ADDITIONAL ETHICAL REVIEW FOR PROTOCOLS INVOLVING HUMAN EMBRYONIC STEM CELLS

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Scope

This Policy on Additional Ethical Review for Protocols Involving Human Embryonic Stem Cells applies to faculty, staff, predoctoral researchers, summer scholars and applicants ("Covered Individuals") of The Graduate School of the Stowers Institute for Medical Research ("The School").

For the purposes of this policy, "Human Embryonic Stem Cells" consist of early stem cells derived from the inner cell mass of a human blastocyst or from an earlier stage of development such as a human morula. This policy would apply equally to cells derived from the trophoblast of a human blastocyst. This policy does not cover research that uses nonhuman stem cells.

Purpose

The purpose of this policy is to establish guidelines for Covered Individuals who use Human Embryonic Stem Cells in research. The policy provides an oversight process to ensure that research with Human Embryonic Stem Cells is conducted in a responsible and ethically sensitive manner and in compliance with all regulatory requirements pertaining to biomedical research in general.

The School is included in the Stowers Group of Companies ("SGC") Organizations and has adopted the following policy as its own.

Policy

The SGC will adhere to the highest ethical standards when using Human Embryonic Stem Cells for research purposes. The ethical issues of donor privacy, informed consent, vendor trustworthiness, custody and disposal of samples, and the need for approval by the SGC's designated Embryonic Stem Cell Research Oversight ("ESCRO") Committee, Institutional Review Board ("IRB"), and Institutional Biosafety Committee ("IBC") will be considered when determining whether a particular protocol should be approved, modified, or disapproved.

All vendors, suppliers, and sources of Human Embryonic Stem Cells, as well as the registration for using these materials, must be approved by the ESCRO Committee, the IRB, the IBC, and the Senior Director of Research Operations prior to their procurement.

No Covered Individual may undertake research with Human Embryonic Stem Cells until these approvals have been obtained.

In addition to the noted requirements for approval, no Covered Individual may

1. attempt to clone a human being by transferring a human blastocyst made by somatic cell nuclear transfer ("SCNT") into a uterus, or
2. use in vitro fertilization ("IVF") to produce a human blastocyst solely for research.

After obtaining approval from the ESCRO, IRB, and IBC, Covered Individuals may

1. use SCNT to produce a human blastocyst for research, and/or
2. obtain and use for research human blastocysts made by IVF at a fertility clinic after the patients responsible for those blastocysts have donated them for research.

Purely in vitro research with Human Embryonic Stem Cells that uses previously derived Human Embryonic Stem Cells lines is permissible provided that the ESCRO Committee receives and approves documentation of the provenance of the cell lines, which consists of: i) acceptable informed consent in their derivation; ii) evidence of compliance with any required review by an IRB, IBC, or other institutionally mandated reviewing body; and iii) IRB concurrence that the proposed research is exempt from further IRB review.

No Covered Individuals may conduct the following types of research:

1. Research involving in vitro culture of any intact human blastocyst, regardless of derivation method, for longer than 14 days or until formation of the primitive streak begins, whichever occurs first
2. Research in which Human Embryonic Stem Cells are introduced into nonhuman primate blastocysts or in which any nonhuman embryonic stem cells are introduced into human blastocysts.

In addition, no animal into which Human Embryonic Stem Cells have been introduced at any stage of development should be allowed to breed.

Covered Individuals whose research involves Human Embryonic Stem Cells should demonstrate respect for the autonomy and privacy of those who donate gametes, blastocysts, or somatic cells and be sensitive to public concerns about research that involves human blastocysts.

Establishment of an Institutional Embryonic Stem Cell Research Oversight Committee

To provide oversight of the derivation and use of Human Embryonic Stem Cell lines, the SGC will either establish its own Embryonic Stem Cell Research Oversight (ESCRO) Committee prior to conducting any research with Human Embryonic Stem Cells or arrange for another institution's ESCRO Committee to review and approve or disapprove any research with Human Embryonic Stem Cells proposed by a Covered Individual. The IBC/ESCRO/IRB coordination and review procedures are outlined in Standard Operating Procedure ("SOP") 400 and are based upon the recommendations of the National Academies of Science.

The ESCRO Committee that reviews research proposed by a Covered Individual will include representatives of the public and persons with expertise in developmental biology, stem cell research, molecular biology, and ethical and legal issues in research with Human Embryonic Stem

Cells. It will have suitable scientific, medical, and ethical expertise to conduct its own review and will have the resources needed to coordinate the management of the various other reviews required for a particular protocol. The ESCRO Committee will:

1. provide oversight over the derivation and use of Human Embryonic Stem Cell lines by Covered Individuals.
2. review and approve the scientific merit of research protocols developed by Covered Individuals that involve Human Embryonic Stem Cells
3. review compliance with all relevant regulations and Institute guidelines of all research conducted by Covered Individuals that involves Human Embryonic Stem Cells
4. maintain registries of Human Embryonic Stem Cell research conducted at the Institute and Human Embryonic Stem Cell lines derived or imported by Covered Individuals
5. facilitate education of Covered Individuals involved in research with Human Embryonic Stem Cells

ESCRO Committee Approval

No Covered Individual may undertake research with Human Embryonic Stem Cells until the registration covering that research has been reviewed and approved by an ESCRO Committee.

The ESCRO Committee responsible for reviewing and approving or disapproving research with Human Embryonic Stem Cells proposed by Covered Individuals will be established by the SGC prior to undertaking such research, or its function will be formally delegated to another institution's ESCRO Committee.

Depending on the source of the Human Embryonic Stem Cells and the affiliations of the individuals involved in the research, approval of other ESCRO Committees may also be required. If either the Covered Individual or a research collaborator holds a faculty appointment at another institution, the ESCRO Committee serving the other institution may also require an opportunity to review and approve or disapprove the research.

IRB Approval

The IRB for the SGC is that of the University of Kansas Medical Center ("KUMC"). The KUMC IRB will review all uses of Human Embryonic Stem Cells classed as "Human Subjects Research" conducted by Covered Individuals. The KUMC IRB will determine if research use of an existing Human Embryonic Stem Cell line is exempt from further IRB review.

Depending on the source of the Human Embryonic Stem Cells and the affiliations of the individuals involved in the research, approval of other IRBs may also be required. If either the Covered Individual or a research collaborator holds a faculty appointment at an institution other than KUMC, the IRB serving that other institution may also require an opportunity to review the research.

IBC Approval

No Human Embryonic Stem Cells may be produced, obtained, received, or used at the Institute until the responsible principal investigator has filed a registration with the Institute Biosafety Committee ("IBC"). The registration is necessary so that the IBC can make the determinations set out in IBC SOP 300 of whether the studies are excluded from classification as "Human Subjects Research," as that term is defined in IBC SOP 300 and applicable regulations. If the IBC determines that the research involves identifiable Human Embryonic Stem Cells, is collected for the purpose of the study outlined, or is uncertain of the classification, a protocol must be submitted to the IRB in order to obtain written approval or determination of exemption.

Receipt of Human Embryonic Stem Cells classed as "Human Subjects Research"
Immediately upon receipt of any Human Embryonic Stem Cells classed as "Human Subjects Research" for use in research at the Institute, the responsible principal investigator must register the cells with the Histology Department.

Reporting Requirements
The responsible principal investigator must fulfill all reporting requirements of each ESCRO Committee and IRB involved in review of the protocol covering the use of Human Embryonic Stem Cells.

By March 1 each year, the ESCRO Committee shall prepare an annual report stating the nature of the Human Embryonic Stem Cells used in, and the purpose of, the research conducted during the prior calendar year by Covered Individuals, and certifying compliance with Missouri's stem cell law, Article III § (38)(d)(4), subdivision (6) of subsection 2. By June 1 each year, the President and CEO of the Stowers Institute shall make the ESCRO Committee's report for the previous calendar year available to the public on the Institute's website and inform the Secretary of State of Missouri how the public may gain access to the report. The report shall not contain private or confidential medical, scientific, or other information. Covered Individuals are not required to prepare and make available to the public a separate report concerning that same research.

This policy was approved by the GSSIMR Board of Directors on September 5, 2018.
This policy was last updated by the GSSIMR Board of Directors on November 09, 2020.
This policy will be reviewed by the GSSIMR Board of Directors in 2022.