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



**UConn Health**

**263 Farmington Avenue**

**Farmington, CT 06030**

**SCRO Amendment Form Phone: 860-679-6004 Fax: 860-679-1005**

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

The following changes to an approved SCRO protocol must be reviewed and approved by the SCRO Committee before being implemented:

* Change in PI or other project personnel
* Change in funding
* Addition of human embryonic stem cell (hESC) lines to be used
* Changes in the procurement of human embryos, gametes or somatic cells
* Changes in experimental protocols in the use of hESC or derivatives, human gametes, or embryos; or changes in *in vivo* research involving implantation of human induced pluripotent stem cells (iPSCs) into prenatal animals or into the central nervous system of post-natal animals

Submit this form and attachments as indicated to eciesielski@uchc.edu. The Principal Investigator (PI) is responsible for notifying Sponsored Program Services (SPS), Institutional Biosafety Committee (IBC), Institutional Animal Care and Use Committee (IACUC), or Institutional Review Board (IRB) of any changes under the oversight scope of these offices.

**I. General Information**

**Date of this form:**

**Project Title:**

**Principal Investigator:**

**SCRO Protocol Number:**

**Contact Info (Campus, Department/Company Name, Address, Email & Phone):**

**II. Categories of Amendment— Check all that apply.**

1. **[ ]  Change in PI or other project personnel**

All new personnel working with hESC must complete the Human Stem Cell Compliance tutorial which can be found on the SCRO website at <http://research.uchc.edu/rcs/stem-cells/training/>.

**Change in PI.**

|  |  |  |
| --- | --- | --- |
| **Name** | **Date Human Stem Cell Tutorial Passed (if applicable)** | **Reason for Change** |
|       |       |       |

**Change in other project personnel** (excluding PIs, including any Co-PI, post-doc, student, etc.). Note: Your SCRO approval letter will list all currently approved staff so be sure to list below individuals who are being added or removed from the protocol.

**Personnel Added**

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

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| **Name**  |
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***Please attach the******Tutorial Answer Sheet for any project personnel who have not yet received their Tutorial Completion Certificate.***

1. [ ]  **Change in funding**

**Please describe change:**

**3.** **[ ]  Additional hESC lines to be obtained.**

|  |  |  |
| --- | --- | --- |
| **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):       |

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

**Reason for addition:**

***Please attach the following:***

1. *For hESC lines to be obtained from the UConn Stem Cell Core (WiCell), please attach the SLA.*
2. *For hESC lines or derivatives not obtained from the UConn Stem Cell Core, please attach the MTA.*
3. *Any relevant IRB approvals/consent forms*

**4.** [ ]  **Changes in the procurement of human embryos, gametes or somatic cells.** Changes in source, procurement procedures, or privacy protections.

|  |  |
| --- | --- |
| **PROPOSED CHANGES IN DONATION OF HUMAN EMBRYOS OR GAMETES** | **REASON FOR PROPOSED CHANGE** |
|       |       |
|       |       |
|       |       |

***Please attach IRB approval/consent form showing proposed changes.***

**5.** [ ]  **Changes in scientific experiments** using hESC or derivatives, human embryos or gametes; or changes in *in vivo* research involving implantation of human induced pluripotent stem cells (iPSCs) into prenatal animals or into the central nervous system of post-natal animals.

|  |
| --- |
| Provide a brief description and rationale for the proposed changes in the expandable box below: |
|       |

***Please attach approvals of these amendments as relevant by the IBC, IACUC, and IRB.***

**Investigator Certification**

**I certify that all information provided on this form and attached documents is true, and that I will notify any other oversight committee (e.g., SPS, IBC, IACUC, IRB) of these changes as required by their policies.**

**PI Name:**

**PI Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:**

**Attachments Checklist**

|  |
| --- |
| **Did you attach…** |
| Human Stem Cell Compliance Tutorial Answer Sheet (for any project personnel who have not yet received their Tutorial Completion Certificate)? | [ ]  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 |