

Embryonic Stem Cell Research Oversight Committee (ESCRO) Modification Form

| 1. Investigator Information <i>NOTE: Attach CV for all personnel being added</i> | | |
|---|--|--|
| Principal Investigator (PI): Department / Division: | Phone: Email: | |
| PI's Administrative Contact: Department / Division: | Phone: Email: | |
| Co-Investigator: | Phone: Email: | <input type="checkbox"/> NYU Faculty/Employee <input type="checkbox"/> Non-NYU Faculty/Employee |
| Co-Investigator: | Phone: Email: | <input type="checkbox"/> NYU Faculty/Employee <input type="checkbox"/> Non-NYU Faculty/Employee |
| Co-Investigator: | Phone: Email: | <input type="checkbox"/> NYU Faculty/Employee <input type="checkbox"/> Non-NYU Faculty/Employee |
| 2. Funding Sponsors | | |
| Sponsor: | Sponsor Type: | Grant #: |
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| 3. Approved Category of Research | | |
| <i>Indicate the category in which your study was initially approved:</i> | | |
| Require ESCRO Committee Registration | 1. <input type="checkbox"/> NIH-Registered Cell Lines: <i>In vitro</i> research using hESC lines that are listed on the NIH hESC Registry: http://stemcells.nih.gov/research/registry/ | |
| | 2. <input type="checkbox"/> ESCRO pre-approved Cell Lines: <i>In vitro</i> research using hESC lines or iPSC lines that have been pre-approved for such use by the ESCRO Committee. | |
| | 3. <input type="checkbox"/> De-Identified IRB Approved Cell Lines: <i>In vitro</i> 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. <input type="checkbox"/> Human Transplant: Research involving transplantation of Human Stem Cells or cells derived from Human Stem Cells into human subjects. | |
| | 5. <input type="checkbox"/> 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. <input type="checkbox"/> 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 <i>in vitro</i> fertilization clinic or other lawful source. | |
| | 2. <input type="checkbox"/> Donor Payment: Payment to a donor solely for the purpose of creating a human embryo to be used in hESC research. | |
| | 3. <input type="checkbox"/> 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. <input type="checkbox"/> Ineligible hESC Lines: Research using NIH Ineligible hESC lines that have not been pre-approved for such use by the ESCRO Committee. | |
| | 5. <input type="checkbox"/> Neural or Gametic Cell Lines: iPSC Research which includes experiments designed or expected to yield neural or gametic cells and tissues. | |
| | 6. <input type="checkbox"/> Mixing Cells & Embryos: Mixing human totipotent stem cells or iPSCs with pre-implantation human embryos (<i>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.</i>) | |
| | 7. <input type="checkbox"/> Implantation: Clinical research in which cells of human totipotent stem cells or iPSCs are transplanted into living human subjects. | |
| | 8. <input type="checkbox"/> Culturing Human Embryo: <i>In vitro</i> culture of intact human embryo. | |
| | 9. <input type="checkbox"/> 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. <input type="checkbox"/> Non-human Primates: Research that involves the introduction of hESCs into non-human primates at any stage of fetal or postnatal development. | |
| | 11. <input type="checkbox"/> Other: Other types of Human Stem Cell Research. Describe: | |
| 4. Modification Details | | |
| a. Select all statements relevant to proposed changes <input type="checkbox"/> <u>Changes in experimental protocols using human embryonic stem cells or derivatives, human gametes, or embryos</u> <input type="checkbox"/> <u>Request for additional types of resources of human embryonic stem cell lines or other human biological materials</u> <input type="checkbox"/> <u>Changes in research personnel, including postdoctoral fellows and graduate students</u> <input type="checkbox"/> <u>Increase the number of subjects to be enrolled</u> <input type="checkbox"/> <u>Addition/Deletion of a Site</u> <input type="checkbox"/> <u>Other (specify):</u> <input type="checkbox"/> <u>Change impacts originally approved category of review. If selected, indicate the new category:</u> <input type="checkbox"/> <u>Change increases risk to human subjects or animals</u> <input type="checkbox"/> <u>Change requires re-consenting of human subjects</u> | | |

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

5. Conflict of Interest

Conflict of Interest forms must be submitted for all individuals being added to the study team.

- All investigators and study staff engaged in the design, conduct, or reporting results of this project and/or their immediate family members must complete and attach a **Investigator Financial Interest Form**:
<https://nyumc.ellucid.com/documents/view/2503/?security=28bcde9092eee95a97cfb87a5dca7f03b8a98d9>
- If the answer to ANY of the questions on the Investigator Financial Form is **yes**, the affected research team member(s) must complete and submit directly to the Conflicts Management Unit the form accessible at:
<https://nyumc.ellucid.com/documents/view/2502/?security=e537079fae57aab71e7d172d6ebaaadf486d4b2>

6. Certification

By signing below, I certify that:

- 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.

Signature of Principal Investigator (actual signature required)

Date