

**RESEARCH COMPLIANCE GUIDANCE, MARCH 2021****GUIDELINES: HUMAN EMBRYONIC STEM CELL RESEARCH OVERSIGHT**

1.0 Scope

- 1.1 These guidelines are intended to define the oversight for human embryonic stem cell use in accordance with federal guidelines. They apply to permissible derivation and/or use of human embryonic stem cells (hESC) and certain uses of induced human pluripotent stem cells (iHPSC) in research conducted by employees of Texas A&M University and/or involving its facilities. To the extent these guidelines conflict with federal regulations or state laws, those regulations/laws supersede these guidelines.

2.0 Background

- 2.1 To facilitate research involving the use of hESC and iHPSC, the National Institutes of Health (NIH) created a Human Embryonic Stem Cell Registry (see <https://stemcells.nih.gov/research/registry.htm>) that lists those cell lines eligible for use in NIH funded research and describes restrictions for use, and implemented the [NIH Guidelines for Human Stem Cell Research](#) to help ensure that NIH-funded research activity in this area is ethically responsible, scientifically worthy and conducted in accordance with applicable law.
- 2.2 Under the NIH Guidelines, some categories of research are permissible subject to mandatory reviews (i.e. IBC, IRB, IACUC) and others are not permitted. Research at Texas A&M University that is not eligible to utilize NIH funds or that uses cell lines not included on the NIH Registry will be evaluated on a case by case basis.

3.0 Requirements

- 3.1 All research must comply with applicable state and federal laws and regulations, as well as any funding agency requirements.
- 3.2 Incoming and outgoing transfers of hESC, hESC lines, hESC derived cell lines, hESC derivatives, and other materials must be documented through material transfer agreements, or other agreements, approved by TAMRA. Research activity must comply with any requirements or restrictions imposed for use of the cell lines.

4.0 Responsibilities

- 4.1 All personnel engaged in research covered by these guidelines are expected to be informed about and to comply with regulations and laws related to research with hESC and iHRSC.
- 4.2 To provide research oversight when required, the Vice President for Research has established an ad hoc Embryonic Stem Cell Research Oversight (ESCRO) Committee to review and approve research in accordance with the review requirements required by the sponsor/cell source. The ESCRO Committee has the authority to condition, approve, disapprove, require modification to, suspend or terminate any research subject to its

review. The ESCRO Committee also has authority to require continuing oversight of any research subject to its review.

- 4.3 Investigators who plan to conduct research with cell lines covered by these guidelines should submit an application to and receive approval from the ESCRO Committee prior to commencing any research.
- 4.4 The Investigator remains responsible for obtaining all applicable required approvals (e.g. IRB, IBC, IACUC), including a determination of whether or not a specific research project involving cell lines covered by these Guidelines constitutes human subjects research requiring IRB review and oversight.

Resources

- National Academies Guidelines Human Embryonic Stem Cell Research
<http://nas-sites.org/stemcells/national-academies-guidelines/>
- Texas Restrictions on Conduct Affecting Public Health ([Texas Penal Code 48.03 and 48.04](#)): Note that Texas restrictions “do not apply to cell lines derived from human fetal tissue or human tissue existing on September 1, 2017, that are used by an accredited public or private institution of higher education in research approved by an institutional review board or another appropriate board, committee, or body charged with oversight applicable to the research.”
- NIH Human Stem Cell Research Guidelines
https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.1.13_human_stem_cell_research.htm
- NIH Stem Cell Basics
<https://stemcells.nih.gov/info/basics.htm>