

NIH Office of Intramural Research (OIR)

Human Induced Pluripotent Stem Cells (iPSCs) Registration

*To Be Used for the Acquisition, Derivation, or Registration of iPSCs for Research in a
NIH Intramural Program Laboratory*

Date:

Please select one of the following:

- Registration of human induced Pluripotent Stem Cells (iPSCs) acquired or to be acquired from a source **outside** NIH
- Registration of human iPSCs acquired or to be acquired from an intramural NIH Source (*including an NIH core facility of collaborator's laboratory*)
- Registration of human iPSCs derived or to be derived in my NIH intramural laboratory

Section 1 – Information About Investigator and iPSC Line

Primary Contact

Name: _____ **Institute or Center (IC):** _____

Phone: _____ **E-mail:** _____

Secondary Contact

Name: _____ **Institute or Center (IC):** _____

Phone: _____ **E-mail:** _____

Cell Line Name:

Cell / Tissue Origin of Cell Used to Make the iPSC:

Indicate the Disease, If Applicable:

List Any Known Genetic Markers:

If the iPSC Were or Will Be Derived in Your Lab

- Did the cells / tissues come from a NIH repository? Yes No
- Is so, please identify the source:

If the iPSC Were Not Derived in Your Lab

- Name and institution of the provider (can be the NIH Intramural Research Program):
- *Please provide a copy of the agreement from your Technology Development Coordinator (TDC) which was used or will be used to obtain the cells, if applicable.*
- Please describe the mechanism that will be used to obtain the cells (e.g., MTA, Purchase Order, etc.)
- If you are obtaining the cells from a foreign country:
 - I am acquiring cells from a foreign country, and therefore have paid the required fees and complete the following shipping forms:
 - [USDA 16-3: Permit to Import Controlled Material or Transport Organisms or Vectors or Animal Products and By-Products](#)
 - [USDA 17-3: Permit to Import Cell Cultures and Their Products](#)

NOTE: Please refer to the [NIH ORS page on Biological Materials Shipping](#) for additional information on imports and exports.

Section 2 – Research Project Details

Project Title:

Synopsis of Proposed Research:

Section 3 – Human Subjects Research

If the iPSC Were or Will Be Derived in Your Lab

- The cells come from unknown donors (NIH has no access to any information allowing linkage of the cells to their donors).
- The cells come from individuals with identities known to you, and the IRB has reviewed and approved a research protocol and consent form.
 - **Name of IRB:**
 - **IRB Number:**
 - **Approval Date:**

If the iPSC Were Not Derived in Your Lab

- The provider of the cells **will not** share any information with the research team that allows linkage of the cells to their donors.
- If information will be provided to you that allows linkage of the cells to their donors, IRB review and approval is required.
 - **Name of IRB:**
 - **IRB Number:**
 - **Approval Date:**

Section 4 – Institutional Biosafety Review

Institutional Biosafety Committee (IBC) registration and approval is required for research with human iPSCs, including when:

- iPSC made by recombinant techniques (either commercially, via collaboration, or by NIH Investigator) are received or made at NIH for further study in the laboratory or in animals.
- iPSC made from human samples are received or derived by an NIH investigator for further study in the laboratory or in animals (regardless of derivation method).

NOTE: For questions, contact Richard Baumann, NIH Institutional Biosafety Officer, at 301-496-2960.

IBC Registration Number:

Date:

Section 5 – Research Requirements

Investigator Must Initial Both

I understand that when this checklist is completed and all approvals have been obtained, I am required to submit it to my TDC to obtain a material transfer agreement (MTA) with the provider, if the provider is not an NIH intramural laboratory. A list of TDCs for NIH can be found at <https://www.ott.nih.gov/tdcs>. ***I agree to NOT receive the cell lines until my IC TDC notifies me that the MTA is complete.***

I understand that human induced pluripotent stem cells **may not** be used for the following:

- Research in which human induced pluripotent stem cells are introduced into non- human primate blastocysts.
- Research involving the breeding of animals where the introduction of human induced pluripotent stem cells may contribute to the germ line.

Guidance for the policy on use of human iPSC by NIH intramural researchers can be found at <https://oir.nih.gov/sourcebook/ethical-conduct/special-research-considerations/use-human-stem-cells>.

Signatures

Investigator Signature:

Date:

Name:

IC:

Lab Name:

Lab Chief Signature:

Date:

Name:

Please forward a copy of the completed, approved iPSC Registration form to Kathryn Partin at kathryn.partin@nih.gov.