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

Definitions:
1. Human embryonic stem cells (hESCs): 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 three primary gene layers. For purposes of this policy and the Vanderbilt Human Stem Cell Research Registry Policy, the definition of hESCs shall also include pluripotent stem cells derived from primordial cells such as germ cells isolated from the gonadal ridges of five to ten week old human embryos (also known as human embryonic germ cells (hEGCs).
2. Human Fetal Tissue (HFT): Tissue or cells obtained from a dead human embryo or fetus after a spontaneous or induced abortion, or after a still birth. HFT does not include cells or tissue obtained from placenta, umbilical cord and cord blood, amniotic fluid and chorionic villi after delivery/birth.
3. Human induced pluripotent stem cells (hiPSCs): Cells derived by the reprogramming of human somatic cells that exhibit the characteristics of hESCs as defined above.
4. 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.
5. Human cloning: The use of human somatic cell nuclear transfer technology to produce a human embryo.
6. Investigator: Includes all faculty, staff or trainees involved in the research covered by this policy, with the understanding that the Principal Investigator has primary responsibility for complying with this Policy.
7. Vanderbilt Human Pluripotent Cell Registry: Institutional database that houses comprehensive information on human pluripotent cell research involving the use of Vanderbilt facilities or resources.

Policy:
I. Establishment and Function of the VIPCRO Committee.
   A. The Associate Vice Chancellor for Research (VUMC) and the Vice Provost for Research (VU) have established the VIHPORO Committee to operate in conjunction with other relevant institutional committees to track, review and oversee all research involving the derivation and use of hESCs, hiPSCs and HFT.
   B. The VIHPORO 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 VIHPORO Committee may be subject to additional requirements and reviews by officials of Vanderbilt University, Vanderbilt University Medical Center 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, hiPC and/or HFT research that involves the use of institutional facilities or resources. Additionally, in coordination with other relevant institutional offices, oversight of a registry of all hESC lines as well as HFT 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 VIHPCRO Committee.

II. VIHPCRO Committee Responsibilities.

A. The VIHPCRO Committee shall have the authority to review the following:
   1. All research using hESCs;
   2. All research involving hSCNT;
   3. All research involving hPCs 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.
   4. All research using HFT, and
   5. All research using human embryos created during in vitro fertilization.

B. Through the review process, the VIHPCRO 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 VIHPCRO Committee shall advise the institution in all matters relating to use and procurement of hESCs and HFT, and shall assure that all such research complies with this policy.

D. The institution may not override a VIHPCRO Committee disapproval. However, the institution may require further review and may make determinations that a proposed hESC, or HFT research project may not continue.

III. VIHPCRO Committee Composition.

The VIHPCRO 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 at the Committee.

IV. Conflict of Interest.

A. All investigators submitting research activities to the VIHPCRO Committee must disclose conflicts of interest in the proposed research. Conflicts of interest are defined in accordance within the Vanderbilt University and/or the Vanderbilt University Medical Center’s Conflict of Interest Policy.

B. No VIHPCRO 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 VIHPCRO Committee.

V. Non-Compliance.

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

B. The VIHPCRO 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 VIHPCRO 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 VIHPCRO Committee, through the Vice Chancellor for Research or the Vice Provost for Research, shall report suspension or termination of research to external funding sources, if applicable. The Associate Vice Chancellor for Research or the Vice Provost 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 VIHPCRO Committee Chair (See the VU or VUMC Faculty Manual).

VI. Policy Oversight.
Questions regarding this policy and its application are directed to the appropriate the Human Research Protection Program (HRPP) who will consult with the Associate Vice Chancellor for Research or the Vice Provost for Research as appropriate.

References:
NIH Guidance Document on Stem Cell Research (2009)
45 CFR 46, subpart A