

Instructions:

Please complete the application and send a copy to:

som-resadmin@case.edu

When completing the SCRO form as part of an IRB/IACUC submission you will need to upload a copy of this SCRO form into iRIS (<https://cortex.case.edu>) as part of your *Study Documents* in addition to emailing a copy to: som-resadmin@case.edu.

Please contact Mark Tennant, iRIS Administrator at 216-368-1102 if assistance is needed uploading this SCRO form into your iRIS submission.

For questions regarding this SCRO form please contact:

Kumar Reddy

Phone: 216-368-1266

Email: kbr4@case.edu

For SCRO use only

Protocol #

Human Stem Cell Research Proposal

SECTION-1: INFORMATION

PI's Name:

Institution:

Address:

Telephone:

Email:

Funding Source:

Laboratory Location:

List of all key personnel involved in the project and their contact information:

SECTION-2: PROJECT TITLE

Project Title:

SECTION-3: CELL TYPES

3a. Definitions:

Pluripotent stem cells: Cells that have the capacity to (1) make identical copies of themselves (i.e. self-renew) and (2) form more specialized cells representing the three germ layers: the ectoderm (e.g. skin, brain); the endoderm (e.g. gut, lungs); the mesoderm (e.g. blood and bone), and the germ line (sperm and eggs).

Multipotent stem cells: Cells that can self-renew and form specialized cells representing the germ line or just one of the three germ layers.

3b. Please indicate the Cell type (check all that apply):

Fully differentiated somatic cells _____

Multipotent stem cells _____

Pluripotent stem cells _____

Provide any additional details (cell line identifier(s), source, and contact information):

SECTION-4: SOURCE OF CELLS

4a. Will cells be sourced directly from a human subject by the PI or his/her team member?

Yes ___ No ___

If the answer is 'Yes', then incorporate the suggested SCRO-informed consent language (to be suggested by SCRO Review Committee in SECTION 7) into the consent form and attach a copy of the consent form to this application.

If No, please explain the following:
How were the cells obtained (purchased/sent to the PI/collaboration)?

Please indicate cell line identifier(s), source, and contact information.

SECTION-5: PROJECT DESCRIPTION

5a. Category 1:

5a1. Does this research involve the derivation of human induced pluripotent stem (hiPS) cells from stored human tissues? Yes ___ No ___

4a2. Is this research limited ONLY to *in vitro* human pluripotent stem cell research (no animals are involved)? Yes ___ No ___

5b. Category 2:

5b1. Does this research involve the derivation of new stem cell lines from human embryos or gametes, including human somatic cell nuclear transfer? Yes ___ No ___

5b2. Does this research involve the introduction of human pluripotent cells or their direct derivatives into animals at any stage of development, other than standard teratoma assays in adult mice? Yes ___ No ___

If Yes, explain the likelihood of human stem cell contribution and/or integration into animal central nervous systems and/or germ lines:

5c. Briefly describe in a few paragraphs the proposed research.

SECTION-6: CERTIFICATIONS and SIGNATURES

6a. The PI certifies that, in accordance with national and international guidelines, the following types of experiments will not be performed:

6a1. *In vitro* culture of intact human embryos (including chimeric) or human somatic cell nuclear transfer products for longer than 14 days of development or until or beyond the onset of gastrulation/primitive streak formation (whichever comes first);

6a2. Introduction of research embryos involving transferred human pluripotent or multipotent cells into any environment conducive to full-term development; or

6a3. Breeding of any chimeric animals into which human stem cells have been introduced that may potentially differentiate into human gametes.

6b. Statements:

The research proposed in this request cannot begin until the PI has received written authorization from the SCRO Chair and has complied with all other applicable research requirements including but not limited to IRB/IACUC review and approval. The PI is responsible for maintaining copies of all required approvals in laboratory files accessible to auditors. The PI further understands that it is his/her responsibility to inform the SCRO Chair in writing of any changes to this research and to submit an amended or revised proposal to the SCRO for review in the event of such changes. The PI is also responsible for complying with all applicable policies, protocols and practices required in conducting human stem cell research as well as applicable provisions of federal and state law.

Signature of PI

Date submitted

I have reviewed the merits of this proposal and recommend its full consideration.

SCRO Chairperson Signature

Date

SECTION-7: REQUIREMENTS FOR INFORMED CONSENT

Item	YES	NO	Informed Consent Requirements
A			Derived cells or cell products may be kept for many years.
B			Whether the identity(ies) of the donor(s) will be ascertainable to those who work with the resulting cells or cell products. If the identity(ies) of the donor(s) are retained (even coded), researchers must discuss any plans for contacting of donors of materials used to derive cell lines and obtain consent for recontacting. This requirement includes both recontacting donors to provide information about research findings and to ask for additional health information. Recontacting may only occur if the donor consents at the time of donation.
C			Researchers may use cell lines for future studies, some of which may not be predictable at this time.
D			Derived cells or cell products may be used in research involving genetic manipulation.
E			Derived cells or cell products may be transplanted into humans or animals.
F			Derived cells or cell products are not intended to provide direct medical benefit to the donor(s), except in the case of autologous donation.
G			The donation is being made without restriction regarding who may be the recipient of transplanted cells, except in the case of autologous donations.
H			That neither consenting nor refusing to donate materials for research will affect the quality of any future care provided to potential donors.
I			That the results of research may be patentable or have commercial potential, and that the donor will not receive patent rights and will not receive financial or any other benefits from future commercial development.
J			Researchers shall offer donors an opportunity to document their preferences regarding future uses of their donated materials. Researchers may choose to use materials only from donors who agree to all future uses.
K			For covered research involving the donation and destruction of embryos for stem cell research, the informed consent process shall include a statement that embryos will be destroyed in the process of deriving embryonic stem cells.
L			For covered research that uses the umbilical cord, cord blood or the placenta, consent shall be obtained from the birth mother.
M			For covered research involving the donation of somatic cells for SCNT, informed consent shall include a statement as to whether the donated cells may be available for autologous treatment in the future.