



7A-30 Policy for the Use of Human Embryonic Stem Cells

Responsible Executive: Gary K. Ostrander, Vice President for Research
Approving Official: Gary K. Ostrander, Vice President for Research
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Revision History: None

I. INTRODUCTION

Purpose

The Human Embryonic Stem Cell Research Advisory Committee (HESRAC) functions as the Embryonic Stem Cell Research Oversight (ESCRO) Committee for Florida State University (FSU).

FSU is committed to the ethical and responsible conduct of research involving federally approved human embryonic stem cells (hESCs). To accomplish this, we endeavor to ensure that all research involving hESCs are accomplished within the National Institutes of Health (NIH) Guidelines for Human Stem Cell Research.

Responsibilities

1. The Researcher is responsible for ensuring that all rules, regulations, guidelines, policies, and procedures relating to use and possession of hESC materials are met.
2. The Office of the Vice President for Research (OVPR) is responsible for legal and ethical oversight of campus issues related to the use of hESCs. Specifically, the OVPR is responsible for:
 - a. Reviewing and approving the ethical and scientific merit of hESC research protocols in coordination with review of the appropriate boards [e.g., HESRAC, HSRC, or Institutional Biosafety Committee (IBC)] and communicating determinations of such reviews to the appropriate board;
 - b. Identifying ongoing hESC research and confirming that such research is in compliance with accepted campus practices or referring specific issues to the administrative or departmental office for appropriate resolution; and
 - c. Reviewing and approving all Material Transfer Agreements involving hESCs.
3. The Department of Environmental Health& Safety (EH&S) is responsible for technical oversight of campus issues related to the use of hESCs. Specifically, EH&S is responsible for:



- a. Recommending actions, guidelines, and policies as needed to the OVPR to ensure compliance of research involving hESCs, including requesting review by the HESRAC;
 - b. Advising researchers regarding additional institutional reviews required for their research (e.g., review by HESRAC, HSRC, IBC, Radiation Safety Committee, etc.);
 - c. Facilitating the education and safety training of researchers involved in hESC research; and
 - d. Ensuring the research facility is appropriate to conduct hESC studies.
4. The Human Subjects Research Committee (HSRC) must review and approve all research or clinical investigations involving human subjects regardless of funding source or sponsorship, including any research involving human subjects and hESCs.
 5. The Human Embryonic Stem Cell Research Advisory Committee (HESRAC) – as described herein.

II. POLICY

Applicability

This policy is applicable to all *non-human subjects research*, as determined by the Human Subjects Research Committee (HSRC), involving hESCs conducted at FSU by its employees and/or involving use of its facilities.

All research involving hESCs that constitutes *human subjects research*, as defined under applicable HSRC Policies & Procedures, shall be reviewed by the HSRC and shall not fall within the jurisdiction of the HESRAC established by this policy.

Under most circumstances, hESC research will not involve human subjects, and in those cases, will not be considered human subjects research. Basic research using cell lines from which the identity of the donor(s) of the embryo that yielded the cell lines cannot readily be ascertained by the investigator, is not considered human subjects research, is not governed by 45 CFR 46 or 21 CFR 50 & 56, and does not require IRB review. Research using cell lines that are identifiable with a donor(s) of the embryo, including cell lines that retain links to coded information that would allow identification of the donor(s), may be considered human subjects research and require an IRB review.

Establishment of the HESRAC

The University has established the HESRAC to review research that falls within the scope of this Policy. The HESRAC consists of three faculty members selected by the OVPR and qualified by training and experience to review hESC research. Alternates may be appointed for each of the members. The committee may recruit ad hoc members as needed. The HESRAC shall meet on an as needed basis to conduct any review of hESC



research required by this Policy or by any research sponsor or cell supplier. A quorum of the HESRAC is required to conduct business.

Policy Details

The OVPR has determined that the restrictions imposed by the NIH on research funded by NIH grants are sufficient for those researchers funded for hESC research by the NIH. Any cases of non-NIH funded hESC research may require further review and/or modification of this policy.

A. General Requirements for Conduct of hESC Research at FSU

Requirements for hESC research conducted at FSU depend on the research's funding source and/or the source of cells used in the research.

1. hESC research supported by funding from the NIH shall be conducted in accordance with the NIH Guidelines for Research Using Human Stem Cells (available at <http://stemcells.nih.gov/policy/2009-guidelines.htm>). 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.
2. The following types of research using hESCs derived from eligible sources are ineligible for NIH funding:
 - a. Research in which hESCs are introduced into non-human blastocysts.
 - b. Research involving the breeding of animals where the introduction of hESCs may contribute to the germ line.
 - c. Research deriving hESCs from human embryos, including from somatic cell nuclear transfer, parthenogenesis, and/or IVF embryos created for research purposes.
3. hESC research that is supported by funding sources other than NIH shall be conducted in accordance with NIH guidelines and with NIH-approved cell lines or, if this is not possible, in accordance with the requirements imposed by the funding source or the source of cells used in the research. Based on the NIH Guidelines, all hESC research that is ineligible for federal funding must be conducted in a manner that does not utilize federal funds. The ability of FSU scientists to conduct research that is considered "federally non-fundable" requires establishment of prudent practices and guidelines for separation of costs associated with hESC activity that are in compliance with federal costing principles 2 CFR Part 200.

B. hESC Research Supported by NIH Funding:

The NIH has published Guidelines for Research Using Human Stem Cells (available at <http://stemcells.nih.gov/policy/2009-guidelines.htm>). These Guidelines apply to any expenditure of NIH funds for research using hESCs. 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 HESRAC:

The HESRAC is responsible for reviewing all research projects using hESCs. The HESRAC shall have the authority to condition, approve, disapprove, require modification to, suspend, or terminate any research project subject to its review. The HESRAC also has the authority to require continuing oversight and review of any research project subject to its review.

Human Subjects Research Committee and other Oversight Committee Review

The HESRAC shall not be responsible for determining whether a specific research project involving the use of hESCs constitutes human subjects research requiring HSRC review and oversight. The Principal Investigator for the research must consult the HSRC for a determination of whether the research constitutes human subjects research, and therefore requires HSRC, in addition to HESRAC, review and approval.

Transfer of Materials

1. Receipt of hESC materials by FSU must comply with the OVPR Material Transfer Agreement (MTA) requirements, or other written acknowledgement;
2. Purchasing of hESC materials must comply with campus Procurement Policies;
3. Any hESC materials to be transferred off campus for use by others must comply with the OVPR requirements for an MTA or license agreement, and ensure all necessary shipping requirements are addressed (contact EH&S for shipping requirements); and
4. Researchers handling such transactions will also be responsible for assuring prior approval from the OVPR, and providing information to the OVPR for campus tracking of such transactions, as appropriate.

Conflicts of Interest.

1. Researcher Significant Financial Interests. All investigators participating in hESC research shall disclose personal financial interests in accordance with the FSU’s Financial Conflict of Interest Disclosure Policy (Policy 7A-21).
2. HESRAC Member Conflicts of Interest. It shall be the responsibility of each HESRAC member to disclose all personal, financial, and other competing interests that could reasonably be seen as affecting the ability of the committee member to impartially discharge the committee member’s duties. Potential conflicts include but are not limited to personal financial interests, professional interests, or personal relationships having a significant connection to a matter under consideration by the



HESRAC. The HESRAC as a whole shall determine whether, and the extent to which, a disclosure disqualifies the committee member from participating in the review of a particular matter under consideration.

III. LEGAL SUPPORT, JUSTIFICATION, AND REVIEW OF THIS POLICY

State of Florida Statute 1004.22

National Institutes of Health Stem Cell Information (<https://stemcells.nih.gov/>)

Executive Order 13505—Removing Barriers to Responsible Scientific Research Involving Human Stem Cells, Memorandum of March 9, 2009 (<https://www.gpo.gov/fdsys/pkg/FR-2009-03-11/pdf/E9-5441.pdf>)

This policy will be reviewed periodically and updated when necessary.

/s/ Gary K. Ostrander

[Proof of approval retained in file]