University of Michigan

**Human Pluripotent Stem Cell Research Oversight (HPSCRO) Program**

**Application for Derivation and/or Use**

**Principal Investigator Information**

|  |
| --- |
| Last Name, First Name, Middle Initial:  |
| Degree:  | Title:  |
| Department:  |
| Address:  |
| Phone:  | Fax:  | Email:  |
| Administrative Contact Name: | Phone: | Email: |

Derivation of and/or research with a human pluripotent stem cell line requires review and approval by the U-M Human Pluripotent Stem Cell Research Oversight (HPSCRO) Committee **before** the research can begin. HPSCRO provides local oversight of the complex ethical issues related to human pluripotent stem cell research as applicable, including but not limited to subject consent, derivation method, and use in animals.

This application pertains to the derivation of and/or research with **human embryonic stem cell (hESC)** lines and/or **induced pluripotent stem cell (iPSC)** lines. This form does not fulfill related IRB or IACUC project review requirements (if relevant). IRB and IACUC submissions must be made separately, but compliance reviews for these submissions may be conducted in parallel with the HPSCRO Committee review.

**Form Instructions**: **Sections A, B, and PI Certification are required**. Sections C and D may be required depending on the type of research you plan to conduct.

**Submission Instructions**: Email the **completed** form with your scanned signature in the certification section to HPSCRO staff at HPSCROquestions@umich.edu.

**Review Process**: Prior to committee review, HPSCRO staff may contact you to clarify information provided on the application form. The Principal Investigator receives notice of the review outcome from the HPSCRO Committee.

**Questions**: Call 734-764-7545 or email HPSCROquestions@umich.edu for assistance. See <http://research-compliance.umich.edu/human-pluripotent-stem-cells> for HPSCRO policies and procedural information.

**Section A: Cell Line Information**

**A.1. Research type** (check all that apply)

*Note*: Related application sections or questions as applicable to the option are highlighted in parenthesis.

|  |  |  |  |
| --- | --- | --- | --- |
| **✓** | **Human Embryonic Stem Cells (hESC)** | **✓** | **Induced Pluripotent Stem Cells (iPSC)** |
|  | In vitro research with pre-existing NIH-registered hES cell lines (A.2, B) |  | In vitro iPSC research (A.2, B) |
|  | In vitro research with pre-existing hES cell lines that are **NOT** NIH-registered (A.2, B, D) |  | Animal research introducing iPSC into animals at any developmental stage (e.g., postnatal) (C) |
|  | Animal research introducing hESC or derivatives into animals at any developmental stage (e.g., postnatal) (C) |  | Human research with iPSC  |
|  | Human research with hESC  |  | Derivation of new iPSC lines (A.2, B) |
|  | Personally identifiable information from donors linked to hESC  |  |  |
|  | Derivation of new hESC lines (A.2, B, D) |  |  |

**Other Research:** (indicate hESC and/or iPSC and briefly describe)

**A.2. Cell Line or BIOSPECIMEN Information**

Complete the table for each source of a cell line or biospecimen. Indicate the type of line, number of lines (if applicable), and whether you are obtaining (O) the line or deriving (D) the line from source material. Spell out the names of providers, commercial vendors, and PIs.

|  |  |
| --- | --- |
| **Internal (U-M) Source** | **External Source** |
| For biospecimens or cell lines acquired from U-M sources, list the applicable IRB number (HUM) or Repository number (REP) number. | For biospecimens or cell lines acquired from external sources, list the applicable external IRB approval number and/or Material Transfer Agreement (MTA) number.  |

Be prepared to provide informed consent and/or MTA documentation upon request.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Type:**hESC** **iPSC** | No. of lines | Action:Obtain (O)Derive (D) | Provider / vendor / repository(e.g., patient sample, WiCell, etc.) | Line/source material:* NIH Registry No. or Name (e.g., H9)
* Vendor No.
* Cell source: embryo or tissue
 | U-M IRB No. (HUM), U-M Repository No. (REP), or external IRB name/number | MTA Number |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
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**SECTION B: RESEARCH INFORMATION**

**B.1. Objectives OF The Research** (briefly describe; be clear and concise)

**B.2. Scientific Rationale** (briefly explain why the proposed experiments require the use of hESC or iPSC lines rather than alternative methodologies)

**B.3. Proposed Experiments** (briefly describe, especially indicate if the work involves human subjects, non-NIH Registry hES cell lines)

**B.4. LOCATION of WORK**

Building:

Room #:

**B.5. Storage of lines when not actively used**

Storage Method:

Location:

**B.6. Sharing of Cells or Derivatives**

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |

If you check **Yes**, describe your plan for sharing:

**B.7. Other relevant information** (e.g., potential ethical concerns, applicable training for derivation, research collaborators, etc.)

**SECTION C: ANIMAL RESEARCH**

*Instructions:* Complete this section if you checked **Animal Research** in section **A.1**

**C.1 IACUC Protocol Number** (list all that apply)
IACUC approval required when using animal subjects in human pluripotent stem cell research

**C.2 ANimal USE** (list the animal and the nature of experiment necessary to accomplish the research goals)

|  |  |
| --- | --- |
| **Animal** | **Nature of experiment** |
| *E.g., scid-hu mice* | *E.g., Transplantation of hES cell-derived neural progenitors into mice* |
|  |  |
|  |  |
|  |  |
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**C.3 ANIMAL EXPERIMENTS** (briefly describe how the experiments contribute to the goals of the research)

**C.4 Will hES cell derivatives, hES cells, or other pluripotent cells be introduced into non-human embryos/fetuses?**

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |

If you check **Yes**, complete questions C.4-1 - C.4-3.

**C.4-1. Will these embryos/fetuses be allowed to develop postnatally?**

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |

**C.4-2. Explain the extent and consequences of human contribution to the resulting animals, including contributions to the brain or germline.**

**C.4-3. Will the animals be allowed to breed?**

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |

If you check **yes**, provide a scientific justification for breeding and list the steps to be taken to ensure that there is no fertilization involving human gametes.

**Section D: hES CELL LINE RESEARCH**

Complete this section only if you will be obtaining **unregistered hESC lines** or deriving new **hESC** lines.

**D.1. FUNDING**

Research with unregistered cell lines is not eligible for NIH funding. List the funding source(s) for personnel, supplies, equipment, and animal care associated with your work with the unregistered cell lines.

|  |  |  |
| --- | --- | --- |
| Source of support | PAF Number / Title of funded project  | Cell line(s) used in project |
|  |  |  |
|  |  |  |
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**D.2. Facilities and Equipment**

Does the location(s) identified in **B.4** contain NIH-funded equipment or supplies?

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |

If you check **yes**, describe the plan for ensuring that federally funded items are not used for work with unregistered cell lines.

**D.3. EFFORT**

List the research personnel and their percentage of NIH-funded effort beginning with the Principal Investigator.

|  |  |
| --- | --- |
| Last Name, First Name, Degree, Title | % Effort (NIH-supported) |
| (PI):  |  |
|  |  |
|  |  |
|  |  |

**Principal Investigator Certification:**

I certify that the information provided in this application is complete and correct.

I understand that as Principal Investigator, I have ultimate responsibility for the conduct of the study, the ethical performance of the project, and strict adherence to any stipulations imposed by the HPSCRO Committee.

I agree to comply with all University of Michigan policies and procedures, as well as with all applicable Federal, State, and local laws regarding human embryonic stem cell research and induced pluripotent stem cell research, including, but not limited to, the following:

1. Performing the project by qualified personnel according to the approved protocol,
2. Seeking advance approval by the HPSCRO Committee for any anticipated change in the research represented in this application,
3. Compliance with the requirements of relevant Material Transfer Agreements.

I agree not to distribute human pluripotent stem cells or their living derivatives without prospective review and approval by the HPSCRO Committee.

Signature of Principal Investigator Date