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

iPSC Checklist

To be used for the acquisition or derivation of iPSCs

for Research in a NIH Intramural Research Program Laboratory

Date: _____

Please check one of the following:

____ Registration of cells derived in my lab within the IRP

____ Request to acquire human induced Pluripotent Stem (iPS) cells for research in my laboratory from *(1) sources outside the NIH or (2) NIH collaborator(s)*

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:_____
- If the cell was derived from a patient, indicate the disease:_____
- List any known genetic markers of interest:_____
- Primary contact for these cells: _____
  Phone:_____Email:_____
- Secondary contact: _____
  Phone:_____Email:_____
- ***If the cells were derived in your lab***
  - Did the cells/tissues come from a NIH repository? If so, please identify source_____
- ***If the cells were not derived in your lab –***
  - Name and institution of the provider_____
    _____
  - Please provide a copy of the agreement from your TDC
  - Please describe the mechanism that will be used to obtain the cells_____
  - *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** Permits to Import or Transport Controlled Material or Organisms or Vectors
  _____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) to obtain a courtesy letter for customs clearance..

Section 2 – Research project details

- Project Title:_____
- Proposed Research:_____

_____

_____

_____

_____

Is this part of a NIH-CRM funded project? _____YES _____NO

If Yes, please supply grant number:_____

Section 3 – Human Subjects Research

- ***If the cells were derived in your lab***
  - If cells come from participants in clinical research, IRB must review and approve the protocol and consent form v.
    - Name of IRB_____
    - IRB number _____ approval date_____
    - ❖ Specific language must used in consent as approved by the IRB; see recommendations from NIH Bioethics Office

- ***If the cells were not derived in your lab –***

- Review by the NIH Office of Human Subjects Research Protection (301-402-3445) is required and a copy of their review must be provided with this checklist *(please attach)*
- Will information be provided to the NIH that allows linkage of the cells to their donors? _____

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 patient 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. A list of TDCs for NIH can be found at http://www.ott.nih.gov/nihstaff/tdc.aspx

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 iPS cells by NIH intramural researchers can be found at http://www1.od.nih.gov/oir/sourcebook/oversight/humanipscells.htm

Signatures

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Investigator:_____	_____
Printed Name, Lab, IC:	Date
Lab Chief: _____	_____
Printed Name	Date

Forward a copy of the completed, approved permission form to Melissa Colbert colbertmc@od.nih.gov and the NIH CRM nihcrm@mail.nih.gov

December, 2011