

Sample Checklist and Request for Permission to Acquire Human Embryonic Stem Cells for Research in an Intramural Research Program Laboratory

Date: _____

I request permission to acquire human embryonic stem cells for research in my laboratory. The NIH identifier for the cells I will acquire is (are):

The following intramural staff will be working on these cells:

_____, _____, _____.

Human Subject Research

I have spoken with the cell providers about whether the cells can be linked to donors. These cells (select A or B):

_____ A. Do not have any information that allow linkage of the cells to their donors

_____ B. Do have information that could link the cells to their donors;

Please complete 1 **AND** 2 below to indicate how you will address human subjects research requirements:

_____ 1. I have/ have NOT obtained and attached an agreement from the cell providers certifying that no identifying information will ever be released to my research group under any circumstances.

_____ 2. I have contacted the NIH Office of Human Subjects Research and was advised to do the following:

Agreements with Cell Provider (Investigator should initial to indicate agreement)

_____ I have attached a copy of my Material Transfer Agreement, Simple Letter Agreement, M-CRADA, or CRADA with the cell provider. I have read this agreement and agreed to abide by its terms.

Shipping of cells from foreign countries (select A or B):

_____ A. I am acquiring the cells from a U.S. provider

_____ B. I am acquiring cells from a foreign country (ES-, SA-, KA- NC-, RL- or TE-series cells, for example), 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) to obtain a courtesy letter for customs clearance. Application does NOT go to CDC

Research Requirements (Investigator should initial each line)

_____ I understand that I am required to track the NIH identifier number through all parts of my research on the cells, including replatings, transfers, and data collection. This identifier must be included in all reports on the cells.

_____ I further understand that human embryonic stem cells **may not** be used to create or contribute to a human embryo. The cells **may not** be used for research in which human embryonic stem cells are combined with an animal embryo; and **may not** be used in combination with somatic cell nuclear transfer for the purposes of reproductive cloning of a human.

Signatures

Investigator: _____

Print name and

Laboratory: _____

Lab Chief: _____

Scientific Director: _____

Institute Director: _____

This acquisition of human embryo stem cells:

_____ Is Approved

_____ Is Not Approved

(Forward a copy of the completed, approved permission form to the Office of Intramural Research, Bldg. 1, Rm. 114)