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I. Introduction

The University of Illinois at Chicago (UIC) is committed to the ethical and responsible use of human embryonic stem (hES) cells in research. As such, the UIC's participation in hES cell research will be conducted in accordance with the general principles expressed in the *Guidelines for Human Embryonic Stem Cell Research (NAS, 2005).*

II. Institutional Delegation of Authority

In June, 2006, the Chancellor of the UIC delegated authority to the Vice Chancellor for Research (the Institutional Official) to establish a committee with oversight responsibility for all institutional hES cell research. The committee shall review all proposed and ongoing hES cell research engaged in by UIC and maintain a registry of all hES cell lines that are imported into or maintained at the UIC.

Human embryonic stem cell research shall include all derivations of hES cell lines and all research using hES cells derived from:

1. Human blastocysts made for reproductive purposes and later obtained for research from in vitro fertilization (IVF) clinics;
2. Human blastocysts made specifically for research using assisted reproductive technology; or
3. Human somatic cell nuclear transfer (NT) into oocytes.

UIC is engaged in hES cell research requiring committee review if the research is:

1. Conducted by UIC faculty, staff or students; or
2. Performed on the premises of UIC; or
3. Using equipment belonging to UIC; or
4. Using funds administered by UIC; or
5. Satisfying a requirement imposed by UIC for the award of a degree or the completion of a course of study; or
6. Conducted by adjunct faculty, including non-salaried faculty, with the intention of citing UIC affiliation in a publication or study documents.

The committee shall be called Embryonic Stem Cell Research Oversight (ESCRO). ESCRO shall have authority to review and approve the following areas of research in which UIC is engaged:

1. All established hES cell lines listed on the National Institutes of Health (NIH) Human Embryonic Stem Cell Research Registry (http://stemcells.nih.gov/research/registry/);
2. All established hES cell lines that are not currently listed on the NIH Registry*; and

3. All new hES cells lines derived from one of the following sources*:

    a. Human blastocysts made for reproductive purposes and later obtained for research purposes from IVF clinics, or
    b. Human blastocysts made specifically for the purpose of research using assisted reproductive technologies, or
    c. Human somatic cell nuclear transfer (NT) into human oocytes for the purposes of creating hES cells.

> **All investigators contemplating research that is covered under 2 or3 above should contact the ESCRO office prior to submitting research to ESCRO.*

Research that is not permitted to be undertaken by UIC shall include the following:

1. Research involving in vitro culture of any intact human embryo, regardless of derivation method, for longer than 14 days or until formation of the primitive streak begins, whichever occurs first;
2. Research in which hES cells are introduced into nonhuman primate blastocysts or in which any embryonic stem cells are introduced into human blastocysts;
3. Research that involves the breeding of any animal into which hES cells have been introduced at any stage of development; or
4. Research that involves human somatic cell NT for the purpose of reproductive cloning.

ESCRO shall advise the Vice Chancellor for Research in all matters relating to UIC use and procurement of hES cells and shall assure that all such research complies with all policies contained within this document.

ESCRO shall develop and provide appropriate training for UIC investigators on the conduct of research using human embryonic stem cells.

The Vice Chancellor for Research is responsible for providing adequate resources to ESCRO to facilitate its charge, including the provision of meeting space, staff support, etc. The Director of the Office for Protection of Research Subjects, who shall report to the Vice Chancellor for Research, will manage the resources.

The Vice Chancellor for Research may not override an ESCRO denial of approval. However, even after ESCRO has approved research, the Vice Chancellor for Research may require further institutional review and may make the determination that certain types of hES research may not be undertaken at UIC.

III. ESCRO Composition

ESCRO shall consist of scientists with expertise in the areas of stem cell research, developmental biology, molecular biology, and assisted reproduction; and individuals with training/credentials in the areas of ethics and law. The Committee shall also consist of an individual who is not affiliated with the institution in any way other than as a member of the ESCRO Committee.

IV. Investigator Responsibilities

1. The investigator in charge of a project that involves hES cells shall prepare and submit to ESCRO such documents as required by ESCRO in conducting its charge.

2. The submission must be approved by ESCRO prior to the investigator's
   a. acceptance of funding; and
   b. the initiation of the research.

   Exception: Research involving only in vitro use of federally approved hES cell lines (all established hES cell lines listed on the National Institutes of Health (NIH) Human Embryonic Stem Cell Research Registry) may begin upon registration with ESCRO and after receiving final approval from other applicable UIC Committees (e.g., ACC, IBC, IRB, etc.). Awards for funding may be accepted prior to registration with ESCRO.

3. Significant changes in registered and/or approved research shall be submitted to ESCRO for review and approval prior to implementation.

4. The investigator in charge of the research project will cooperate with ESCRO and the institution and prepare any requested reports.

V. ESCRO Approval and Oversight

1. ESCRO shall have the authority to review and approve, require modifications in (to secure approval) or deny approval of all research activities involving hES cells engaged in by UIC. Initial approval will be for a maximum of one-year and, after review, a research activity may be reapproved for a continued period.

2. In making its determination, ESCRO will consider the following:

   a. Conformity with all applicable state and federal laws, regulations, and guidelines and all applicable University policies; and
   b. The anticipated risks, benefits and significance of the knowledge to be gained; and
   c. The qualifications and training of the investigator and key personnel to conduct the research.

3. Research activities using hES cells that require review and approval by other UIC Committees (e.g., ACC, IBC, IRB, etc.) should be submitted to ESCRO as follows:

IF	THEN
In vitro use of NIH cell lines	Register with ESCRO after obtaining approval of other UIC committees
In vivo use in animals of NIH cell lines	Submit to ESCRO simultaneously with submissions to other UIC committees

In vivo use in humans of NIH cell lines	Submit to ESCRO simultaneously with submissions to other UIC committees
All research involving established non-federally approved hES cell lines	Submit to ESCRO first
All research involving derivation of new hES cell lines	Submit to ESCRO first

No research may be initiated until ALL required approvals are obtained.

4. ESCRO shall conduct continuing review of approved studies at intervals that it deems appropriate. As part of the continuing review, ESCRO may obtain and review materials submitted to other committees (ACC, IBC, IRB, etc.).

5. ESCRO shall have the authority to observe or have a third party observe the conduct of any research activity subject to ESCRO oversight. ESCRO has the authority to request all records associated with the conduct of the research.

VI. Conflict of Interest

All Investigators submitting research activities to ESCRO must disclose conflicts of interest in the research proposed. Conflicts of interest are defined in accordance with UIC Conflict of Interest Policy (http://tigger.uic.edu/depts/ovcr/research/conflict/RNUA/policy/index.shtml).

No ESCRO committee member may participate in the review or approval of a research activity in which they have a real or perceived conflict of interest, except to provide information requested by ESCRO. In addition to the UIC Conflict of Interest Policy, conflicts of interest may include a member's association with the research (e.g., listed investigator, employment in the laboratory of the principal investigator or co-investigator).

VII. Recordkeeping

ESCRO shall maintain a complete file of each hES cell study including research application, correspondence, etc.

ESCRO shall maintain copies of meeting minutes. Minutes shall document attendance, conflict of interest, research reviewed, controverted issues and their resolution, and committee vote.

Records shall be retained in accordance with UIC policies and all applicable state and federal laws, regulations, and guidelines.

VIII. Non-compliance

Alleged deviations from the UIC ESCRO policies should be reported to the ESCRO chair for investigation, resolution and reporting to the Vice Chancellor for Research and UIC committees with shared jurisdiction (IRB, ACC, IBC, etc.). ESCRO shall have the authority to suspend or terminate its approval of hES cell research that is not being performed in compliance with ESCRO

policies, University policies, applicable state or federal laws, regulations, and/or the general principles expressed in the NAS *Guidelines for Human Embryonic Stem Cell Research.*

ESCRO, through the Vice Chancellor for Research, shall report suspension or termination of research to external funding sources, if applicable. The Vice Chancellor for Research, or designee, has the authority to further review suspected deviations and to suspend or terminate approval of hES cell research.

IX. Additional Policies, Guidelines, Plans and Procedures

ESCRO may develop policies, guidelines, and/or procedures to execute its charge. Such documents will be made available to the UIC community.