonic Stem Cells is a third party, that party’s explicit permission must be obtained prior to the transfer.
- C. The acquisition, maintenance and storage of human embryonic stem cells must be consistent with the provisions of all University policies governing custodial responsibilities for human cells or tissues.