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

NIH Form 2890
OMB Approval 0925-0601
Expiration Date: October 31, 2022

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 for Human Stem Cell Research (74 FR 32170). All information submitted with regard to a request for approval of a human embryonic stem cell line must be submitted in a form so that it may be made available by NIH to the public. Do not submit any financial, commercial, confidential or proprietary information. Do not submit consent documents with the personally identifying information/names of donor(s) of the embryos (the individual(s) who sought reproductive treatment). Proprietary and/or personal information may be redacted by the submitters. PLEASE NOTE: **NIH Intends to treat all information which is submitted, unless there is written agreement to the contrary, as information which may be made available to the public.**

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 also posts the organization name and the name of the stem cell line for institutions intending to submit hESC lines for review (those submissions begun and saved but not submitted), lines pending review, and lines not approved for NIH funding eligibility. 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 17 hours, including time to collect and prepare supporting information, 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 (0925-0601).

Introduction

NIH Guidelines for Human Stem Cell Research, effective July 7, 2009, established an 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 determination of whether a hESC line is approved for use in NIH funded research. All approved lines are listed on the NIH Registry. The Registry also contains basic information about organizations intending to submit lines to the Registry, lines pending NIH review and lines not approved for NIH funding eligibility.

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/commons/quick_queries/index.cfm#commons. 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. If your organization does not have a DUNS number you may obtain one from: http://fedgov.dnb.com/webform/displayHomePage.do.

Signing Official Authority: Requests may be submitted by the individual with a Signing Official (SO) role for the organization. Requests may also be submitted by another appropriate individual within an organization who has an eRA Commons UserID and password, provided that the SO approves the submission and provides the necessary certification and assurance via a signed letter on institutional letterhead, and attached as an uploaded document with the request. A sample letter (MS Word - 44 KB) is provided for this purpose. To log into the system and complete NIH 2890, the individual must provide his/her eRA Commons UserID and password. Once a Commons user enters a draft request, only that individual has the rights to edit and submit the request. However, the system provides a way to email copies of draft requests to the individuals of their choosing for review.

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.

NIH Form 2890 hESC Request Support: Questions about this system may be emailed to the hESC Registry Help Desk . In addition, Instructions for Completing NIH Form 2890 and a Sample Web Version of the form are available for review. Note that the sample is not an interactive form and you may not enter data into the sample.

Login

[Users with special characters such as "@" in their eRA Commons UserID have experienced difficulty entering this website. If you have a special character in your eRA Commons UserID (!, @, #, $, %, ^, &, *, (,), +) please contact the eRA Commons Help Desk for assistance.]

eRA Commons UserID and Password Required:

Login to NIH Form 2890 Web Site

Go to NIH Stem Cell Information Page

Note: For help accessing PDF or MS Word files, see Help Downloading Files.

HHS Vulnerability Disclosure

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

NIH Form 2890
OMB Approval 0925-0601
Expiration Date: October 31, 2022

NIH Administration Page

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 for Human Stem Cell Research and the Instructions for Completing NIH Form 2890 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 Advisory Committee to the Director (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 individuals who sought reproductive treatment ("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.

NOTE: NIH encourages you to select NIH Administrative Review if you believe that your cell line meets the Section II(A) requirements. If NIH determines that the line is not approvable under Section II(A), NIH will then refer the submission for ACD review under Section II(B) if the line is eligible.

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. You may contact the NIH Registry at hescregistry@mail.nih.gov and request that a submission be deleted or to answer questions about this system.

Enter New Request : **Edit Draft Request(s):**

Select Either Administrative or ACD Review:

- ○ **NIH Administrative Review (ADM)**
- ○ **Working Group of the ACD Review**

Enter New Request

Select Draft Request to Edit:

(No Draft Requests Available)

Note: Draft Requests not submitted within 6 months after the Last Updated Date, will be deleted.

All Draft Requests are posted on the

Draft Requests in Process page.

Login: NIH\chengi3
Date: 04/12/2022

Logout of NIH Form 2890

Go to NIH Form 2890 Login Page

Go to NIH Stem Cell Information Page

Add New hESC Registry Request for NIH Administrative Review

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.

Login Information: NIH\chengi3 (04/12/2022)

Administrative Information ?

*** 1. Signing Official (SO):**

A. SO Name:
B. SO Phone Number:
C. SO Email Address:

2. Submitter of Request:
(* Complete only if different from Signing Official)

A. Submitter Name:
B. Submitter Phone Number:
C. Submitter Email Address:

(Important Note: If submitted by anyone other than the Signing Official, a copy of a letter signed by the SO must be provided as one of the documents in the Supporting Information section below. See the sample letter (MS Word - 44 KB) for appropriate language. In addition, users have the ability to send the SO or other individuals a copy of the draft request upon saving draft changes and from the main NIH Form 2890 selection screen in the "Edit Draft Request(s)" section.)

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

*** 4. Organization Address:**

5. NIH Grant or Application Number(s): (if applicable)

(Please use this format: HL123456, AI654321, AG345678)

Save DRAFT for Further Editing ?

(To avoid potential timeout and loss of data, be sure to save data often - Every 10-15 minutes)

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. Provider Restrictions (if any) on Use of Stem Cell Line:

(* If the answer to Question 7 is "Yes", an answer to Question 8 is required.
Enter "None" if there are no restrictions.
Please limit comments to 750 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:

(* If the answer to Question 7 is "Yes", answer to 9A is required: 9B-D are optional.)

*** 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. In what year(s) was the embryo donated?

(If the donation was in 2009, please also include the month and day in this order: month/day/year)

Add Another Cell Line with Identical Supporting Information ?

Adding Additional Related Cell Lines: You may add additional hESC lines to your request. The method of review and the supporting information (see next section Uploading Supporting Information) must be precisely identical to the information for the hESC line identified in item 6. If the method of review or any of the supporting information for another hESC would differ in any way (even in a non-substantive way), you must complete separate requests. You will be required to complete items 6-10, as appropriate, for any additional cell lines that are added to this request.

Save DRAFT for Further Editing ?

(To avoid potential timeout and loss of data, be sure to save data often - Every 10-15 minutes)

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 element of II(A) will result in the cell line not being approved for NIH funding under the NIH Administrative Review process. Applicants are encouraged to write a summary document which provides overall information about the embryo donation process, provides a timeline of events, and/or explains the other supporting documents. Supporting documents should be those that were used (such as a consent form) or in force (such as a policy) at the time of the relevant activity, such as embryo donation or reproductive treatment. Documents may include, for example, the consent for donation of embryos for research purposes; the research protocol or other document(s) demonstrating the relative timing of reproductive treatment and the donation of embryos for research purposes; the consent for reproductive treatment (including the consent for cryopreservation of embryos, if applicable); relevant written policies; or other documents, such as a copy of the Embryonic Stem Cell Research Oversight (ESCRO) or Institutional Review Board (IRB) or ethics committee approval to derive or use the line, or documentation of a committee's exemption from review. For consents, please submit the signed version (with any identifiers redacted), or confirm that a unsigned document was the version signed by the donors. Aside from signatures on consents, when possible, NIH would appreciate receiving typed documents (rather than handwritten information) in order to make documents more readily accessible (508-compliant). For scanned documents, please scan at a minimum of 200 dots per inch (dpi).

All supporting information must be in English. For materials presented to embryo donors: please indicate the language in which the documents provided to the donors were written. Please also address whether the donors received the information in their native/preferred language or in a language in which they were sufficiently fluent.

To upload supporting information:

- Click the "Browse" buttons below to select a file from your computer. Valid document file type extensions are doc, xls, ppt, pdf, rtf, wpd, gif, jpg, txt or csv.
- Provide a brief description (limit 100 characters) of the file (e.g., consent document, clinic policy, SO letter, 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. Select "Other" if the document includes additional information not necessarily associated with specific elements.

Note: All information submitted with regard to a request for approval of a human embryonic stem cell line must be submitted in a form so that it may be made available by NIH to the public. Do not submit any financial, commercial, confidential or proprietary information. Do not submit consent documents with the personally identifying information/names of donor(s) of the embryos (the individual(s) who sought reproductive treatment). Proprietary and/or personal information may be redacted by the submitters. PLEASE NOTE: **NIH Intends to treat all information which is submitted, unless there is written agreement to the contrary, as information which may be made available to the public.**

Document 1:

Choose File No file chosen

Content Description:

Select which Element(s) Document 1 supports:

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

Document 2:

Choose File No file chosen

Content Description:

Select which Element(s) Document 2 supports:

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

Document 3:

Choose File No file chosen

Content Description:

Select which Element(s) Document 3 supports:

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

Document 4:

Choose File No file chosen

Content Description:

Select which Element(s) Document 4 supports:

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

Document 5:

Choose File No file chosen

Content Description:

Select which Element(s) Document 5 supports:

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

Document 6:

Choose File No file chosen

Content Description:

Select which Element(s) Document 6 supports:

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

Document 7:

Choose File No file chosen
Content Description:
Select which Element(s) Document 7 supports:
☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8
☐ 9 ☐ 10 ☐ 11 ☐ 12 ☐ 13 ☐ 14 ☐ 15 ☐ Other

Document 8:

Choose File No file chosen
Content Description:
Select which Element(s) Document 8 supports:
☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8
☐ 9 ☐ 10 ☐ 11 ☐ 12 ☐ 13 ☐ 14 ☐ 15 ☐ Other

Document 9:

Choose File No file chosen
Content Description:
Select which Element(s) Document 9 supports:
☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8
☐ 9 ☐ 10 ☐ 11 ☐ 12 ☐ 13 ☐ 14 ☐ 15 ☐ Other

Document 10:

Choose File No file chosen
Content Description:
Select which Element(s) Document 10 supports:
☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8
☐ 9 ☐ 10 ☐ 11 ☐ 12 ☐ 13 ☐ 14 ☐ 15 ☐ Other

Save DRAFT for Further Editing ?

(To avoid potential timeout and loss of data, be sure to save data often - Every 10-15 minutes)

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 and check "Other" for the supporting Elements question.

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

Save DRAFT for Further Editing ?

(To avoid potential timeout and loss of data, be sure to save data often - Every 10-15 minutes)

Assurance, Certification, Authority and Final Submission ?

Note: If you are a Signing Official with formal designated or delegated authority to sign on behalf of the organization, check the Assurance, Certification, and Authority boxes to provide the required certifications. If you are not a Signing Official with formal designated or delegated authority to sign on behalf of the organization, do not check the boxes, but provide, as one of the attached supporting documents, a letter signed by the SO that provides the required certifications (see Sample Letter (MS Word - 44 KB)).

Assurance (* Required, if submitted by SO. To be completed by SO only)

☐ 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 (* Required, if submitted by SO. To be completed by SO only)

☐ By submitting this request, 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). 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.

Authority (* Required, if submitted by SO. To be completed by SO only)

☐ I hereby confirm that I have the authority and/or 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 Request Submission and Subsequent Changes:
After clicking "Submit FINAL Registry Request", all data validations will be invoked. If any required data is missing, you will need to make any necessary corrections prior to the submission being accepted as final. Note that only partial data validation is performed when saving drafts, which allows you to have incomplete work-in-progress requests. Once all final validations are passed, 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 unless requested. If changes are necessary, you may send an email to the hESC Registry Help Desk.

Acknowledgement:
By submitting this request (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 ?

Questions about this system may be emailed to the hESC Registry Help Desk.

Logout of NIH Form 2890 Without Saving

Return to NIH Form 2890 Page

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.

Login Information: NIH\chengi3 (04/12/2022)

Administrative Information ?

* **1. Signing Official (SO):**
  - **A.** SO Name:
  - **B.** SO Phone Number:
  - **C.** SO Email Address:

2. Submitter of Request:
(* Complete only if different from Signing Official)
- **A.** Submitter Name:
- **B.** Submitter Phone Number:
- **C.** Submitter Email Address:

(Important Note: If submitted by anyone other than the Signing Official, a copy of a letter signed by the SO must be provided as one of the documents in the Supporting Information section below. See the sample letter (MS Word - 44 KB) for appropriate language. In addition, users have the ability to send the SO or other individuals a copy of the draft request upon saving draft changes and from the main NIH Form 2890 selection screen in the "Edit Draft Request(s)" section.)

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

* **4. Organization Address:**

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

Save DRAFT for Further Editing ?

(To avoid potential timeout and loss of data, be sure to save data often - Every 10-15 minutes)

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. Provider Restrictions (if any) on Use of Stem Cell Line:

(* If the answer to Question 7 is "Yes", an answer to Question 8 is required.

Enter "None" if there are no restrictions.
Please limit comments to 750 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:

(* If the answer to Question 7 is "Yes", answer to 9A is required: 9B-D are optional.)

*** 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. In what year(s) was the embryo donated?

(If the donation was in 2009, please also include the month and day in this order: month/day/year)

Add Another Cell Line with Identical Supporting Information ?

Adding Additional Related Cell Lines: You may add additional hESC lines to your request. The method of review and the supporting information (see next section Uploading Supporting Information) must be precisely identical to the information for the hESC line identified in item 6. If the method of review or any of the supporting information for another hESC would differ in any way (even in a non-substantive way), you must complete separate requests. You will be required to complete items 6-10, as appropriate, for any additional cell lines that are added to this request.

Save DRAFT for Further Editing ?

(To avoid potential timeout and loss of data, be sure to save data often - Every 10-15 minutes)

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). Supporting documents should be those that were used (such as a consent form) or in force (such as a policy) at the time of the relevant activity, such as embryo donation or reproductive treatment. Documents may include, for example, the consent for donation of embryos for research purposes; the research protocol or other document(s) demonstrating the relative timing of reproductive treatment and the donation of embryos for research purposes; the consent for reproductive treatment (including the consent for cryopreservation of embryos, if applicable); relevant written policies; or other documents, such as a copy of the Embryonic Stem Cell Research Oversight (ESCRO) or Institutional Review Board (IRB) or ethics committee approval to derive or use the line, or documentation of a committee's exemption from review. For consents, please submit the signed version (with any identifiers redacted), or confirm that a unsigned document was the version signed by the donors. Aside from signatures on consents, when possible, NIH would appreciate receiving typed documents (rather than handwritten information) in order to make documents more readily accessible (508-compliant). For scanned documents, please scan at a minimum of 200 dots per inch (dpi).

All supporting information must be in English. For materials presented to embryo donors: please indicate the language in which the documents provided to the donors were written. Please also address whether the donors received the information in their native/preferred language or in a language in which they were sufficiently fluent.

To upload supporting information:

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

Note: All information submitted with regard to a request for approval of a human embryonic stem cell line must be submitted in a form so that it may be made available by NIH to the public. Do not submit any financial, commercial, confidential or proprietary information. Do not submit consent documents with the personally identifying information/names of donor(s) of the embryos (the individual(s) who sought reproductive treatment). Proprietary and/or personal information may be redacted by the submitters. PLEASE NOTE: **NIH Intends to treat all information which is submitted, unless there is written agreement to the contrary, as information which may be made available to the public.**

Document 1:

Choose File No file chosen
Content Description:

Document 2: Choose File No file chosen
Content Description:

Document 3: Choose File No file chosen
Content Description:

Document 4: Choose File No file chosen
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Document 5: Choose File No file chosen
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Document 6: Choose File No file chosen
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Document 7: Choose File No file chosen
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Document 8: Choose File No file chosen
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Document 9: Choose File No file chosen
Content Description:

Document 10: Choose File No file chosen
Content Description:

Save DRAFT for Further Editing ?
(To avoid potential timeout and loss of data, be sure to save data often - Every 10-15 minutes)

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.)

Save DRAFT for Further Editing ?
(To avoid potential timeout and loss of data, be sure to save data often - Every 10-15 minutes)

Assurance, Certification, Authority and Final Submission ?

Note: If you are a Signing Official with formal designated or delegated authority to sign on behalf of the organization, check the Assurance, Certification, and Authority boxes to provide the required certifications. If you are not a Signing Official with formal designated or delegated authority to sign on behalf of the organization, do not check the boxes, but provide, as one of the attached supporting documents, a letter signed by the SO that provides the required certifications (see Sample Letter (MS Word - 44 KB)).

Select the appropriate Assurance Statement from the two options below:

(* Required, if submitted by SO. To be completed by SO only)

○ **Assurance in accord with Section II(B) of the NIH Guidelines:**

The applicant organization identified above assures that the embryo from which the cell line identified in item 6 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. 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 embryo ; (2) offered any inducements for the donation of the embryo ; and (3) informed about what would happen to the embryo 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 embryo from which the cell line identified in item 6 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) of the NIH Guidelines on Human Stem Cell Research.

Certification (* Required, if submitted by SO. To be completed by SO only)

☐ By submitting this request, 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). 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.

Authority (* Required, if submitted by SO. To be completed by SO only)

☐ I hereby confirm that I have the authority and/or 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 Request Submission and Subsequent Changes:
After clicking "Submit FINAL Registry Request", all data validations will be invoked. If any required data is missing, you will need to make any necessary corrections prior to the submission being accepted as final. Note that only partial data validation is performed when saving drafts, which allows you to have incomplete work-in-progress requests. Once all final validations are passed, 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 unless requested. If changes are necessary, you may send an email to the hESC Registry Help Desk.

Acknowledgement:
By submitting this request (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 ?

Questions about this system may be emailed to the hESC Registry Help Desk.

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