Human Stem Cell Research Oversight (hSCRO) Committee

**Human Stem Cell Research Protocol Form**

Please submit an electronic copy to the IBC Office via email (IBCommittee@utoledo.edu), from the PI’s UToledo email address.

Protocol # (Office entry only) Click or tap here to enter text.

# Basic Information

Type of Protocol Choose an item.

Title of Protocol Click or tap here to enter text.

PI Name Click or tap here to enter text. Rocket # Click or tap here to enter text.

Date Click or tap here to enter text. Department Click or tap here to enter text.

Office Building Click or tap here to enter text. Office Room # Click or tap here to enter text.

Office Phone #Click or tap here to enter text. [ ]  Main Campus [ ]  Health Science Campus Email Address Click or tap here to enter text.

# General Details

* 1. All work with human stem cells requires approval by the Institutional Biosafety Committee (IBC). Please provide proof of approval or pending approval below.

IBC protocol number Click or tap here to enter text.

* 1. If this work involves the use of human stem cells taken from patient donors or embryonic or fetal stem cells taken from donors, it will require approval by the Institutional Review Board (IRB). Please provide proof of approval or pending approval below.

IRB protocol number Click or tap here to enter text.

* 1. If this work involves the use of human stem cells administered to live animals, it will require approval by the Institutional Animal Care and Use Committee (IACUC). Please provide proof of approval or pending approval below.

IACUC protocol number Click or tap here to enter text.

* 1. Please provide a list of all sources of funding, including granting/funding agency and grant/fund title.

Click or tap here to enter text.

# Protocol Description

* 1. Provide a general description of the project and the experimental design.

Click or tap here to enter text.

* 1. State the scientific rationale for the project, including the purpose for stem cell research over non- stem cell research.

Click or tap here to enter text.

* 1. Describe the procedures to be used, including the focus on how stem cells are used, produced, and differentiated.

Click or tap here to enter text.

# Types of Research

Please answer the following questions regarding the types of research you are proposing and answer all applicable, associated questions.

* 1. Will you be performing research involving human embryonic stem cells (including somatic cell nuclear transfer)?

Choose an item.

If yes, confirm that these human embryonic stem cells will **not** derive from abortions or a patient undergoing an abortion [ ]  (Ohio state law prohibits research on stem cells from abortion)

Where will these stem cells be stored, please give building and room location, as well as information on security measures.

Click or tap here to enter text.

Please scientifically justify the use of human embryonic stem cells over the use of other types of stem cells.

Click or tap here to enter text.

Please confirm that all embryonic stem cell lines used, derived, or collected in this research are on the NIH Human Embryonic Stem Cell Registry or will be placed on the NIH Human Stem Cell Registry. [ ]

* 1. Will you be performing in-vitro research involving human stem cells derived from fetal tissue?

Choose an item.

If yes, confirm that these fetal stem cells will **not** derive from abortions or a patient undergoing an abortion [ ]  (Ohio state law prohibits research on stem cells from abortion)

Will cells (or tissues) be sourced directly from human subjects by the PI and/or his/her team members?

Choose an item.

If yes, please confirm that IRB approval has been obtained (and informed consent obtained), if necessary. [ ]

Please scientifically justify the use of fetal stem cells over the use of other types of stem cells.

Click or tap here to enter text.

* 1. Will you be performing research introducing embryonic or other human pluripotent stem cells into animals or introducing neural stem cells into the central nervous system of animals at any stage (embryonic, fetal, or post-natal)?

Choose an item.

If yes, answer the following.

Cell migration is theoretically possible. Please address the likelihood of cell migration to other sites, how you will address migration, and the effects expected of that migration should it occur.

Click or tap here to enter text.

For research involving transplantation of human cells into the central nervous system or germ line – address the potential for animals to develop human-like traits. Include the reporting plan should this occur.

Click or tap here to enter text.

Per University and NIH policy, no animals into which human embryonic or human pluripotent stem cells have been introduced are allowed to breed. Describe the management plan to prevent breeding.

Click or tap here to enter text.

* 1. Will you be performing research involving the derivation or creation of new embryonic or other human pluripotent stem cell lines, through somatic cell nuclear transfer or work on donated blastocysts or created embryos?

Choose an item.

If yes, answer the following.

How long will blastocysts be kept developing in culture?

Click or tap here to enter text.

Is there any payment or reimbursement to any donors for gametes, blastocysts, or somatic cells? Please explain if yes.

Click or tap here to enter text.

Document how stem cells will be characterized, validated, stored, and distributed to ensure the privacy of the donor is protected and the confidentiality of identifiable information is maintained.

Click or tap here to enter text.

Please confirm that IRB approval has been obtained (and informed consent obtained) for the use of any gametes, blastocysts, or somatic cells. [ ]

* 1. Will you be performing in-vitro research involving human stem cells derived from adult tissue?

Choose an item.

* 1. Will cells (or tissues) be sourced directly from human subjects by the PI and/or his/her team members?

Choose an item.

If yes, please confirm that IRB approval has been obtained (and informed consent obtained), if necessary. [ ]

* 1. Will you be performing in-vitro research involving human pluripotent stem cells where the experiment is not designed to yield gametes?

Please explain how the cells were obtained (purchased, sent to PI by a collaborator, provide by Core Facility). If an MTA was required, please state.

Click or tap here to enter text.

Does your project involve the derivation of human induced pluripotent stem cells?

Choose an item.

If yes, please explain how cells will be derived.

Click or tap here to enter text.

* 1. Will you be performing other types of research not described above?

Choose an item.

If yes, please explain

Click or tap here to enter text.

I certify that the information in this application is complete and accurate. I understand that as the Principal Investigator, I have the responsibility to train the personnel in my laboratory on safe and ethical use of Human Stem Cells. [ ]

I also agree to obtain prior approval from the hSCRO Committee before amending or altering this research protocol/application. [ ]

By typing my name below, I attest that I have reviewed and approved this entire protocol, understand the study, and comply with all applicable requirements and regulations.

Click or tap here to enter text.