**University of Connecticut/UConn Health**



**Stem Cell Research Oversight (SCRO) Committee**

**SCRO Office**

**UConn Health**

**263 Farmington Avenue**

**Farmington, CT 06030**

**SCRO Initial Application Phone: 860-679-6004 Fax: 860-679-1005**

**e-mail:** **eciesielski@uchc.edu**

**P**lease note that all research projects in the following categories are required to complete this application form and receive SCRO Committee approval before acquiring cells or cell lines and commencing research:

* All stem cell research projects funded by the State of Connecticut, including those that do not use human embryonic stem cells;
* All stem cell research involving human embryonic stem cells and their derivatives;
* All stem cell research involving human gametes and human embryos;
* *in vitro* human induced pluripotent stem cell research involving the generation of gametes, embryos, or other types of totipotent cells;
* *in vivo* research involving implantation of human induced pluripotent stem cells into prenatal animals or into the central nervous system of post-natal animals.

**Submit this form and attachments as indicated to** **eciesielski@uchc.edu**. **Submit application to SCRO Office after or at the same time as application to the Institutional Biosafety Committee (IBC), Institutional Animal Care and Use Committee (IACUC), or Institutional Review Board (IRB). SCRO will not approve protocols until documentation of all other necessary approvals has been received. The Principal Investigator is responsible for submitting approval documents to the SCRO.**

**I. General Information**

|  |  |  |
| --- | --- | --- |
| **Date** **of this application:**\*If this is a **revised submission**, please be sure to change the date to reflect the current date. Also, please sign and date the final page again. |      \* | Is this an **original** submission? [ ] Is this a **revised** submission? [ ]  |
| Study Title: |       |
|  | Name | Email | Phone | Fax |
| Principal Investigator |       |       |       |       |
| Contact Person |       |       |       |       |
| **Mailing address** |       |
| **Campus:** | Storrs [ ]  UConn Health [ ]  |
| **Department:** |       |
| **Company Name:****(if applicable)** |       |
| **Estimated Duration of Project:**      | **Project Start Date**:       |

**Project Personnel at UConn/UConn Health**

|  |  |  |  |
| --- | --- | --- | --- |
| Name | Role (Co-PI, Co-I, post-doc, grad student, tech) | Email | Phone |
|       |       |       |       |
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**Non-UConn/UConn Health Project Personnel**

|  |  |  |  |
| --- | --- | --- | --- |
| Name and Institution | Role (Co-PI, Co-I, tech, etc.) | Email | Phone |
|       |       |       |       |
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**II. Ancillary Reviews**

**1a. Scientific Review**

Has this project been reviewed by an expert scientific panel (e.g., an NIH study group or other form of peer review)? [ ]  **Yes** [ ]  **No**

**1b.** If **Yes**, please identify the review panel(s). No acronyms, please.

**2a. Financial Conflict of Interest**

Does the principal investigator, any co-investigator, or research staff involved with this study (or in aggregate with his/her spouse or dependent children) have a financial relationship with the source of funding? [ ]  **Yes** [ ]  **No**

**2b.** In this project, do you test or evaluate any products or services from an entity with which you have any significant financial interest? [ ]  **Yes** [ ]  **No**

**3. Research Oversight Committees**

Submit application to SCRO after or at the same time as application to the IBC, IACUC, or IRB. SCRO will not approve protocols until documentation of all other necessary approvals has been received. The PI is responsible for submitting approval documents to the SCRO.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| A. Has an Institutional Biosafety Committee (\*IBC) approval covering the research in this SCRO protocol been obtained? | Not Applicable [ ] Pending [ ]  Yes [ ]  | Protocol Number:       | Expiration Date:       | Project Title:       |
| B. Has an Institutional Animal Care and Use Committee (IACUC)approval covering the research in this SCRO protocol been obtained?   | Not Applicable [ ] Pending [ ] Yes [ ]  | Protocol Number:       | Expiration Date:       | Project Title:       |
| C. Has an Institutional Review Board (\*\*IRB)approval covering the research in this SCRO protocol been obtained? | Not Applicable [ ] Pending [ ] Yes [ ]  | Protocol Number:       | Expiration Date:       | Project Title:       |

\* At UConn Health, IBC approval is required for research involving recombinant or synthetic nucleic acid molecules (rsNA). At UConn-Storrs, IBC approval is required for research and teaching activities that involve biological materials including but not limited to: recombinant or synthetic nucleic acid molecules (rsNA), biological agents and toxins, bacteria and their phages and plasmids, viruses, fungi, mycoplasmas, prions, and parasites; human and non-human primate tissues, body fluids, blood, blood byproducts, and cell lines, animal remains and insects that may harbor zoonotic pathogens.

\*\* IRB approval is required for donation of human gametes, somatic cells, embryos, and human biological materials for which the donor can be identified.

**4. Please include any notes related to oversight committee approval(s) here:** [ ]  N/A

**Please attach all relevant Research Oversight Committee approvals. For IRB, please attach the currently approved consent form showing approval date.**

**III. Funding Source(s)**

1. What are the current sources of funding for this project?Check all that apply.

[ ]  State of Connecticut Regenerative Medicine Research Fund

[ ]  Other Connecticut State Funds

[ ]  Federal Funds

[ ]  Private Research Foundation Funds

[ ]  Private Industry

[ ]  UConn Start-Up Funds

[ ]  Other (Please specify. No acronyms, please.):

**Please attach grant application.**

**IV. Research Activities**

## Does your project involve:

|  |  |
| --- | --- |
| 1. Research using human fetal tissue or human embryos at any stage  | [ ]  **Yes** [ ]   **No** |
| 2. *In vitro* research using human embryonic stem cells (hESCs) or their derivatives  | [ ]  **Yes** [ ]   **No** |
| Uses federally **eligible** lines (i.e., lines on the **NIH registry)** List available here: <https://grants.nih.gov/stem_cells/registry/current.htm>  | [ ]  **Yes** [ ]   **No** |
|  Uses federally **ineligible** lines (i.e., lines **not** on the **NIH registry**) | [ ]  **Yes** [ ]   **No** |
| 3. Research using hESCs, human induced pluripotent stem cells (iPSCs), or other human cells that is funded by the State of Connecticut Regenerative Medicine Research Fund | [ ]  **Yes** [ ]   **No** |
| 4. Production of human gametes from hESCs or human iPS cells | [ ]  **Yes** [ ]   **No** |
| 5. Introduction of hESCs or hESC derivatives into animals | [ ]  **Yes** [ ]   **No** |
| 6. Introduction of hESCs and/or human iPS cells into the central nervous system of animals | [ ]  **Yes** [ ]   **No** |
| 7. Derivation of hESC from donated excess embryos from fertility treatments\* | [ ]  **Yes** [ ]   **No** |
| 8. Use of hESCs or human iPS cells to contribute to a human embryo | [ ]  **Yes** [ ]   **No** |
| 9. Creation of human embryos intended for research purposes using somatic cell nuclear transfer (SCNT)\*\* | [ ]  **Yes** [ ]   **No** |
| 10. Creation of human embryos from donated human gametes, or from gametes derived from hESC or human iPS lines \*\*\*  | [ ]  **Yes** [ ]   **No** |
| 11. Any research funded by the State of Connecticut Regenerative Medicine Research Fund (RMRF) | [ ]  **Yes** [ ]   **No** |
| \* Requires IRB approval for embryo donation\*\*Requires refined SCNT techniques that reduce the quantity of required oocytes and requires stringent written policies and practices to ensure that derived embryos are used only for the intended research purpose\*\*\* Requires IRB approval for gamete donation and written procedures and practices to protect human oocyte donors |

**V. Training of Research Staff using hESC**

1. Does the project involve hESC lines or the derivation of new hESC lines? [ ]  **Yes** [ ]   **No**

If **No,** proceed to next section. If **Yes**, identify all personnel who will be handling hESC, human gametes or human embryos, including PIs, post-docs, and students. Appropriate scientific training with hESC is required prior to working with these materials. All personnel must complete the Human Stem Cell Compliance Tutorial which is available on the SCRO website: <http://research.uchc.edu/rcs/stem-cells/training/>.

**A bio-sketch in NIH form may be requested. Please attach the Tutorial Answer Sheet for any project personnel who have not yet received their Tutorial Completion Certificate.**

|  |  |  |
| --- | --- | --- |
| **Name** | **Status**(e.g., faculty, post-doc,grad student, tech) | **Date Human Stem Cell Tutorial Passed (if applicable)** |
|       |       |       |
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**VI. Human Biological Materials**

1. Does the research involve human cells/tissues? **[ ]** **Yes [ ]  No**

If **No**, proceed to next section. If **Yes**, continue**.**

|  |  |  |
| --- | --- | --- |
| **Material** | **Source** | **Status of** **Material Transfer Agreement (MTA) or Simple Letter Agreement (SLA)**  |
| [ ]  NIH-Registered hESC lines | Cell Line Name(s)      NIH Cell Line Name(s), if different      [NIH Registration Number(s)](https://grants.nih.gov/stem_cells/registry/current.htm)       | [ ]  MTA/SLA(s) completed[ ]  MTA/SLA(s) in progress\*[ ]  Other (Explain):       |
| [ ]  Non-NIH-Registered hESC lines | Cell Line Name(s)      Institutions(s)      Principal Investigator(s)       | [ ]  MTA/SLA(s) completed[ ]  MTA/SLA(s) in progress\*[ ]  Other (Explain):       |
| [ ]  Human iPS or other Non-Embryonic Derived Human Pluripotent Stem Cells  | Cell Line Name(s)      Institutions(s)      Principal Investigator(s)       | [ ]  MTA/SLA(s) completed[ ]  MTA/SLA(s) in progress\*[ ]  Other (Explain):       |
| [ ]  Human Somatic Cells to be used for iPS  | Cell Line Name(s)      Institution(s)       | [ ]  MTA/SLA(s) completed[ ]  MTA/SLA(s) in progress\*[ ]  Other (Explain):       |
| [ ]  Multipotent Human Neural Stem Cells (if there is the potential that they may contribute to central nervous system of chimeric animals) | Cell or Tissue identifier, Description     Materials used to generate or obtain tissue:       | Owner:     If not you, status of MTA/SLA:      Owner:      |
| [ ]  Embryos Quantity:       | IRB Numbers(s)      Institutions(s)      Principal Investigator(s)       | Note: Human Subjects - Requires IRB review |
| [ ]  Sperm  | IRB Numbers(s)      Institutions(s)      Principal Investigator(s)       | Note: Human Subjects - Requires IRB review  |
| [ ]  Oocytes  | IRB Numbers(s)      Institutions(s)      Principal Investigator(s)       | Note: Human Subjects - Requires IRB review |
| [ ]  Other Please specify:       | Source:       | [ ]  MTA/SLA(s) completed[ ]  MTA/SLA(s) in progress\*[ ]  Other (Explain):       |

**\*The SCRO Committee will provide a *contingent* approval letter to the PI to supply to Sponsored Program Services (SPS) in order to begin the process to fully execute the MTA/SLA. Upon SCRO’s receipt of the fully executed MTA/SLA, the SCRO Office will provide a *final* approval letter to the PI.**

**More information about human ESCs (hESCs) and human iPSCs (hiPSCs):** [UConn Stem Cell Core](https://sites.google.com/site/ctstemcellcorehipsc/home)

WiCell hESCs MTA process:

<https://sites.google.com/site/ctstemcellcorehipsc/home/mta-with-wicell-for-hescs>

CT-hESCs:

<https://sites.google.com/site/ctstemcellcorehipsc/home/ct-hesc-lines>

hiPSCs banked at Stem Cell Core, availability:

<https://sites.google.com/site/ctstemcellcorehipsc/home/ipscs-available>

Deriving your own hiPSCs by Stem Cell Core:

<https://sites.google.com/site/ctstemcellcorehipsc/home/reprogramming-service>

**More information about human specimens:**

Institutional Review Board (IRB) Human Subjects Review

UConn IRB: <http://research.uconn.edu/irb/> UConn Health IRB: <http://research.uchc.edu/rcs/hspp/>

When Submission to the IRB is Required

A protocol application must be submitted to the IRB for any study for which research is the intent and the researcher proposes to use or involve any of the following:

* identifiable data collected for non-research purposes (e.g., academic or medical records);
* interaction (communication or interpersonal contact between investigator and participant) through interviews, surveys, and other forms of communication;
* intervention (physical procedures by which data are gathered and manipulations of the participant or the participant’s environment that are performed for research purposes);
* student research projects conducted as part of Research Methods Courses;
* **access to medical records and data through the medical information systems;**
* **pathological specimens (directly identifiable or identifiable via codes);**
* **diagnostic specimens (directly identifiable or identifiable via codes).**

The IRB reviews projects when the research:

* is sponsored by the institution;
* is conducted by or under the direction of an employee or agent of the institution in relation to his/her institutional responsibilities;
* is conducted by or under the direction of an employee or agent of the institution using resources of the institution; or
* involves the use of the institution’s non-public information (i.e. alumni, students, staff, etc.) to identify or contact human research participants or prospective participants.”

**VII. Research Plan**

**1. Does your research plan involve the injection of human stem cells into non-human animals?**

[ ]  **Yes**  [ ]  **No**

**2. Summarize your study:** To the extent possible, the summary should be written in language intelligible to a layperson. Provide clear and concise statements of research objectives, research hypotheses, study rationale and methodology, and expected results. The length should be at least one half of a page and no more than one page.

**3. Rationale:** Explain the scientific significance of the expected results.

**4. Experimental procedures:**

Outline the proposed experiments, including description of animal use, and their scientific rationale. Clearly present the sequence and projected timeline for the experiments. Chart format is helpful. Special attention should be given to specifying activities for the first year of the study and clearly describing the timeline and scientific rationale for ethically controversial areas of research (e.g., creation or destruction of human embryos; research involving human gametes; experiments with the potential for the integration of human and nonhuman cells or DNA in animal brains, germ lines, or new pluripotent cell lines).

**VIII. Stem Cell Research Using Animal Models**

[ ]  N/A If your experiment does not involve the injection of human stem cells into non-human animals, proceed to next section.

**Note:** SCRO approval will not be granted until documentation of all required IACUC approvals is received.

|  |
| --- |
| **In most cases, the mixing of human and animal cells is regarded as ethically unproblematic from the perspectives of both the public and the SCRO. However, ethical concerns exist with respect to two issues:****Issue 1.** It is possible (though unlikely) human cells can migrate to animal gametes, therefore, animals into which hESC or hESC derivatives are implanted are NOT *allowed to breed.* **Issue 2.** Enhancement of animal cognitive abilities due to implantation of human cells, particularly in the context of brain studies is a sensitive area. It is believed that the risks of this type of effect increase with increasing numbers of implanted cells, increasing plasticity of the implanted human cells, and earlier developmental stages of the research animal at the time of implantation. Depending on the numbers and types of human cells used and the host’s developmental stage at implantation, PIs may be required to work with the SCRO in developing a risk management plan.Keeping these concerns in mind, please answer the following questions. |

1. Animals into which hESC or hESC derivatives have been introduced are not allowed to breed. Describe how you will prevent adult animals from breeding.

[Note: Any deviation from your plan or unexpected event that increases the risk of breeding must be reported to the SCRO immediately.]

2. If you are doing brain studies with hESC or neuro-progenitors:

a. In terms of the average numbers of cells normally in the animal’s brain, up to what percentage of the animal’s brain could be constituted by the injected human cells?

b. Describe your plan and timetable for monitoring the effects of the human cells, including any behavioral effects.

[Note: Any unusual or unexpected effects should be reported to the SCRO immediately.]

3. If hESC and/or human iPS cells are introduced into animal blastocysts, embryos, or fetuses, explain why experiments using more developed human cells or animals cannot provide relevant information.

**IX. Justification for Creating or Modifying Embryos for the Purpose of Stem Cell Research**

[ ]  N/A If your experiment does not involve creating/modifying embryos, proceed to next section.

**Note:** Methods in this category require stringent scientific and ethical justification. They may require external expert scientific review.

|  |
| --- |
| **Check all that apply:**[ ]  Creates human embryos solely for research purposes using IVF.[ ]  Creates human embryos using parthenogenesis or androgenesis (embryo contains only maternal/paternal chromosomes respectively).[ ]  Uses somatic cell nuclear transfer with human DNA and **animal** oocytes.[ ]  Uses somatic cell nuclear transfer with human DNA and **human** oocytes.[ ]  Other (explain):       |

1. Discuss ethically less controversial alternatives to achieving the same benefits as this study and justify the chosen method.

2a. Describe and justify the anticipated number of human oocytes to be used, showing that the number is the smallest necessary to achieve the research objectives.

2b. Describe previous experience, research, or innovations that will enable personnel conducting this study to minimize the number of human oocytes.

3a. Describe and justify the number of embryos to be generated, showing that the number is the smallest necessary to achieve the research objectives.

3b. Describe previous experience, research, or innovations that will enable personnel conducting this study to minimize the numbers of embryos generated.

4a. Describe the protocols for ensuring that the embryos will be used only for the research described in this application.

4b. Describe the protocols for determining that an embryo is not suitable for the derivation of stem cells and for disposing of these embryos.

4c. Describe the protocols for ensuring that no embryos develop past day 14 or past the point of primitive streak development, whichever comes first.

5. Describe prior experience or training in handling gametes or embryos for each member of study staff.

**X. Investigator Certification**

|  |
| --- |
| *The following are the minimum responsibilities of Principal Investigators as stated in the formal agreement between the University of Connecticut/UConn Health and the SCRO Committee. I, the Principal Investigator, certify that:* |
| I have answered all questions on this document and its attachments truthfully and with completeness.  |
| I understand that **all** personnel (researchers and staff) involved with human embryonic stem cell research must complete the Human Stem Cell Compliance Tutorial and have completed appropriate scientific training.  |
| I understand that I must file an amendment form for any change in research personnel and that all new hESC personnel must complete the Human Stem Cell Compliance Tutorial mentioned above. |
| I will send the SCRO any SLA/MTAs for cell lines I may receive from approved sources other than the UConn Stem Cell Core. |
| I agree that I will adhere to the University Stem Cell Lab policies as published on the university’s web site (which includes security measures for all hESC lines for which I have an MTA.) |
| I will not perform experiments for human reproductive cloning. |
| I will not allow any human embryo to develop past day 14 or the point of primitive streak development, whichever comes first.  |
| I understand that at this time no investigator will introduce any type of embryonic stem cells or iPS cells into human subjects or human blastocysts, or any hESC into nonhuman primate blastocysts. |
| I will not allow an animal into which hESC or hESC derivatives or human iPS cells have been introduced to breed. |
| I am responsible to notify the SCRO Committee of any amendments to my IBC, IACUC or IRB protocols relevant to hESC research prior to implementation. In addition, I am responsible to notify the IBC, IACUC, and IRB of any amendments to my hESC protocols under the jurisdiction of those committees. |
| I understand that the Research Compliance Services at UConn Health and Storrs have the right to perform unannounced audits of laboratories involved with hESC. |
| Principal Investigator Signature |
| Date |       |
| Print Name |       |
| Signature | ***I agree to comply with the policies listed in the Investigator Certification and any other relevant guidelines from University of Connecticut/UConn Health and Federal and State agencies.***      \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Co-Principal Investigator Signature (if applicable) |
| Date |       |
| Print Name |       |
| Signature | ***I agree to comply with the policies listed in the Investigator Certification and any other relevant guidelines from University of Connecticut/UConn Health and Federal and State agencies.***      \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**Attachments Checklist**

|  |  |
| --- | --- |
| **Did you attach…** |  |
| the project grant application? | [ ]  Yes [ ]  N/A |
| MTA(s)/SLA(s)? | [ ]  Yes [ ]  N/A |
| IRB approval letter and currently approved/stamped consent form? | [ ]  Yes [ ]  N/A |
| IBC approval? | [ ]  Yes [ ]  N/A |
| IACUC approval? | [ ]  Yes [ ]  N/A |
| Tutorial Quiz Answer Sheet for any project personnel who have not yet received their Human Stem Cell Compliance Tutorial Completion Certificate? | [ ]  Yes [ ]  N/A |