TIPS FOR COMPLETING
THE STEM CELL RESEARCH APPLICATION (SCRO)

If your research ONLY involves cell lines with limited differentiation potential (ie. tissue specific or multipotent stem cells) and you do not intend to use these cells to generate cells with pluripotent traits, then you **DO NOT** need to submit a SCRO application.

You DO need to submit a stem cell research application if your research:

- Uses existing human induced pluripotent stem cells (hiPSCs), human embryonic stem cells (hESCs), or other similar pluripotent stem cell lines.
- Will generate new pluripotent stem cell lines.

If you will be making new stem cell lines you will also need the following approvals:

- ***IBC approval*** is required if you will be introducing Yamanaka or similar genes into the primary cell lines to convert them to iPSCs
- ***IRB approval*** is required
- ed for generating new hiPSCs from patient cells. If patient cells are collected by another investigator, you must check with human subject approval committee to determine if you will need human subject approval to use the cells.

If you will be introducing recombinant DNA and/or virus into existing iPSC cells your will need:

- ***IBC approval*** is required when manipulating iPSCs with any DNA, RNA, or Viral constructs. The manipulations in the stem cell application must be consistent with the IBC application.

If you will be introducing your cell lines into animals, you will need:

- ***IACAC approval*** is required if your cell lines will be introduced into animals. Procedures/manipulations in the stem cell application must be consistent with the IACUC.

Your staff listed in the Stem Cell Protocol will need to be up to date with training:

- All relevant Stony Brook University Safety courses will depend upon your research.
    - Typical courses are: **CITI training** – Responsible Conduct in Research, Human Stem Cell Research, Research Security Training; and ***Brightspace*** - ELS003 Biological Safety and EOS 004 Blood Born Pathogens.

Completing the SCRO application

Basic Information

1. Select admin office: Choose Office of Research compliance (Stem Cells)

2. Title of proposal: Use a title that will distinguish your Stem cell application from your other IBC and IRB applications (makes it easier for you to locate)

3. Short title: Pick a shortened title

4. Summary of Research: Enter a short, high-level overview of the research to be performed. Be sure your description:

- States the central question the research is intended to answer
- States the primary objectives of the study
- Includes a brief description of the methods you will be using for your stem cell work.
- The research description should include a general description of the types of pluripotent cells you will be using as well as the sources of these cell lines (specific cell lines, sources, MTAs, etc. will be entered later in the application).
- Provides a brief description of the source of the primary/starting cells and how you will make the cells lines and what you will use for your control cell lines specific cell lines (sources, MTAs, IRB approval, etc. will be entered later in the application).
- Explicitly states if your research will be conducted *in vitro*. If your research involves introduction of pluripotent cells into animals, this should be stated in your description of research.
- Methodologies relevant only to your pluripotent stem cell work.

5. Select appropriate review:

- Select “Stem Cell Research Oversight”

- **6. Principal Investigator:**

- State name of Principal Investigator

7. Are any parts of this study related to COVID-19 (e.g. intended to understand the effects of COVID-19 on individuals and/or society as a whole, explore potential treatment options, etc.)?:

- Select “Yes” or “No”

Protocol Team Members

1. Identify each additional person involved in the design, conduct, or reporting of the research:

- For each SBU staff member on the project, provide Name, Employee ID, Role, Additional Roles, Involved with Procedures, email, and phone number.

List any external team member information:

- Upload a document listing any external members and provide their Name, position, institution, Role and involved procedures, email, and phone number.

Funding Sources:

- Identify each funding organization supplying funding for the protocol

- Click the “+” button and add funding information. A popup screen will allow ask you to provide the 1) name of the funding organization, 2) sponsor’s funding ID, 3) Grants office ID, and 4) use the “+” to attach copy of your grant aims and/or grant.

Stem Cell Summary:

1. Select all human materials and procedures involved in the protocol: (select all that apply) Your selections will determine which pages you will be required for fill out. The choices are:

- Embryonic stem cells and induced pluripotent cells – including somatic cell nuclear transfer (SCNT)

- Introduction of embryonic or human pluripotent stem cells or multipotent cells into non-human animals or embryos (IACUC approval required before submission to SCRO).
- Derivation or creation of new embryonic or other human pluripotent stem cell lines
- Oocytes
- Human embryos
- Introduction of stem cell lines into humans (IRB approval required befor submission to SCRO)
- Other

2. If other, Specify:

- If you chose other above you should fill in the box.

3. List the origin of each stem cell line (human patient lines must have IRB approval or waiver before submission to SCRO)

- List the name and origin of each stem cell line and indicate whether it is IRB exempt or IRB approved.

4. Review and confirm (by checking each box) that your research does NOT involve:

- Research is intended to derive new stem cell lines from human embryos or fetuses.
- Research involving in vitro culture of any intact human embryo, regardless of derivation method, for longer than 14 days or until formation of the primitive streak begins (whichever occurs first).
- Research in which hESCs, human totipotent, or human pluripotent stem cells are introduced into human or other vertebrate pre-implantation embryos.
- Research in which human multipotent stem cells (ie neural stem cells) are introduced into vertebrate embryos and could significantly contribute to development of the brain.
- Research in which any products of research involving human totipotent or pluripotent cells are implanted into a human or non-human primate uterus.
- Research involving the breeding of chimeric animals where the introduction of hESCs or human pluripotent stem cells could contribute to the germ line.

- Research on a cell line derived from human embryos created for research purposes rather than reproductive purposes.
- Research on a cell line derived from human somatic cell nuclear transfer.
- Research on a cell line derived from human parthenogenesis.

Stem Cell Lines

1. Stem Cell Type (select all relevant):

- Embryonic
- Pluripotent
- Multipotent

2. Are the embryonic stem cell lines used, derived, or collected in this research on the existing NIH Human Embryonic Stem Cell Registry? This will only appear if you selected "embryonic" stem cell type. Choose "Yes" or "No".
https://stemcells.nih.gov/registry/eligible-to-use-lines

3. If yes, provide the NIH code:

4. If no, upload documentation with this application to validate that the embryo derived stem cell line(s) being used in the study: (Note that federal funds may not be used for research involving human embryonic stem cells not listed on the NIH Registry).

- Was isolated after July 7th, 2009.
- Was isolated from embryos created using in vitro fertilization for reproductive purposes.
- Was donated by individuals who sought reproductive treatment and gave voluntary written consent for the human embryos to be used for research purposes.
- Was isolated from embryos obtained from a health care facility where all options available for embryos no longer needed for reproductive purposes were explained to the individual(s) who sought reproductive treatment.
- Was not obtained from donated embryos where the patient seeking reproductive treatment was offered payments, cash or in kind, for the donated embryos.
- Was obtained from donated embryos/or SCNT obtained from a health care facility where policies and/or procedures were in place to ensure the quality and care of the

potential donor(s) and that these policies were not affected by the decision to consent or refuse to donate embryos for research.

- There was clear separation between the prospective donor(s)'s decision to create human embryos for reproductive purposes and the prospective donor(s)'s decision to donate human embryos for research purposes.

Specifically:

- Decisions related to creation of human embryos for reproductive purposes should have been made free from the influence of researchers proposing to derive or utilize hESCs in research
- Consent for the donation of embryos for research purposes should have been given at the time of embryo donation
- Donor(s) should have been informed that they retained the right to withdraw consent for the donation of the embryo(s) until the embryos were actually used to derive embryonic stem cells or until information which could link the identity of the donor(s) with the embryo was no longer retained.
  The embryo donor(s) was informed during the consent process of the following:

Embryo(s) would be used to derive hESCs for research:

- What would happen to the embryos in the derivation of hESCs
- hESCs derived from the embryos might be kept for many years
- The donation was made without any restriction or direction regarding the individual(s) who may receive medical benefit from the use of the hESCs, such as who may be the recipient of cell transplants
- The hESC research was not intended to directly benefit the donor
- The results of research using the derived hESCs may have commercial potential and the donor(s) would not receive financial or other benefits from such commercial development
- Whether information that could identify the donor(s) would be vailable to researchers.
- Cell lines not listed in the NIH stem cell registry and isolated prior to July 7th, 2009 may be considered for research at Stony Brook University, but must be first be approved by a Working group of the Advisory Committee to the Director (ACD). (http://acd.od.nih.gov/hesc.htm) The ACD will make recommendations to the NIH

Director, who will make a final decision about eligibility for NIH funding (criteria for use at Stony Brook University)

5. Stony Brook University researchers must execute, with the SBU's Office of Technology Transfer and Licensing, a Material Transfer Agreement prior to obtaining any human stem cell lines from an external entity. Are there Materials Transfer Agreements for this study?:

- Select "Yes" or "No"
- Upload relevant transfer agreements or confirmation from the provider that no MTA is required.

Derivation or Creation of Cell Lines (The questions in this section will vary depending upon the type of cell lines you indicated that you will be generating)

1. What type of stem cells will be derived or created?

- Embryonic
- Pluripotent

2. How long will blastocysts be kept developing in culture? This question appears for making embryonic stem cells.

3. If the research involves somatic cell nuclear transfer, justify the use: This question appears only if SCNT was indicated.

4. Is there any payment or reimbursement to any donors of gametes, blastocysts, or somatic cells? Choose "Yes" or "No".

5. If yes, justify payment or reimbursement to donors: complete text box.

6. Describe how the stem cell lines will be characterized, validated, stored, and distributed to ensure that the privacy of the donor is protected, and confidentiality of identifiable information is maintained. Complete text box. Be sure to include a detailed description of how you will validate the cell lines and what measures you will use throughout the study to ensure the integrity of the cell lines taking into consideration at a minimum these factors:

- pluripotent qualities
- cell line genotype,
- free of human pathogens, bacteria, fungi, and mycoplasma).

With respect to “description of storage” be sure to state how long cell lines will be stored and what will happen to the patient derived cell lines at the end of the study.
If you will be distributing the cell lines, you will need to provide proof that the original donor/patient agreed to generation of stem cell lines and distribution and execute any necessary MTAs.

7. Are human cells used to generate pluripotent stem cells primary cells derived from patient or control donors? Select “yes” or “no”.
If yes you will need to provide: Human IRB protocol # (or indicate IRB approval is pending, IRB approval date, IBC protocol # (or indicate pending), and IBC approval date.

8. Attach additional supporting documents: Useful documents include IRB protocols, IBC protocols, IACAC protocols, Patient agreements.