EMORY UNIVERSITY SCHOOL OF MEDICINE

Policy for the use of Human Embryonic Stem Cells and Induced Human Pluripotent Stem Cells

Responsible Office: SOM Research Office
Effective Date: April 2010

Purpose: To define the oversight for human embryonic stem cell use in accordance with federal guidelines.

Applicability: This policy is applicable to all nonhuman subject research, as determined by the IRB, involving Human Embryonic Stem Cells (hESCs) or Induced Human Pluripotent Stem Cells (iHPSCs) conducted at Emory University by its employees and/or involving use of its facilities. All research involving hESCs or iHPSCs that constitutes human subjects research, as defined under applicable IRB Policies & Procedures, shall be reviewed by the IRB and shall not fall within the jurisdiction of the University Embryonic Stem Cell Research Oversight Committee established by this policy.

Policies and Responsibilities:

A. General Requirements for hESC and iHPSC Research at Emory University
   1. Requirements for hESC and iHPSC Research conducted at Emory depend on the Research's funding source and/or the source of cells used in the Research.
      a. hESC and iHPSC research supported by funding from the National Institutes of Health (NIH) shall be conducted in accordance with the NIH Guidelines for Research Using Human Stem Cells (available at http://stemcells.nih.gov/policy/pages/2009guidelines.aspx). In addition, such research also shall comply with any requirements imposed by the source of cells used in the Research that are equivalent to or stricter than the requirements of the NIH Guidelines.
      b. The following types of research using hESCs and/or Induced pluripotent Stem Cells which, although derived from eligible sources, are ineligible for NIH funding:
         i. Research in which hESCs or hIPSCs are introduced into non-human primate blastocysts.
         ii. Research involving the breeding of animals where the introduction of hESCs or human IPSCc may contribute to the germ line.
         iii. Research using hESCs or hIPSC derivation of stem cells from human embryos is.
         iv. Research using hESCs derived from other sources, including somatic cell nuclear transfer, parthenogenesis, and/or IVF embryos created for research purposes.
      c. hESC and iHPSC research that is supported by funding sources other than NIH shall be conducted in accordance with the requirements imposed by the funding

source or the source of cells used in the Research and shall not be performed in space otherwise supported by NIH reserach.

2. Review by ESCRO Committee. Emory University does not require that hESC or iHPSC Research be reviewed by Emory's ESCRO Committee unless the Research sponsor or source of cell used in the Research requires review by an ESCRO Committee. An Investigator may also request a review at any time.

B. hESC and iHPSC Research Supported by NIH Funding:

The National Institutes of Health has published Guidelines for Research Using Human Stem Cells (available at http://stemcells.nih.gov/policy/pages/2009guidelines.aspx).[1] These Guidelines apply to any expenditure of NIH funds for research using hESCs and certain uses of IHPSCs. The Guidelines further specify that prior to expending NIH funds, a funding recipient will be required to assure NIH that hESCs involved in the funded project appear on the NIH Human Embryonic Stem Cell Registry created under the Guidelines. This assurance will be required "when endorsing applications and progress reports submitted to NIH for projects using hESCs."

The NIH Human Embryonic Stem Cell Registry may be accessed at http://grants.nih.gov/stem_cells/registry/current.htm.

NIH supported research must comply with these Guidelines and use cells included within the NIH Human Embryonic Stem Cell Registry.

Responsibilities of the ESCRO Committee:

The ESCRO is responsible for the following -

1. If review is required by a Research sponsor or cell source, then the Emory ESCRO Committee shall provide review in accordance with review requirements required by the sponsor/cell source.
2. The Emory ESCRO shall have the authority to condition, approve, disapprove, require modification to, suspend or terminate any Research subject to its review. The ESCRO Committee also has the authority to require continuing oversight and review of any Research subject to its review.

Institutional Review Board (IRB) and other Oversight Committee Review

1. The ESCRO shall not be responsible for determining whether a specific research project involving the use of hESCs or iHPSCs constitutes human subject research requiring IRB review and oversight. The Principal Investigator for the research must consult the Emory IRB for a determination of whether the research constitutes human subject research and therefore requires IRB, rather than ESCRO, review and approval. The Principal Investigator also remains responsible for obtaining any other required approvals from University Oversight Committees, including from the IACUC, the Radiation Safety Committee, and the IBC.

Revision History: last updated April 2013

[1] The Guidelines implement Executive Order 13505.