

TECH UNIVERSITY HEALTH SCIENCES CENTER

Operating Policy and Procedure

HSC OP: 73.19, Human Pluripotent Stem Cell Research

PURPOSE: The purpose of this HSC OP is to detail the process available for formal review and approval of research activities that involve the use of human embryonic stem cells (hESC) or human pluripotent stem cells (hPSC) conducted by TTUHSC faculty. The policy includes procedures related to the function of an Embryonic Stem Cell Research Oversight (ESCRO) Committee. The criteria for projects to be considered by the Committee are specified herein as are the composition and functions of the ESCRO.

REVIEW: This HSC OP will be reviewed by June 1 of each even-numbered year (ENY) by the Assistant Vice President for Research Integrity and the Chairperson of the ESCRO, with recommendations for revision forwarded to the Senior Vice President for Research (SVPR).

POLICY/PROCEDURE:

1. Introduction

Texas Tech University Health Sciences Center (TTUHSC) is committed to the highest ethical standards and responsible use of human embryonic stem cells (hESC) or human Pluripotent Stem Cells (hPSC) in research. As part of that commitment, TTUHSC has established an Embryonic Stem Cell Research Oversight (ESCRO) Committee that provides local oversight of ethical issues related to deviation and research of these types of cells in experiments expected to yield gametes or with the intent to integrate these cells in the central nervous system of animals. This oversight is completed through review and approval of all proposed uses of human embryonic stem cells prior to their use in research conducted by TTUHSC Principal Investigators. The committee's review will be conducted in accordance with general principles expressed in the National Academies' [Guidelines for Human Embryonic Stem Cell Research](#) and the [NIH Guidelines on Human Stem Cell Research](#) 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

Chimera — An organism composed of cells derived from at least two genetically different cell

Research falling within the ESCRO's scope of review can only be initiated after an applicTc 0.008 T2Tw 0.262 0 To

- a. Designated/Expedited review: The ESCRO Chairperson or designee may review and approve applications protocols that meet the following criteria:
- i. Research projects only involve in vitro experiments with federally approved hES cell lines (those found on the current [NIH Human Embryonic Stem Cell Registry](#)) human iPS cells or hPS cells.
 - ii. Research projects only involve in vitro experiments with derived and coded hES cell lines. Documentation must include provenance of all hES cell lines, evidence of IRB approval of the procurement process and of adherence to basic ethical and legal principles of procurement. In the case of hES cell lines being imported from another institution, documentation that these criteria were met at the time of derivation will suffice.
 - iii. ~~to include the~~ (I)-7.9 (R)-16.3 (B)TJ -0.008 Tc 0.00vIRI

- 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 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.~~