and the [redacted] that became effective July 7, 2009.

2. Applicability

This policy applies to all permissible research involving human embryonic stem cells and human pluripotent stem cells (defined below in Sections 6 and 7) that is conducted by TTUHSC Principal Investigators (as defined in TTUHSC OP 73.08). The policy and requirement for ESCRO review applies regardless of the source of funding for the research and applicability of federal regulations. The information in this HSC OP is not intended to cover all applicable parts of the federal regulations and state laws. TTUHSC Principal Investigators are expected to be familiar with and to comply with regulations and laws related to research with human stem cells. If information in this policy conflicts with federal regulations or state laws, those regulations/laws supersede this policy.

3. Definitions

Adult stem cell/somatic stem cell — Undifferentiated multipotent cells found throughout the body that have the capacity to self-renew and to differentiate into cell types within a particular organ.

Blastocyst

Chimera — An organism composed of cells derived from at least two genetically different cell types. The cells could be from the same or separate species.

Embryo — In humans, the developing organism from the time of fertilization until the end of the eighth week of gestation, when it becomes known as a fetus.

Embryonic stem (ES) cells — Pluripotent cells that are derived from early stage embryos, up to and including the blastocyst stage, 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.

Fertilize — The process whereby male and female gametes unite to form a zygote (fertilized egg).

Gamete — A mature male or female germ cell, that is, sperm or oocyte, respectively

Human embryonic stem (hES) cell — A type of stem cell derived from a human embryo.

Human pluripotent stem (hPS) cell — Pluripotent stem cells derived either from a human embryo or from a somatic cell that has been reprogrammed into an induced pluripotent stem cell.

Induced pluripotent stem (iPS) cell – Somatic (embryonic, fetal, or adult) cells reprogrammed to enter an embryonic stem cell -like state by being forced to express factors important for maintaining the "stemness" of embryonic stem cells.

Institutional Animal Care and Use Committee (IACUC) — TTUHSC Research compliance committee charged with reviewing the use of animals in research, testing, teaching and related activities and compliance with federal regulations.

Institutional Biosafety Committee (IBC) – TTUHSC Research compliance committee charged with reviewing research that involves biological, chemical infectious, and select agents and dual use research of concern.

Institutional Review Board (IRB) – TTUHSC Research compliance committee charged with reviewing proposed research involving human subjects to ensure the protection of those subjects and compliance with federal regulations.

In vitro — Literally "in glass," in a laboratory dish or test tube; in an artificial environment.

In vitro fertilization (IVF) – An assisted reproductive technique in which fertilization is accomplished outside the body

In vivo — In the living subject; in a natural environment.

Multipotent stem cell — In the liv Rohe;16.1(.)]TJ /TT2 1 Tf 0 Tcn8(hn)-en -0.0euo eecrtlng 1(.)]

Recombinant DNA Biosafety Committee (RDBC) — TTUHSC Research compliance committee charged with reviewing research that involves recombinant or synthetic DNA molecules and compliance with federal regulations.

Registered human embryonic stem cell lines — hESC lines currently included on the NIH Human Embryonic Stem Cell Registry

Reproductive Cloning — The process of using somatic cell nuclear transfer to produce a normal, fully-grown organism genetically identical to the organism that donated the somatic cell nucleus.

Somatic cells — Any cell of a plant or animal other than a germ cell or germ cell precursor.

Somatic cell nuclear transfer (SCNT) — The transfer of a cell nucleus from a somatic cell into an egg (oocyte) whose nucleus has been removed. The newly nucleated egg is then stimulated, prompting it to take on the genetic and molecular characteristics of a fertilized ovum.

Stem cell — A cell that can renew itself and give rise to a more committed progenitor.

Totipotent stem cell — A stem cell that can differentiate into all differentiated cells in an organism, including the three germ layers (endoderm, mesoderm, and ectoderm) and the trophoblast (the outermost cells of the blastocyst that become part of the placenta).

4. Institutional Oversight

The Senior Vice President for Research (SVPR) has responsibility for the TTUHSC Human Pluripotent Stem Cell Program. The SVPR, in conjunction with the Assistant Vice President for Research Integrity oversees institutional compliance with applicable federal regulations, state laws and institutional policies and procedures related to human stem cell activities. The SVPR

Research falling within the ESCRO's scope of review can only be initiated after an application has been submitted to, reviewed by and approved by the ESCRO. Details of the application and review process can be found below in Section 9.

6. Types of hESC research that may be permissible following ESCRO approval:

   a. Research involving all established hES cell lines listed on the National Institutes of Health (NIH) Human Embryonic Stem Cell Research Registry
   b. Research with established hES cell lines that are not currently listed on the NIH Registry
   c. Research with human pluripotent stem (hPS) cells designed to yield gametes or integrate cells into the CNS of animals.
   d. New hES cell lines derived from the following sources:
      i. blastocysts made for reproductive purposes and later obtained for research from in vitro;
      ii. fertilization (IVF) clinics, with consent of donor (refer to the [redacted] for additional information).

Note that additional review by other TTUHSC Research Committees may also be required before initiation of an ESCRO-approved protocol. This may include the IRB, IACUC, IBC, RDBC, and/or Conflict of Interest in Research Committee (COIRC).

7. Prohibited research involving Human Embryonic Stem Cells

   a. Derivation of new hES cell lines by nuclear transfer [Note: this research is currently prohibited by the NIH].
   b. Research involving in vitro culture of any intact human embryo, regardless of the derivation method, for longer than 14 days or beyond formation of the primitive streak.
   c. Research in which hES cells are introduced into non-human primate blastocysts or in which any embryonic stem cells are introduced into human blastocysts.
   d. Research that involves breeding of any animal into which hES cells have been introduced (at any stage of development).
   e. Blastocysts made specifically for research using IVF [Note: this research is currently prohibited by the NIH].
   f. Somatic cell nuclear transfer (NT) into oocytes without intent to create a hES cell line.
   g. Reproductive cloning of human beings; this prohibition specifically includes any use of SCNT to produce a human being.
   h. The sale of hES cells. This prohibition does not limit TTUHSC 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.

8. ESCRO Membership and Meeting process

   a. The ESCRO shall consist of at least six voting members to include:
      i. A community member who is not affiliated with TTUHSC as a current or former employee

ii. At least two TTUHSC faculty members familiar with hESC research
iii. One faculty member, preferably a clinician, from OB/GYN
iv. One faculty member with a knowledge of ethical , legal, and social issues involved in biomedical research
v. At least one Research Compliance Committee chairperson (IRB, IACUC, IBC, RDBC)
vi. Non-voting, ex-officio members of the ESCRO will include the Assistant Vice President for Research Integrity and a representative from the TTU System Office

a. Designated/Expedited review. The

d. **Annual review of approved projects.** All projects approved by the ESCRO Committee will require at least an annual review. More frequent reviews may be required by the Committee if warranted. The annual review may be conducted by designated/expedited review or by the full Committee.

e. **Authority of the ESCRO.** The ESCRO shall have the authority to review, approve, require modifications in, or deny approval of all research activities involving hES cells engaged in by TTUHSC Principal Investigators. The Committee shall also have the authority to require ongoing review of the status of each project at a specified time frame determined by the Committee. The ESCRO shall have the authority to observe or have a third party observe the conduct of any research activity subject to ESCRO oversight and has the authority to request and review all records associated with the conduct of the research.

10. **Breach of Policy**

Alleged deviations from this policy must be reported by anyone who becomes aware of the violation in accordance with the TTUHSC Institutional Compliance Plan, HSC OP 52.01. Alleged deviations or violations may be reported to the Chairperson of the ESCRO, the Assistant Vice President for Research Integrity, the Research Compliance Officer, or through the system-wide EthicsPoint hotline number (1-866-294-9352). Allegations of non-compliance will be investigated by the ESCRO with assistance from any compliance authorities at TTUHSC. Allegations may be shared as appropriate with other institutional committees/personnel with shared jurisdiction (IRB, IACUC, IBC, Research Integrity Officer, etc.). Confirmed breaches of this policy, state laws, or federal regulations will be reported to the SVPR and other institutional offices or external funding sources. The ESCRO may also recommend additional sanctions to the SVPR. These sanctions may include, but are not limited to:

- A letter of reprimand to the employee with a copy to the employee's manager, chairperson, dean, and personnel file;
- Temporary or permanent suspension of the individual to submit new applications for external funding and/or research involving human subjects or animals;
- Temporary or permanent suspension of research privileges;
- Other discipline up to and including dismissal or termination.

The SVPR shall make the final determination regarding which sanctions, if any, shall be imposed on the investigator or research personnel.

11. **Amendments and Termination**

TTUHSC reserves the right to modify, amend or terminate this policy at any time. Nothing in this policy should be construed as a contract between TTUHSC and its employees or agents.