When available to the public this form will be web based with form functionality. This document contains the content of the form.

Request for Human Embryonic Stem Cell Line to be Approved for Use in NIH Funded Research

NIH Form 2890
OMB Approval 0925-XXXX
Expiration Date: XX-XX-XXXX

Privacy Notice: This collection of information is authorized by Executive Order 13505, Removing Barriers to Responsible Scientific Research Involving Human Stem Cells (3/9/09) and 42 CFR 52.4, pertaining to documentation and assurances that must accompany requests for NIH funding. Information submitted through this web site about human embryonic stem cell (hESC) lines is wholly voluntary, and will be reviewed by NIH to determine eligibility of lines for use in NIH funded research in accord with the NIH Guidelines on Human Stem Cell Research (74 FR 32170). If hESC lines are approved for use in NIH funded research, the stem cell lines, and provider information if the lines are available for distribution, will be posted on the NIH Human Embryonic Stem Cell Registry. NIH will also post the following information about institutions intending to submit hESC lines for review (those submissions begun and saved but not submitted), lines pending review, and lines reviewed by NIH: organization name, name of the stem cell line, and the method of NIH review (Administrative Review or review by the Working Group of the Advisory Committee to the Director). Final, but incomplete submissions of information may obviate NIH's ability to conduct a review to determine eligibility for use in NIH funded research.

Burden Disclosure Statement: The NIH estimates that the average time to complete this form is 3 hours, including 2.5 hours to collect and prepare supporting information and 30 minutes to physically complete the form and upload all supporting information. An agency may not conduct or sponsor the collection of information unless it displays a currently valid OMB control number. Nor is a person required to respond to requests for the collection of information without this control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Office, 6705 Rockledge Drive MSC 7974, Bethesda, MD 20892-7974, ATT: PRA (0925-0001).

Introduction

NIH Guidelines on Human Stem Cell Research, effective July 7, 2009, establish a new NIH Human Embryonic Stem Cell Registry listing human embryonic stem cells (hESCs) eligible for use in NIH funded research. Only hESCs that have been reviewed and deemed eligible by the NIH in accordance with the Guidelines may be used in NIH supported research.

NIH Form 2890 is provided for the purposes of submitting information about hESC lines to the NIH, along with assurances and supporting documentation of compliance with the NIH Guidelines. NIH will conduct either an Administrative Review, or review by a Working Group of the Advisory Committee to the [NIH] Director (ACD). The Working Group of the ACD will make recommendations to the ACD, which will advise the NIH Director who will make the final determine whether a hESC line may be approved for use in NIH funded research. All approved lines will be listed on the NIH Registry. The Registry will also contain basic information about organizations intending to submit lines to the Registry, lines pending NIH review and lines that have been reviewed and not approved for use in NIH funding.

Submission of hESC line through the NIH Form 2890 Web Site

eRA Commons Registration: An organization wishing to submit a hESC line for review must be registered in the eRA Commons. This is a one-time registration and is necessary for NIH validation purposes. Organizations may verify their current registration status by accessing the *List of Grantee Organizations Registered in NIH eRA Commons* at http://era.nih.gov/userreports/ipf_com_org_list.cfm. To register an Organization in the eRA Commons follow these instructions: https://commons.era.nih.gov/commons/registration/registrationInstructions.jsp. Note that a DUNS number must be included in the Institutional Profile. Instructions for obtaining a DUNS number are available through the eRA Commons registration process.

Signing Official Authority: Only an individual with a Signing Official (SO) role in the eRA Commons may submit a request that NIH review a hESC line to be approved for use in NIH funded research. To log into the system and complete NIH 2890, the SO must provide his/her eRA Commons UserID and password.

eRA Commons Support: For questions or problems concerning obtaining an eRA Commons account, please contact Commons Support at 1-866-504-9552, or email commons@od.nih.gov and a customer service representative will be in contact with you.

Login

eRA Commons UserID: _____

Password: _____

NIH Form 2890

You have successfully logged in to complete NIH Form 2890 Request for Human Embryonic Stem Cell Line to be Approved for Use in NIH Funded Research

The NIH Guidelines on Human Stem Cell Research and the Instructions for Completing NIH Form 2890 [link] should be read prior to beginning the submission process. They include important information about submitting cell lines to the NIH Registry, saving data during the submission process, NIH handling of draft submissions, uploading supporting information and other considerations (e.g., assurances, authority to submit, and information that will appear on the NIH Registry).

Before entering any information you must select the appropriate method of NIH review of your request. The two methods of review are Administrative Review and review by the Working Group of the ACD. Your selection is based on a number of factors, including where and when the embryo from which the stem cells were derived was donated, and whether you are able to provide supporting documentation that the embryo was donated in accordance with Section II(A) of the NIH Guidelines.

Please use the Guidelines to determine the appropriate method of review. A cell line that meets the requirements of Section II(A) should be reviewed by NIH Administrative Review. Review by the Working Group of the ACD is only appropriate for:

- cell lines donated prior to July 7, 2009 which do not meet the exact specifications of Section II(A) but for which the embryos 1) were created using in vitro fertilization for reproductive purposes and were no longer needed for this purpose; and 2) that were donated by donor(s) who gave voluntary written consent for the human embryos to be used for research purposes, and
- cell lines from embryos donated outside the US on or after July 7, 2009 that do not meet the exact specifications of Section II(A), but for which the applicant believes the procedural standards of the foreign country provide protections at least equivalent to Section II(A) and were followed.

It is important that you make the selection of method of review carefully. Once you have made a selection you cannot change your selection without exiting the system and logging in again. After a request is submitted, NIH does not have the ability to change the method of review. You may contact the NIH Registry at hescregistry@mail.nih.gov and request that a submission be deleted.

Make your selection here:

_____ NIH Administrative Review

OR

_____ Working Group of the ACD Review

[If user selects Administrative Review, they are automatically routed to this page]

Request for Human Embryonic Stem Cell Line to be Approved for Use in NIH Funded Research Under Section II(A) of the Guidelines

The instructions for completing this form should be read prior to entering any information.

*Required fields are marked with a red asterisk.

Administrative Information

1.* Signing Official (SO)
(submitting this request)
A. SO Name: _____
B. SO Phone Number: _____
C. SO Email Address: _____

2. Point of Contact (POC):
(if different from Signing Official)
A. POC Name: _____
B. POC Phone Number: _____
C. POC Email Address: _____

3.* Applicant Organization Name:_____
DUNS Number: _____

4.* Applicant Organization Address:
_____
_____
_____
_____

5. NIH Grant or Application Number(s): _____
(if applicable)
(Please use this format: HL123456, AI654321, AG345678)

Stem Cell Line Information

6.* Name of Stem Cell Line: _____

7. * Cell Line Availability: If the cell line is approved for use with NIH funding, will it be available for distribution to the research community?
Yes _____ No_____ Other _____
If Other, please specify: _____
(Please limit to 250 Characters and Spaces)

If the answer to Question 7 is "Yes," please complete Questions 8 and 9 below for posting on the NIH Registry.

8. Restrictions (if any) on Use of Stem Cell Line:
_____
_____
Please limit comments to 500 characters and spaces.

9. Provider of Stem Cell Line:
A. Name of Individual or Company: _____
B. Provider Phone Number: _____
C. Provider Email Address: _____
D. Provider URL: _____

10. Embryo Donation:
A. Was the embryo from which the stem cell line was derived donated in the United States?
_____Yes
_____No
_____Don't Know
B. If known, in what year was the embryo donated? _____ (e.g., 2001)

Add Another Cell Line with Identical Supporting Information *[link]*

Adding Additional Related Cell Lines: You may add additional cell lines to this request if the method of review (Administrative Review or Working Group of the ACD review) and all supporting information (item 11 below) are precisely identical for the cell line identified in item 6. You will be required to complete items 6-10, as appropriate, for any additional cell lines that are added to this request.

*If the [link] "Add Another Cell Line with Identical Supporting Information" is clicked, the user is provided with a new screen in which to enter **Stem Cell Line Information** (items 6-10). The user may add multiple cell lines to one submission.*

Supporting Information (Document Attachments)

11.* Supporting Information:
You are expected to provide adequate documentation to support each element of II(A) of the NIH Guidelines. Failure to provide documentation of any one element of II(A) will result in the cell line not being approved for NIH funding under the NIH Administrative Review process.

All supporting information must be in English.

To upload supporting information:
- Click the "Browse" buttons below to select a file from your computer. Valid attachment file type extensions are doc, xls, wpd, rtf, pdf, ppt, gif, jpg or txt.
- Provide a brief description (limit 100 characters) of the file (e.g., consent document, clinic policy, etc.) in the box provided.
- Select which element(s) of Section II (A) of the Guidelines are supported by the document from the list provided. You may choose multiple elements for each document.

Note: Materials submitted will be subject to the United States Freedom of Information Act. Do not

submit consent documents with personally identifying information of the donor(s) of the embryos (the individuals who sought reproduction treatment). Submission of consent documents with such personal identifiers will cause this request to be invalidated and NIH to delete all submitted information.

Document 1: _____ [Browse link]
Content Description: _____
Select which Element(s) Document 1 supports:

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8
☐ 9 ☐ 10 ☐ 11 ☐ 12 ☐ 13 ☐ 14 ☐ 15

Document 2: _____ [Browse link]
Content Description: _____
Select which Element(s) Document 2 supports:

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8
☐ 9 ☐ 10 ☐ 11 ☐ 12 ☐ 13 ☐ 14 ☐ 15

Document 3: _____ [Browse link]
Content Description: _____
Select which Element(s) Document 3 supports:

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8
☐ 9 ☐ 10 ☐ 11 ☐ 12 ☐ 13 ☐ 14 ☐ 15

Document 4: _____ [Browse link]
Content Description: _____
Select which Element(s) Document 4 supports:

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8
☐ 9 ☐ 10 ☐ 11 ☐ 12 ☐ 13 ☐ 14 ☐ 15

Document 5: _____ [Browse link]
Content Description: _____
Select which Element(s) Document 5 supports:

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8
☐ 9 ☐ 10 ☐ 11 ☐ 12 ☐ 13 ☐ 14 ☐ 15

Document 6: _____ [Browse link]

Content Description: _____
Select which Element(s) Document 6 supports:

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8
☐ 9 ☐ 10 ☐ 11 ☐ 12 ☐ 13 ☐ 14 ☐ 15

Document 7: _____ [Browse link]
Content Description: _____
Select which Element(s) Document 7 supports:

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8
☐ 9 ☐ 10 ☐ 11 ☐ 12 ☐ 13 ☐ 14 ☐ 15

Document 8: _____ [Browse link]
Content Description: _____
Select which Element(s) Document 8 supports:

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8
☐ 9 ☐ 10 ☐ 11 ☐ 12 ☐ 13 ☐ 14 ☐ 15

Document 9: _____ [Browse link]
Content Description: _____
Select which Element(s) Document 9 supports:

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8
☐ 9 ☐ 10 ☐ 11 ☐ 12 ☐ 13 ☐ 14 ☐ 15

Document 10: _____ [Browse link]
Content Description: _____
Select which Element(s) Document 10 supports:

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8
☐ 9 ☐ 10 ☐ 11 ☐ 12 ☐ 13 ☐ 14 ☐ 15

Comments

12. Comments: If there is any additional information you wish to provide regarding this submission, you may enter it here. If your comments exceed 1,000 characters and spaces, you may upload additional information as one of the attachments above.

_____

_____
_____
_____
(Please limit comments to 1,000 Characters and Spaces)

Assurance, Certification, Authority and Final Submission

Assurance:
The applicant organization identified above hereby assures that the donation of the embryo from which the cell line identified in item 6 was derived was in accordance with the elements of Section II (A) of the NIH Guidelines on Human Stem Cell Research.

Certification:
By submitting this application, I certify that the statements and Assurance herein 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, Section 1001).

Authority:
I hereby confirm that I have the legal authority and/or legal rights pertaining to the human embryonic stem cell line identified in item 6 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). I have clearly and completely identified any and all restrictions on the use of the stem cell line in item 8.

Final Application Submission and Subsequent Changes:
After clicking "Submit FINAL Registry Request", you will receive an email confirmation and an NIH assigned number that pertains to the submission. Once a request is submitted, NIH will not change your selection of the method of review or any data or supporting documents. If changes are necessary, you may send an email to the hESC Registry Help Desk requesting that the application be deleted, and then begin the submission process again, as appropriate.

Acknowledgement:
By submitting this application (clicking the "Submit FINAL Registry Request" button below) you acknowledge that you have read, understood, and agreed to the information provided on this form, including the Instructions for completing the form and the Assurance, Certification, Authority and Final Submission information above.

Submit FINAL Registry Request *[link]*

[If user selects review by the Working Group of the ACD, they are automatically routed to this page. Items 1-10, and item 12 are identical to Administrative Review above.]

Request for Human Embryonic Stem Cell Line to be Approved for Use in NIH Funded Research Working Group of the ACD review

The instructions for completing this form should be read prior to entering any information.

*Required fields are marked with a red asterisk.

Administrative Information

1.* Signing Official (SO)
(submitting this request)
A. SO Name: _____
B. SO Phone Number: _____
C. SO Email Address: _____

2. Point of Contact (POC):
(if different from Signing Official)
A. POC Name: _____
B. POC Phone Number: _____
C. POC Email Address: _____

3.* Applicant Organization Name:_____
DUNS Number: _____

4.* Applicant Organization Address:
_____
_____
_____
_____

5. NIH Grant or Application Number(s): _____
(if applicable) (Please use this format: HL123456, AI654321, AG345678)

Stem Cell Line Information

6.* Name of Stem Cell Line: _____

7. * Cell Line Availability: If the cell line is approved for use with NIH funding, will it be available for distribution to the research community?
Yes _____ No_____ Other _____
If Other, please specify: _____
(Please limit to 250 Characters and Spaces)

If the answer to Question 7 is "Yes," please complete Questions 8 and 9 below for posting on the NIH Registry.

8. Restrictions (if any) on Use of Stem Cell Line:
_____
_____
Please limit comments to 500 characters and spaces.

9. Provider of Stem Cell Line:
A. Name of Individual or Company: _____
B. Provider Phone Number: _____
C. Provider Email Address: _____
D. Provider URL: _____

10. Embryo Donation:
A. Was the embryo from which the stem cell line was derived donated in the United States?
_____Yes
_____No
_____Don't Know
B. If known, in what year was the embryo donated? _____ (e.g., 2001)

Add Another Cell Line with Identical Supporting Information *[link]*

Adding Additional Related Cell Lines: You may add additional cell lines to this request if the method of review (Administrative Review or Working Group of the ACD review) and all supporting information (item 11 below) are precisely identical for the cell line identified in item 6. You will be required to complete items 6-10, as appropriate, for any additional cell lines that are added to this request.

*If the [link] "Add Another Cell Line with Identical Supporting Information" is clicked, the user is provided with a new screen in which to enter **Stem Cell Line Information** (items 6-10). The user may add multiple cell lines to one submission.*

Supporting Information (Document Attachments)

11.* Supporting Information:
Applicants are encouraged to provide, as document 1, a summary document explaining how the remaining attachments address the materials that the Working Group will consider (as described in the Assurances below).

All supporting information must be in English.

To upload supporting information:
- Click the "Browse" buttons below to select a file from your computer. Valid attachment file type extensions are doc, xls, wpd, rtf, pdf, ppt, gif, jpg or txt.
- Provide a brief description (limit 100 characters) of the file (e.g., consent document, clinic policy, etc.) in the box provided

Note: Materials submitted will be subject to the United States Freedom of Information Act. Do not submit consent documents with personally identifying information of the donor(s) of the embryos (the individuals who sought reproduction treatment). Submission of consent documents with such personal identifiers will cause this request to be invalidated and NIH to delete all submitted information.

Document 1: _____ [Browse link]
Content Description: _____

Document 2: _____ [Browse link]
Content Description: _____

Document 3: _____ [Browse link]
Content Description: _____

Document 4: _____ [Browse link]
Content Description: _____

Document 5: _____ [Browse link]
Content Description: _____

Document 6: _____ [Browse link]
Content Description: _____

Document 7: _____ [Browse link]
Content Description: _____

Document 8: _____ [Browse link]
Content Description: _____

Document 9: _____ [Browse link]
Content Description: _____

Document 10: _____ [Browse link]
Content Description: _____

Comments

12. Comments: If there is any additional information you wish to provide regarding this submission, you may enter it here. If your comments exceed 1,000 characters and spaces, you may upload additional information as one of the attachments above.

_____

_____
_____
_____
(Please limit comments to 1,000 Characters and Spaces)

Assurance, Certification, Authority and Final Submission

Select the appropriate Assurance Statement from the two options below:

_____**Assurance in accord with Section II(B) of the NIH Guidelines**: The applicant organization identified above assures that the embryos from which the cell line identified in item 6 was derived were donated prior to July 7, 2009, and were derived from human embryos: 1) that were created using in vitro fertilization for reproductive purposes and were no longer needed for this purpose; and 2) that were donated by donor(s) who gave voluntary written consent for the human embryos to be used for research purposes. The applicant is advised that the Working Group of the Advisory Committee to the NIH Director will consider submitted materials taking into account the principles articulated in Section II(A) of the NIH Guidelines for Human for Human Stem Cell Research, 45 CFR 46 Subpart A, and the following points to consider: during the informed consent process, including written and oral communications, whether the donor(s) were: (1) informed of other available options pertaining to the use of the embryos; (2) offered any inducements for the donation of the embryos; and (3) informed about what would happen to the embryos after the donation for research.

OR

_____**Assurance in accord with Section II(C) of the NIH Guidelines:** The applicant organization identified above assures that the embryos from which the cell line identified in item 6 was derived were 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) of the NIH Guidelines on Human Stem Cell Research.

Certification:
By submitting this application, I certify that the statements and Assurance herein 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, Section 1001).

Authority:
I hereby confirm that I have the legal authority and/or legal rights pertaining to the human embryonic stem cell line identified in item 6 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). I have clearly and completely identified any and all restrictions on the use of the stem cell line in item 8.

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be deleted, and then begin the submission process again, as appropriate.

Acknowledgement:
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Submit FINAL Registry Request *[link]*