NYU Langone Health

Human Research Protections
Embryonic Stem Cell Research Oversight Committee
1 Park Avenue | 6th Floor | New York, NY 10016
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Embryonic Stem Cell Research Oversight Committee (ESCRO) Modification Form

If you are submitting a modification of a study with ESCRO approval, complete this form and submit to ESCRO@nyulangone.org. This form documents information required to ensure research is performed in accordance with the NYU Langone Human Research Protections Policy and Procedure Manual, available on the Human Research Protections (HRP) website.

1. Investigator Information *NOTE: Attach bio sketch for all listed personnel*

Principal Investigator (PI): Department / Division:	***Phone:*** ***Email:***	
PI's Administrative Contact: Department / Division:	***Phone:*** ***Email:***	
Co-Investigator:	***Phone:*** ***Email:***	☐ NYU Faculty/Employee ☐ Non-NYU Faculty/Employee
Co-Investigator:	***Phone:*** ***Email:***	☐ NYU Faculty/Employee ☐ Non-NYU Faculty/Employee
Co-Investigator:	***Phone:*** ***Email:***	☐ NYU Faculty/Employee ☐ Non-NYU Faculty/Employee

2. Study Information

Study Title:

Very brief description of study *NOTE: Limit description to 2 or 3 sentences*
Please also include the study protocol with this application, and also indicate the embryonic research section, if part of a larger study.

3. Category of Research

The following categories of research do not require registration with the ESCRO Committee:

- Use of non-Human Stem Cells
- Use of human cord blood;
- Transplantation of Stem Cells as part of a recognized and accepted medical treatment for a disease or condition
- The creation and **ex vivo** passage of induced pluripotent stem cells (iPSC)

Choose the categories below that best describes your research*:*

Require ESCRO Committee Registration

1. ☐ **NIH-Registered Cell Lines**: *In vitro* research using hESC lines that are listed on the NIH hESC Registry: http://stemcells.nih.gov/research/registry/
2. ☐ **ESCRO pre-approved Cell Lines**: *In vitro* research using hESC lines or iPSC lines that have been pre-approved for such use by the ESCRO Committee.
3. ☐ **De-Identified IRB Approved Cell Lines**: *In vitro* research using Human Stem Cells that have been obtained using an IRB approved process and the cell lines have been de-identified such that the identity will never be released to the Investigator.
4. ☐ **Human Transplant**: Research involving transplantation of Human Stem Cells or cells derived from Human Stem Cells into human subjects.
5. ☐ **Other:** Other types of Human Stem Cell Research that the Vice Dean for Science (or her designee) has made a written determination, after due consideration of the likely risks and benefits of such research, that such categories are permissible without the additional review of the ESCRO Committee.

Require Full ESCRO Committee Review

1. ☐ **New hESC Cell Line:** Creation of a new hESC line by any means, including through use of SCNT, human zygotes, spindle transfer, or a human embryo furnished by an *in vitro* fertilization clinic or other lawful source.
2. ☐ **Donor Payment**: Payment to a donor solely for the purpose of creating a human embryo to be used in hESC research.
3. ☐ **Donor Identifiers**: Research in which personally identifiable information about the donor of the blastocysts, morulae, gametes, or somatic cells from which the hESCs or iPSCs were derived is readily ascertainable or might become known to the investigator.
4. ☐ **Ineligible hESC Lines**: Research using NIH Ineligible hESC lines that have not been pre-approved for such use by the ESCRO Committee.
5. ☐ **Neural or Gametic Cell Lines**: iPSC Research which includes experiments designed or expected to yield neural or gametic cells and tissues.
6. ☐ **Mixing Cells & Embryos**: Mixing human totipotent stem cells or iPSCs with pre-implantation human embryos (*In no case shall such experiments be allowed to progress for more than 14 days of development in vitro, or past the point of primitive streak formation, whichever is first*).
7. ☐ **Implantation**: Clinical research in which cells of human totipotent stem cells or iPSCs are transplanted into living human subjects.
8. ☐ **Culturing Human Embryo:** In vitro culture of intact human embryo.
9. ☐ **Chimeric human cells:** Research that generates animal chimeras using human cells, including, but not limited to, introducing hESCs, human totipotent stem Cells or iPSCs into animals other than humans or primates at any stage of embryonic, fetal, or postnatal development.
10. ☐ **Non-human Primates**: Research that involves the introduction of hESCs into non-human primates at any stage of fetal or postnatal development.
11. ☐ **Other**: Other types of Human Stem Cell Research. Describe:

4. Modification Details

a. Select all statements relevant to proposed changes:

☐ *Changes in experimental protocols using human embryonic stem cells or derivatives, human gametes, or embryos*
☐ *Request for additional types of resources of human embryonic stem cell lines or other human biological materials*
☐ *Changes in research personnel, including postdoctoral fellows and graduate students*
☐ *Increase the number of subjects to be enrolled*
☐ *Addition/deletion of a site*
☐ *Other(specify):*

☐ *Change impacts originally approved category of review, if selected, indicate new category:*
☐ *Change increases risk to human subjects or animals*
☐ *Change requires re-consenting of human subjects*

b. Provide brief description and clear rationale of change(s) being made:

5. Conflict of Interest

All investigators and study staff engaged in the design, conduct, or reporting results of this project and/or their immediate family members must first complete an Annual Disclosure: http://era.med.nyu.edu/disclosures.

If you do not have an associated IRB research electronic disclosure, you must complete and attach a Research Financial Interest Disclosure Form. If answers to ANY of the questions on the Investigator Financial Form are 'yes', the affected research team member(s) must complete and submit a Supplemental Disclosure Form directly to the Conflicts Management Unit.

Contact cimu.disclosures@nyulangone.org for any questions related to your COI Disclosure.

6. . Certification

By signing below, I certify that:

- I have reviewed this protocol submission in its entirety and I am fully cognizant of and in agreement with all submitted statements.
- I have adequate resources and facilities to carry out the proposed research.
- I will comply with the current state and federal regulations and NYU Langone Health ESCRO Committee requirements governing this research.
- I will ensure that all individuals associated with this project have the appropriate credentials to conduct the portion of the study in which they are involved.
- I have completed and will require my research team to complete an educational program on the protection of human subject research participants.
- I will ensure that all co-investigators and other personnel assisting in the conduct of this research study have been provided a copy of the entire current version of the research protocol and are fully informed of the current (a) study procedures (including procedure modifications); (b) potential risks associated with the conduct of this study and the steps to be taken to prevent or minimize these potential risks; (c) data and record-keeping requirements; and (d) the current approval status of the research study.
- I will respond promptly to all requests for information or materials solicited by the NYU Langone Health ESCRO Committee.
- I will maintain adequate, current, and accurate records of research data, outcomes, and adverse events (if applicable) to permit an ongoing assessment of this research project.
- **I have read and understood all of the questions in this application and that all of the foregoing information and statements submitted in this application and its attachments and supporting documents are true and correct to the best of my knowledge and that all responses to the questions are full and complete, omitting no material information.**

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Signature of Principal Investigator (actual signature required) ***Date***