Signing Official Certification and Assurance for hESC Registry Request

Date:

NIH Stem Cell Registry:

I hereby certify that the statements in the Request for Human Embryonic Stem Cell Line *(insert hESC line name)* to be approved for use in NIH Funded Research ([NIH Form 2890](http://hescregapp.od.nih.gov/)), submitted by *(insert name of PI or designee)* and below, are true, complete and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties (U.S. Code, Title 18, Section1001). **I also hereby confirm that any materials translated into English were accurately translated by an individual independent of my institution, who is fluent in English and the original language of the translated documents.**

I further confirm that that I have the authority and/or rights pertaining to the human embryonic stem cell line(s) identified in item 6 of the form to make this request for NIH review and determination of eligibility for use in NIH funded research (*e.g.,* I am the owner, deriver or licensee or have written permission of the same to submit). Any and all restrictions on the use of the stem cell line are clearly and completely identified in item 8 of the form.

**Assurance Statements** (mark the appropriate statement with an “X”; you may only check **one** Assurance statement.):

**\_\_\_\_\_ Assurance in accord with Section II(A) of the NIH Guidelines:**

I hereby assure that the donation of the embryo from which the cell line(s) identified in item 6 was derived was in accordance with the elements of [Section II(A)](http://stemcells.nih.gov/policy/pages/2009guidelines.aspx#section2a) of the NIH Guidelines on Human Stem Cell Research.

**OR**

**\_\_\_\_\_ Assurance in accord with** [**Section II(B)**](http://stemcells.nih.gov/policy/pages/2009guidelines.aspx#section2b) **of the NIH Guidelines:**

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| I hereby assure that the embryo from which the cell line(s) identified in item 6 of the form was derived was donated prior to July 7, 2009, and the embryo: 1) was created using in vitro fertilization for reproductive purposes and was no longer needed for this purpose; and 2) was donated by individuals who sought reproductive treatment ("donor(s)") who gave voluntary written consent for the human embryo to be used for research purposes. |

  **OR**

**\_\_\_\_\_ Assurance in accord with** [**Section II(C)**](http://stemcells.nih.gov/policy/pages/2009guidelines.aspx#section2c) **of the NIH Guidelines:**

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| I hereby assure that the embryo from which the cell line(s) identified in item 6 of the form was derived was donated outside the United States on or after July 7, 2009, and the alternative procedural standards of the foreign country where the embryo was donated provide protections at least equivalent to those provided by [Section II(A)](http://stemcells.nih.gov/policy/pages/2009guidelines.aspx#section2a) of the NIH [Guidelines on Human Stem Cell Research](http://stemcells.nih.gov/policy/pages/2009guidelines.aspx). |

I acknowledge that I have read, understood, and agreed to the information provided on the form, including the Instructions for completing the form, and the Certification, Authority and Assurance provided above.

Sincerely,

Edward Kuczynski

Director, Human Research Protection Program

Office of Research

University of California, San Francisco