UIC UNIVERSITY OF ILLINOIS AT CHICAGO

Office for the Protection of Research Subjects
Institutional Review Board

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ESCRO/IRB Coordination

Version: 1.0
Date: 12/22/2008
Approved by: Interim Vice Chancellor for Research
AAHRPP REF#: 168
AAHRPP Elements: 1.2.D; 1.3.B

POLICY:

I. UIC defines human embryonic stem cell research as including all derivations of hES cell lines and all research using hES cells derived from:
   A. Human blastocysts made for reproductive purposes and later obtained for research from IVF clinics;
   B. Human blastocysts made specifically for research using assisted reproductive technology; or
   C. Human somatic cell nuclear transfer into oocytes.

II. The UIC ESCRO Committee reviews all research involving the use of hES cells in research accordance with the principles set forth in the U.S. National Academy of Sciences *Guidelines for Human Embryonic Stem Cell Research* (NAS Guidelines, 2005).
   A. The use of fetal or adult stem cells in research is not subject to review by the ESCRO Committee.
   B. For additional information, refer to the UIC policy *ESCRO Committee Charge and Authority*.

III. If ESCRO approval is needed for a research study involving human subjects, the UIC IRBs will only grant final IRB approval to research protocols reviewed and approved by the UIC ESCRO Committee.
   A. An investigator must have an UIC affiliation to submit a protocol for review by the UIC ESCRO Committee.
   B. The ESCRO approval from other institutions will not be accepted in place of UIC ESCRO approval. For additional information regarding the ESCRO review process, refer to the UIC Policy *ESCRO Review Process*.

IV. In accordance with the U.S. President's criteria, which was announced on August 9, 2001, research involving the derivation of new stem cells from human embryos or the use of human embryonic stem cells that are not listed on the NIH Human Embryonic Stem Cell Registry may not be conducted with Federal support.

V. VA regulations prohibit research involving the use of human fetal tissue from being conducted by VA investigators or at VA facilities or at approved off-site facilities. Therefore, the JBVAMC/NU/UIC Collaborative IRB (UIC IRB#4) will not review research protocols involving the use of hES cell lines.

PROCEDURES:

I. Committee Membership.
   A. The Chair of the ESCRO Committee is a Chair/Vice-Chair on a Biomedical IRB. In addition the ESCRO Committee may include other members of the IRB.
   B. During the IRB review of a research protocol involving hES cell lines, either an IRB member reviewing the research protocol will be a member on the ESCRO committee or a member of the ESCRO Committee will be serve as an *ad hoc* consultant (Refer to the UIC HSPP policy *Identification and Use of ad hoc Consultants* policy and procedure).
   C. Both the IRBs and the ESCRO Committee are supported by the OPRS.

II. Types of hES Cell Lines Research and IRB Review Processes.
   A. The *in vitro* use or *in vivo* use in animals of established hES cell lines listed on the NIH Human Embryonic Stem Cell Research Registry is not human subject research, but requires registration with the ESCRO Committee prior to initiation of the research.
   B. All research involving the use of established, non-NIH registered hES cell lines requires ESCRO approval. The *in vitro* use or *in vivo* use in animals of these hES cell lines may be eligible for review through the "Determination of Whether an Activity Represents Human Subject Research" or may require the submission of a protocol application for an exemption determination or IRB review. Research involving established non-NIH registered hES cell lines may not be initiated without written notification from the HSPP through OPRS that the research may begin.
   C. All research involving the derivation of new hES cell lines requires both IRB and ESCRO Committee approval prior to the initiation of the research. This research may be subject to both HHS regulations (45 CFR 46, including SubPart B) and FDA regulations (21 CFR 50, 56, 312, 812).
   D. The *in vivo* use in humans of hES cell lines requires both convened IRB and ESCRO Committee approval prior to the initiation of the research. This research may be subject to both HHS regulations (45 CFR 46, including SubPart B) and FDA regulations (21 CFR 50, 56, 312, 812).

III. Initial Protocol Submission and Review.
   A. When a PI proposes research involving hES cells that fall into categories listed in Section II.B-D above, the PI must submit the protocol for ESCRO review prior to or concurrently with submitting the protocol for IRB review.
   B. If OPRS staff receives an IRB application, which in their judgment may require ESCRO approval and documentation of submission for ESCRO review is not evident, the OPRS staff will contact the ESCRO Chair or staff supporting the ESCRO Committee for assistance in determining whether ESCRO review is required. If it is determined that the proposal does fall under the purview of the ESCRO Committee, OPRS will send written notification to the PI of the requirement for ESCRO review and approval.

C. Although the IRB may review a protocol prior to final ESCRO approval, IRB approval will not be granted without documentation of ESCRO Committee approval. The UIC ESCRO will provide a copy of all correspondence related to the protocol to the OPRS Assistant Director of the Biomedical IRB assigned to review the protocol.
D. Upon receipt of an appropriately completed protocol submission that falls under the ESCRO purview, OPRS staff will assign an IRB number to the protocol. The protocol will also be identified in the OPRS information system, RiSC, as falling under the ESCRO's purview. This will ensure that the ESCRO Committee will be copied on all correspondence between the PI and the IRB.
E. OPRS staff will be responsible for providing the OPRS staff person supporting the ESCRO Committee with agenda notices and IRB protocol review materials for protocols that fall under the jurisdiction of the ESCRO prior to the IRB meeting.
F. The ESCRO Chair or another member of the ESCRO Committee will attend the convened IRB meeting or may send comments in writing. The ESCRO member may be either an IRB member or function as *an ad* hoc consultant.
G. Once the protocol receives IRB approval, the ESCRO Committee will receive a copy of the approval notice and the approved final version of the informed consent document, if applicable. Additionally, the ESCRO Committee will be copied on any subsequent correspondence sent on behalf of the IRB to the PI and will receive copies of revised versions of the IRB approved informed consent documents, if applicable.

IV. Amendments to Approved Protocols.
A. The PI is responsible for submitting amendments to the approved research protocol to the IRB for prospective review and approval. In addition, substantive changes to the research protocol must also be submitted to the ESCRO committee for approval prior to initiation.
B. An amendment that requires convened IRB approval often requires ESCRO approval prior to the issuance of final IRB approval. When such an amendment is received by OPRS, the OPRS IRB staff will contact the OPRS ESCRO staff member for assistance in determining whether approval is needed.
C. The amendment will follow the steps outlined in Section III.C-G above.

V. Unanticipated Problems, Subject Complaints and Allegations of Research Non-compliance.
A. The PI is responsible for dually reporting to the IRB and the ESCRO Committee alleged research non-compliance, including unanticipated problems or other events requiring prompt reporting; protocol violations; a complaint from a subject, subject family member, staff, or researcher concerning subject rights and welfare; and other allegations of research non-compliance.
B. When an unanticipated problems or other events requiring prompt reporting, protocol violation, subject complaint or an allegation of research non-compliance is received in a protocol under joint IRB and ESCRO jurisdiction,

the OPRS Director will be notified within two working days of receiving the report. The OPRS Director may confer with the Associate Director for Research Compliance or the HPA to assess whether the incident falls under the purview of the IRB, ESCRO, or both committees.

C. The unanticipated problems or other events requiring prompt reporting /protocol violation/complaint/non-compliance allegation will be reviewed in accordance with the applicable human subject protections policies.
D. After the review of the non-compliance issue is completed, the findings will be communicated to the other respective review committees (IRB or ESCRO) and the Associate Director for Research Compliance and Institutional Officials, as appropriate.
E. The OPRS Director or the HPA will determine whether the incident meets requirements for reporting to the federal regulatory agencies. In making the determination, the UIC HSPP policy *Reporting of Unanticipated Problems, Suspensions, Terminations, and Non-Compliance* will be followed.

VI. Quality Assurance/Improvement Audit Findings.

A. If the OPRS or OVCR conducts a directed or not for cause audit of an IRB/ESCRO protocol, the UIC OPRS Director will receive with a copy of the findings of the audit.

REFERENCES:

U.S. National Academy of Sciences *Guidelines for Human Embryonic Stem Cell Research* (NAS Guidelines, 2005)
OHRP *Guidance for Investigators and Institutional Review Boards Regarding Research Involving Human Embryonic Stem Cells, Germ Cells and Stem Cell-Derived Test Articles*
VA Handbook 1200.05, Appendix D (4)