

HUMAN EMBRYONIC STEM CELL RESEARCH

Title: Human Embryonic Stem Cell Research		
Doc Type: Policy- Procedure	Policy-Procedure #: RC.05.001.PP	Effective Date: February 18, 2015
Owner(s) (Name and Title): Vice Chancellor for Research	Revision Date: 1	Applies To: HSC Investigators

PURPOSE

Research with human stem cells, including human embryonic stem cells (hESC), offers significant potential to further our understanding of fundamental biology and to develop cell-based therapies to treat disease. Advances in our understanding of processes for cellular development, repair, and replacement in living organisms provides a basis for developing promising new clinical treatments to eradicate or counteract the effects of devastating illness. The University of New Mexico Health Sciences Center (HSC) strongly supports the use of stem cells for research and therapeutic purposes.

The HSC recognizes that human embryonic stem cell research raises significant ethical concerns and that public policy on stem cell research must carefully balance the ethical and medical considerations, yet at the same time, enable researchers to fulfill the promise of stem cell research for providing medical therapies. Accordingly, HSC will not support research involving the use of human stem cells conducted with the objective of human reproductive cloning or that utilizes methodologies allowing for somatic nuclear transfer from human cells into animal tissues or vice versa. The purpose of this policy is to ensure that research involving the use of human embryonic stem cells at HSC is conducted under strict scientific and ethical guidelines established by State and Federal regulations and by other University policies.

APPLICABILITY

Vice Chancellor for Research
 Embryonic Stem Cell Research Oversight (ESCRO) Committee
 Human Research Review Committee (HRRC)
 Institutional Animal Care and Use Committee
 HSC Office of Financial Services

POLICY STATEMENT

The University of New Mexico Health Sciences Center Policy on Human Embryonic Stem Cell Research is consistent with and derived from the *Guidelines for Human Embryonic Stem Cell Research* prepared by the National Research Council with the Institute of Medicine, and *Guidelines for the Conduct of Human Embryonic Stem Cell Research* prepared by the International Society for Stem Cell Research. These guidelines, intended to “ensure that the highest ethical, legal, and scientific standards are met in the derivation, storage, and use of [human embryonic stem cells] in research,” govern the research utilizing hESC at UNMHSC. The hESC are derived from human blastocysts initially intended for use in reproductive or research-related *in vitro* fertilization techniques as well as somatic cell nuclear transfer into oocytes.

In order to provide appropriate oversight of hESC research, The HSC has established the Embryonic Stem Cell Research Oversight (ESCRO) Committee, reporting to the Vice Chancellor for Research.

Formation and Responsibilities of the ESCRO Committee

ESCRO Committee members will be appointed by the Vice Chancellor for Research. The membership of this committee should reflect the scientific, medical, and ethical expertise necessary to perform the referenced responsibilities. Committee membership will be adjusted as necessary to meet all relevant state and federal regulations and any other nationally accepted guidelines. Appointments will be for 2 year terms. The Human Tissue Oversight Committee Chair will serve as Chair of the ESCRO. The ESCRO membership will consist of at least 9 members, or their designee, to include the following:

- ESCRO Committee Chair (Human Tissue Oversight Committee Chair)
- HRRC Chair (one chair representing the HRRCs)
- Institute for Ethics Director
- IACUC Chair
- Human Tissue Repository Director
- Representative from OB/GYN
- Ad hoc faculty representative familiar with hES cell research at UNMHSC
- Community Representative
- Clinical faculty familiar with human stem cell application

Categories for Oversight of Human Embryonic Stem Cell Research

The ESCRO Committee will categorize hESC research into three categories as recommended by the *Guidelines for Human Embryonic Stem Cell Research*:

1. Research that is permissible after notification of the ESCRO Committee and completion of the reviews mandated by current requirements.
 - a. Purely *in vitro* hESC research with pre-existing coded or anonymous human stem cell lines in general is permissible provided that the notice of the research, documentation of the origin of the cell lines, and evidence of compliance with any required Institutional Review Board, Institutional Animal Care and Use Committee, Institutional Biohazard Committee, or other mandated reviews, is provided to the ESCRO Committee.
2. Research that is permissible only after review and approval by the ESCRO Committee, such as:
 - a. The ESCRO Committee will evaluate all requests for permission to attempt derivation of new hESC lines from donated blastocysts, from *in vitro* fertilized oocytes, or by nuclear transfer. The scientific rationale for the need to generate new hESC lines, by whatever means, should be clearly presented, and the basis for the numbers of blastocysts or oocytes needed should be justified. Such requests should be accompanied by evidence of HRRC approval of the procurement process.
 - b. All research involving the introduction of non-somatic hESC lines into nonhuman animals at any stage of embryonic, fetal, or postnatal development should be reviewed by the ESCRO Committee. Particular attention should be paid to the probability pattern and effects of differentiation and integration of the human cells into the nonhuman animal tissues.

- c. Research in which personally identifiable information about the donors of the blastocysts, gametes, or somatic cells from which the hESC line was developed is readily ascertainable by the investigator also requires the ESCRO Committee review and approval.
3. Research that is not be permitted at this time, for example:
 - a. Research involving *in vitro* culture of any intact human embryo, regardless of derivation method, for longer than 14 days or until formation of the primitive streak begins, whichever comes first.
 - b. Research in which human embryonic stem cells are introduced into nonhuman primate blastocysts or in which any embryonic stem cells are introduced into human blastocysts.
 - c. No animal into which human embryonic stem cells have been introduced at any stage of development should be allowed to breed.

Administrative and Financial Documentation

HSC research utilizing hESC's will be conducted in accordance with University policies for the conduct of research as well as applicable State and Federal regulations governing the research. As a recipient of Federal research and development funding, HSC has accepted certain obligations and restrictions related to a wide variety of University research activities.

To help ensure the University's ability to meet the regulatory expectations of our funding and oversight agencies, members of HSC's research community who plan to conduct human stem cell research must provide a protocol to the ESCRO Committee for review and approval prior to beginning work on the protocol. The application for the ESCRO Committee review will include sufficient information for the Committee to complete its review as well as clarification of the source of funding and the University location in which the research will be conducted.

Research using human pluripotent stem cells that are not included in the NIH Embryonic Stem Cell Registry must be clearly identified to ensure the University's appropriate treatment of both direct and indirect costs.

All requests to conduct hESC research must be accompanied by the UNM Human Embryonic Stem Cell Research Application. Federal regulations may prohibit the use of federally-funded equipment, supplies, and personnel to support research using non-Registry stem cell lines. It is the responsibility of the principal investigator and all research personnel involved in hESC research to understand and adhere to these Federal restrictions. The Human Embryonic Stem Cell Research Application will help ensure that federal funds will only be used to support those activities allowable under Federal guidelines, statute or law.

As with all sponsored programs, direct costs such as supplies and salary costs must be separately monitored and charged to appropriate research accounts. It is inappropriate to share resources among research projects without an accurate allocation of costs to the funding source. Therefore, with respect to research using non-approved stem cell lines, it is essential that supplies and personnel supporting these projects are segregated from other research activities.

Additional Requirements

The transfer of hESC's 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 hESC's is a third party, that party's explicit permission must be obtained prior to the transfer.

The acquisition, maintenance and storage of hESC's must be consistent with the provisions of all University policies governing custodial responsibilities for human cells or tissues.

DEFINITIONS

- **Human Embryonic Stem (hES) Cells:** Pluripotent stem cells from a human embryo that have the potential to develop into a wide variety of specialized cell types.
- **Human embryonic germ cells:** Cells found in a specific part of a human embryo/fetus called the gonadal ridge that normally develop into mature gametes.
- **Human Adult Stem Cells:** Undifferentiated cells found in fetal, neonatal, and adult human tissues that can regenerate themselves and, with certain limitations, differentiate to yield all of the specialized cell types of the tissue from which the cells originated.
- **NIH Human Embryonic Stem Cell Registry:** A list of derivations of stem cells which are eligible for federal funding. The purpose of the Registry is to provide investigators with a unique NIH code for each cell line that must be used when applying for NIH funding and contact information to facilitate investigators' acquisition of stem cells.
- **Human Stem Cell Research:** Research involving the derivation and use of human embryonic stem cells, human embryonic germ cells, human umbilical cord stem cells, and human adult stem cells from any source. Human somatic cell nuclear transplantation and use of stem cells derived from nuclear transfer are also considered "hES research."
- **Blastocyst:** The blastocyst is formed by pluripotent stem cells and multiplies to create the developing embryo. The outside layer of cells of the blastocyst multiplies to form the placenta, and the inner core of cells forms the embryo
- **Human Reproductive Cloning:** A procedure utilizing nuclear transfer from a human donor cell into an enucleated human egg cell and which implants the resulting blastocyst into a uterus with the intent of developing a fetus..
- **Somatic Cell Nuclear Transplantation:** A procedure utilizing nuclear transfer from a human donor cell into an enucleated human egg cell and which does not implant the resulting blastocyst but uses the blastocyst to develop stem cell lines for research.

REFERENCES

Committee on Guidelines for Human Embryonic Stem Cell Research, National Research Council (2005). *Guidelines for Human Embryonic Stem Cell Research, Prepublication Copy*. The National Academies Press, 2005.

International Society for Stem Cell Research, *Guidelines for the Conduct of Human Embryonic Stem Cell Research*. Draft 6-30-06 Presented to the ISSCR Membership for Comment

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Northwestern University, Policy on Human Stem Cell Research at Northwestern University. [online] Evanston, IL Available from World Wide Web:
<http://www.research.northwestern.edu/research/ori/hscr/#Policy>

The University of California, San Francisco. *Human Stem Cell Research Policy* [online]. San Francisco, CA Available from World Wide Web: <http://www.research.ucsf.edu/SC/Policy/scPolicy.asp>

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RESPONSIBILITY

- **Embryonic Stem Cell Research Oversight (ESCRO) Committee.** The ESCRO Committee is an advisory body with responsibility for the review of issues related to the derivation and use of Human Embryonic Stem Cells. The ESCRO Committee is responsible for the following:
 1. Provide scientific and ethical review of any proposed research project involving hESC and provide recommendations to the HRRC and its decision to the principal investigator.
 2. Provide oversight regarding issues related to derivation and use of hESC lines;
 3. Ensure documentation of the provenance (origin) of hESC lines including evidence of HRRC review and approval of the procurement process;
 4. Educate investigators on the ethical, legal, and policy issues associated with hESC research
- **Research Personnel.** Researchers are responsible for maintaining the highest ethical standards in hESC research. Principal investigators are responsible for ensuring that this University policy is communicated to and maintained by all who work under their supervision, directly or indirectly, as appropriate. Research support staff are responsible for ensuring that financial and administrative requirements established by this policy are appropriately applied and documented.
- **Human Research Review Committee.** The HRRC receives recommendations from the ESCRO Committee related to the conduct of human embryonic stem cell research protocols and will consider the Committee's recommendation in the HRRC's analysis of risk and benefit. Where indicated, the HRRC should not waive the requirement for obtaining informed consent from any person whose somatic cells, gametes, or blastocysts are used for research, and ensure that no financial or avoidable non-financial incentives exist that may be perceived to influence the donor's decision.
- **The Institutional Animal Care and Use Committee (IACUC)** has responsibility for review and approval of research protocols for hESC research involving animal subjects conducted under UNM's institutional assurance.
- **Office of Financial Services.** Health Sciences Financial Services will review the portion of the application for hESC research that identifies the research location and other financial considerations to ensure that HSC is able to meet applicable Federal guidelines for the conduct of this research.



RESOURCES AND TRAINING

Resource/Department	Contact Information
HSC, Office of Research	505-272-6950

SUMMARY OF CHANGES

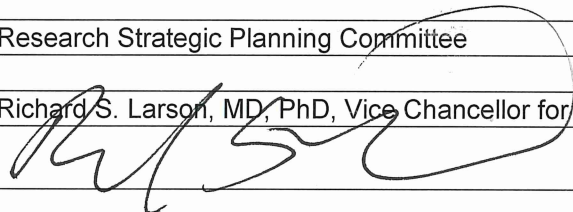
8/31/2007

- Approved by Dean, School of Medicine and Research Strategic Planning Committee

2/16.2015

- Transferred to HSC Policy Template
- Changed reporting from Senior Associate Dean for Research to Vice Chancellor for Research
- Changed ESCRO committee composition

DOCUMENT APPROVAL & TRACKING

Item	Contact	Date	Approval
Owner	Vice Chancellor for Research, Office of Research		
Consultant(s)	[Name, Title]		
Recommender(s)			[Y or N/A]
Committee(s)	Research Strategic Planning Committee		
HSC Legal Office			[Y or N/A]
Official Approver	Richard S. Larson, MD, PhD, Vice Chancellor for Research		
Official Approver Signature		Date: 2/18/2015	Yes
2nd Approver			
2nd Approver Signature (Optional)		Date:	
Policy Origination Date: 8/31/2007 as approved by the Dean, School of Medicine			

ATTACHMENTS

- *Human Embryonic Stem Cell Research Application*