

# OIR Registration Form for Human Induced Pluripotent Stem Cells (iPSCs)

(formerly iPSC Checklist)

To be used for the acquisition, derivation or registration of iPSCs  
for Research in a NIH Intramural Research Program Laboratory

Date: \_\_\_\_\_

**Please check one of the following:**

\_\_\_\_ Registration of cells derived or to be derived in my IRP lab

\_\_\_\_ Request to acquire human induced Pluripotent Stem (iPS) cells for research in my  
laboratory from (1) *sources outside the NIH*

**Section 1 – Information about Investigator and iPSC line**

- Name: \_\_\_\_\_
- Institute/Center: \_\_\_\_\_
- Cell line name: \_\_\_\_\_
- Cell/tissue origin of cell used to make the iPS cell: \_\_\_\_\_
- Indicate the disease, if applicable: \_\_\_\_\_
- List any known genetic markers: \_\_\_\_\_
- Primary contact for these cells: \_\_\_\_\_  
Phone: \_\_\_\_\_ Email: \_\_\_\_\_
- Secondary contact: \_\_\_\_\_  
Phone: \_\_\_\_\_ Email: \_\_\_\_\_
- ***If the iPS cells were or will be derived in your lab –***
  - Did the cells/tissues come from a NIH repository? If so, please identify source \_\_\_\_\_
- ***If the iPS cells were not derived in your lab –***
  - Name and institution of the provider \_\_\_\_\_  
\_\_\_\_\_
  - Please provide a copy of the agreement from your TDC which was used or will be used to obtain the cells.
  - Please describe the mechanism that will be used to obtain the cells \_\_\_\_\_

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- *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 completed the following shipping forms:  
\_\_\_\_ USDA **16-3** Permits to Import or Transport Controlled Material or Organisms or Vectors  
\_\_\_\_ USDA **16-7** Application for Permit to Import Cell Cultures and Their Products  
\_\_\_\_ CDC Application for Permit for Import or Transport of Agents or Vectors of Human Disease (Document #101000--sent to NIH Quarantine Permit Service Office Bldg. 13, Rm. 3KO4; 301-496-2960 (Application does NOT go to CDC – NIH provides a courtesy letter for customs clearance)).

## Section 2 – Research project details

- Project Title: \_\_\_\_\_
  - Proposed Research: \_\_\_\_\_
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## Section 3 – Human Subjects Research

- ***If the iPS cells were or will be derived in your lab –***
  - If cells come from unknown donors (NIH has no access to any information allowing linkage of the cells to their donors), OHSRP must review and approve a request for determination for the research project:
    - OHSRP number \_\_\_\_\_ Approval Date \_\_\_\_\_
  - If cells come from participants in clinical research with known identities, the IRB must review and approve the protocol and consent form:
    - Name of IRB \_\_\_\_\_
    - IRB number \_\_\_\_\_ Approval Date \_\_\_\_\_

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- ***If the iPS cells 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 Review is required when:*
  - iPS cells made by recombinant techniques (commercially or by another institution) are received by an NIH investigator for further study or use in animals.
  - iPS cells from human samples are received by an NIH investigator for further study or use in animals (regardless of derivation method).

For questions contact Richard Baumann, Institutional Biosafety Officer, 301-496-2960

- **IBC registration number** \_\_\_\_\_ date \_\_\_\_\_.

## Section 5 – Research Requirements (Investigator must initial)

\_\_\_\_\_ 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 <http://www.ott.nih.gov/technology-development-coordinators>

*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.

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

## Signatures

<b>Investigator:</b> _____	_____
Printed Name, Lab, IC:	Date
<b>Lab Chief:</b> _____	_____
Printed Name:	Date

*Forward a copy of the completed, approved registration form to Melissa Colbert [colbertmc@od.nih.gov](mailto:colbertmc@od.nih.gov)*

*April 2017*