

Policy

DEPARTMENT:	INSTITUTIONAL REVIEW BOARD
POLICY NUMBER:	XIII.A
SECTION:	Human Pluripotent Cell Research Oversight
REVIEW RESPONSIBILITIES:	IRB Policy and Procedure Committee
ORIGINAL CREATION DATE:	January 10, 2014
REVISION DATES:	

Subject: Vanderbilt Institutional Pluripotent Cell Research Oversight Committee (VIPCRO) Establishment and Function

Definitions:

- 1. Human embryonic stem cells (hESCs):** Human cells that are (1) derived from the inner cell mass of blastocyst stage human embryos, (2) are capable of dividing without differentiating for a prolonged period in culture, and (3) are known to develop into cells and tissues of all of the three primary germ layers.
- 2. Human induced pluripotent stem cells (hiPSCs):** Human cells that are capable of dividing without differentiating for a prolonged period of time in culture, and are known to develop into cells and tissues of all three primary germ layers.
- 3. Human somatic cell nuclear transfer (hSCNT):** Transferring the nucleus of a human somatic cell into an egg cell from which the nucleus has been removed or rendered inert.
- 4. Human cloning:** The use of human somatic cell nuclear transfer technology to produce a human embryo.
- 5. Human embryonic germ cells (hEGCs):** Pluripotent stem cells derived from primordial germ cells isolated from the gonadal ridges of five to ten week old embryos.
- 6. Investigator:** For the purposes of this policy includes all faculty, staff or trainees involved in any research covered by this policy.
- 7. Vanderbilt University Human Pluripotent Cell Registry:** An institutional database that houses comprehensive information on human stem cell research involving the use of VU/VUMC facilities or resources.

Policy:

I. Establishment and function of the VIPCRO Committee.

- A. The Associate Vice Chancellors for Research in both clinical and basic science research have established the VIPCRO Committee to operate in conjunction with other relevant institutional committees to track, review and oversee all research involving the derivation and use of hESCs and hiPSCs.
- B. The VIPCRO Committee has the authority to approve, require modification of, suspend, disapprove or terminate all research activities that fall within the scope of this policy.
- C. Research reviewed and approved by the VIPCRO Committee may be subject to additional approvals and/or disapprovals by officials of Vanderbilt University or from other institutional committees including the Institutional Review Board (IRB), the Institutional Biosafety Committee (IBC), and/or the Institutional Animal Care and Use Committee (IACUC), as appropriate.
- D. The Committee shall review all proposed and ongoing hESC and hiPSC research that involves the use of institutional facilities or resources. Additionally, in coordination with other relevant institutional offices, a registry of all hESC lines that are imported into or maintained at Vanderbilt (See VUMC Human Embryonic Stem Cell Registry Policy).
- E. The Vanderbilt Human Research Protection Program manages the resources necessary to provide operational support to the VIPCRO Committee.

II. VIPCRO Committee Responsibilities.

- A. The VIPCRO Committee shall have the authority to review the following:
 1. All research using hESCs;
 2. All research involving hSCNT;

3. All research involving hIPSCs and hEGCs where the research involves:

- a. Introduction of the cells into humans;
- b. Introduction of the cells into the central nervous system of non-human primates;
- c. Introduction of the cells into non-human animals and where there is a reasonable possibility of the cells giving rise to gametes; or
- d. Creation of gametes or embryos.

B. Through the review process, the VIPCRO Committee has the authority to grant approval for a maximum of one year and, after annual review, the research may be approved for a continued review period.

C. The VIPCRO Committee shall advise that appropriate Associate Vice Chancellor for Research in all matters relating to use and procurement of hESCs and shall assure that all such research complies with this policy.

D. The Associate Vice Chancellors for Research may not override a VIPCRO Committee disapproval. However, an Associate Vice Chancellor for research may require further institutional review and may make determinations that a proposed hESC research project may not commence.

III. VIPCRO Committee Composition.

The VIPCRO Committee shall consist of scientists with expertise in the areas of stem cell research, developmental biology, molecular biology, and assisted reproduction; and individuals with training and/or credentials in the areas of ethics and law. Additionally, an individual who is not affiliated with the institution shall be represented on the Committee.

IV. Conflict of Interest.

A. All investigators submitting research activities to the VIPCRO Committee must disclose conflicts of interest in the proposed research. Conflicts of interest are defined in accordance within the [Vanderbilt University Conflict of Interest Policy](#).

B. No VIPCRO Committee Member may participate in the initial or continuing review of a research activity in which the Member has a conflict of interest, except to provide information requested by the VIPCRO Committee.

V. Non-Compliance.

A. Alleged assertions of non-compliance are reported to the VIPCRO Committee Chair for investigation, resolution and reporting to the appropriate Associate Vice Chancellor for Research and any other institutional officials or committees (IRB, IBC, IACUC, COI, etc.).

B. The VIPCRO Committee shall have the authority to suspend or terminate its approval of hESC research that is not being performed in compliance with the research protocol or plan, the VIPCRO Committee's policies, institutional policies, applicable state and federal laws, regulations, and/or the general principles expressed in the NAS Guidelines for Human Embryonic Stem Cell Research.

C. The VIPCRO Committee, through the Vice Chancellor for Research shall report suspension or termination of research to external funding sources, if applicable. The Associate Vice Chancellor for Research or designee, and other relevant institutional officials have the authority to further review suspected non-compliance and to suspend or terminate approval of hESC research.

D. Instances meeting the definition of research misconduct will be reported to the Dean of the investigator's School by the VIPCRO Committee Chair (See the [VU Faculty Manual](#)).

VI. Policy Oversight.

Questions regarding this policy and its application are directed to the appropriate Associate Vice Chancellor for Research and/or the Human Research Protection Program (IRB).

References: