January 3, 2013  **STEM CELL PROTOCOL**  Protocol # XXX

Page 1 of 13 **APPLICATION FORM**

**STANFORD UNIVERSITY**

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**Title:**

**Protocol Director:**

**Approval Period: Draft**

**Important Notice: This Print View may not reflect all comments and contingencies for approval. Please check the comments section of the online protocol.**

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**\* \* \* Protocol Personnel \* \* \***

**Protocol Director**

**Name:** **Phone:**

**Department: Mail Code:**

**E-mail:**  **Fax:**

**Degree (program/year if student): Title:**

**Affiliation:**

**Admin Contact**

**Name:** **Phone:**

**Department: Mail Code:**

**E-mail:**  **Fax:**

**Degree (program/year if student): Title:**

**Affiliation:**

**Co-Protocol Director**

**Name:** **Phone:**

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**Name:** **Phone:**

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**Faculty Sponsor**

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**Affiliation:**

**Other Personnel**

**Name:** **Phone:**

**Department:**  **Mail Code:**

**E-mail:**  **Fax:**

**Degree (program/year if student): Title:**

**Affiliation:**

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**\* \* \*Stem Cell Checklist \* \* \***

Y/N **Research Involves HUMAN EMBRYONIC STEM CELLS (hESC)**

Y/N **NIH-Registered Human Embryonic Stem Cell Lines**

(Those included on the National Institutes of Health (NIH) Human Embryonic Stem Cell Registryat [http://escr.nih.gov](http://stemcells.nih.gov/research/registry/))

Y/N **Research involving Non-registered hESC lines. See Stem Cell Matrix for provenance requirements**

Y/N **Human Embryonic Stem Cell Lines derived under other Guidelines**

**Specify which Guideline: [CIRM, UK, Canada, Japan, etc.]**

**CIRM**

**UK**

**Canada**

**Japan**

**Other**

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Y/N **Research involving Human Gametes, Embryos, or Embryo-like Structures (Documentation of Consent Required)**

Y/N **Stem Cells isolated from tissues**

Y/N **Human Stem Cells used in humans (IRB/consent review required)**

Y/N **Human Neural Progenitor Cells used in humans (IRB/consent review required)**

Y/N **Human Neural Progenitor Cells used in animals (APLAC review required)**

Y/N **Human Pluripotent Stem Cells used in animals (APLAC review required)**

Y/N **Induced Pluripotent Stem Cells (iPSC)**

Y/N **Research involving Derivatives of any human Pluripotent stem cells**

Y/N **Research involving Derivatives of Human Embryos or Embryo-like Structure**

Y/N **Somatic Cell Nuclear Transfer (SCNT)**

Y/N **Use of Human Fetal Tissues (Attach Provenance Documentation)**

Y/N **Use of Cord Blood, Placental Tissue, or Foreskins (Attach Provenance Documentation)**

Y/N **Parthenogenesis**

Y/N **Other types of Human Stem Cells**

Y/N **Other hESC methods.**

**Notes/Comments:**

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**\* \* \*Project Locations \* \* \***

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| **Type** | Location Name | Address | Contact Information |
| On-Campus | Stanford University |  |  |
| Off-Campus | VA (Specify PA at VA) |  |  |
| Other |  |  |  |

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**\* \* \* Funding \* \* \***

**Y/N No Funding at this time**

**Funding - Grants/Contracts:**

**Funding - Fellowships**

**Gift Funding**

**Other Unrestricted Funding**

**Dept. Funding**

**Other Funding (e.g. OTL, Medical Scholars)**

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**\* \* \* Protocol Information \* \* \***

**1. Project Summary and Cell Line Information**

**a) In layperson's language state the purpose of the study in 36-5 sentences.**

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**b) Explain the scientific rationale for the study and describe the methods to be used.**

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**c) Check Yes or No to the following**

**Y/N The research involves derivatives of nonregistered hESC or Pluripotent cell lines [list lines below]**

**Y/N The research involves existing human stem cell lines [list lines below]**

**d) Y/N Were all hESC lines "acceptably derived" per a recognized authority?**

**e) Y/N Has proof of acceptable provenance been provided for all stem cells listed below?**

**Affiliation**

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| **f)** | **Stem Cell Information - hESC** |
| **List all human stem cells used in this protocol. Indicate 'To Be Determined' orTBD if stem cells do not yet exist:**  **Provide name of stem cells:**    **Provide a description of the current characterizations of each cell line. For example, cell line has been characterized for potency, karyotype, or**  **safety, e.g., the presence of human pathogens.**    **Provide a description of the storage and maintenance methods that will be used for each cell line:**    **If applicable, provide documentation of licensure of UK or Canadian stem cell lines.** | |

**Some cell lines have funding or research restrictions. See** [**Stem Cell Matrix**](https://scro.stanford.edu/docs/stem_cell_matrix.xlsx) **for further information.**

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|  | **Stem Cell Information - iPSC** |

**List all human stem cells used in this protocol. Enter 'To Be Determined' or TBD if stem cells do not yet exist:**

**Provide name of stem cells:**

**Type of Stem Cell:**

**Provide a description of the current characterizations of each cell line. For example, cell line has been characterized for potency, karyotype, or safety, e.g., the presence of human pathogens:**

**Provide a description of the storage and maintenance methods that will be used for each cell line:**

**How did the provider(s) obtain the stem cells or the tissue to derive or Isolate the stem cells?**

**Contact information for the provider(s) of the stem cells or tissues:**

**Answer the following questions:**

* **Was the consent of the tissue donor obtained for research?**
* **Was the tissue obtained under an IRB approved research consent form or a clinical consent form?**
* **Was monetary or other compensation given to the donor(s)? If yes, provide the details of the compensation.**
* **Has the maintenance and use of the stem cell line been performed under an approved IRB research protocol? If yes, provide a copy of the IRB approval letter and sample donor consent in the Attachments section.**

**g) Describe your expertise, experience or training in the culture and use of human or non-human stem cells.**

**h) Y/N Does the research involve use of biohazard agents or recombinant DNA?**

**Describe your expertise, experience or training in the use biohazard agents, rDNA.**

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**2. Material Transfer Agreement (MTA)**

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| **You must have a Material Transfer Agreement with a non-Stanford provider of hESC lines prior to receipt of cells and before an award can be processed** |
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| \* Please select Material Transfer Agreement(s) to delete. |
| [Contact ICO](http://stanford.edu/group/ICO/researcher/reMTA.html" \t "_blank) to determine if an MTA is needed. |
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**3. New derivations, human oocytes, embryos, somatic stem cells, induced pluripotent stem cells (iPSC)**

**a) Y/N The research involves the derivation of new human stem cell lines.**

**If Yes, please complete the following questions (i) and (ii)**

**i) Type of cell line: examples might include hESC, fetal tissue-derived stem cells, adult tissue-derived stem cells, bone marrow stem cells, cord blood stem cells, iPSC, cancer stem cells or any other type of human stem cell.**

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**ii) Describe your expertise, experience or training in the handling and use of**

**human or non-human stem cells, oocytes or embryos, including SCNT or**

**other stem cell derivation and culture methods.**

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**b) Y/N Will the research involve human oocytes, embryos or embryo-like structures for Somatic Cell Nuclear Transfer (SCNT) or similar research?,**

**If Yes, please complete the following questions (i), (ii) and (iii)**

**i) Describe the rationale for the need to use human oocytes or embryos.**

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**ii) Y/N Is SCNT or any other method to create embryos or embryo-like**

**structures going to take place with human cells or nuclei?**

**iii) Provide a justification for use of human rather than non-human materials.**

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**c) Y/N Are the donors of the human embryos, somatic cells, or gametes readily identifiable?**

**If Yes, please complete the following questions (i), (ii) and (iii)**

**i) How will you maintain confidentiality of records?**

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**ii) Will donors be re-contacted?**

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**iii) Is there any payment or reimbursement to any donors of gametes, blastocysts, or somatic cells? If yes, please explain.**

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**d) If your research involves the use of human oocytes, embryos or embryo-like structures created by Somatic Cell Nuclear Transfer (SCNT) or similar methods, please complete the following (i through iii) and (e):**

**i) How many oocytes or embryos will be used?**

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**ii) Please provide a justification for how this number was derived.**

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**iii) How long will blastocysts be kept developing in culture? (California law limits culture to 12 days.)**

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**e) Y/N Were new donors proactively recruited?**

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**f) Describe your expertise, experience or training in the handling and use of human or non-human oocytes or embryos including SCNT and derivation or culture of human or non-human stem cells if applicable (Copy response from 3aii if appropriate).**

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**4. Human stem cell use in animals**

**a) Y/N The research involves in vitro experiments only.**

**b) Y/N The research involves the introduction of either (a) embryonic, (b)**

**human pluripotent or (c) any human stem cell or (d) cellular**

**derivatives of human stem cells, or (e) neural progenitor cells into nonhuman animals.**

**i) Y/N Will human pluripotent stem cells or neural progenitor cells be used in animals?**

**ii) Y/N Will human pluripotent cells be placed in nonhuman primates?**

**iii) What animal species will be used?**

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**iv) What is the developmental stage of the animal when human cells will be introduced?**

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**v) What type of human cell will be introduced?**

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**vi) Where will cells be placed (anatomical location)?**

**vii) Evaluate the probable pattern and effects of differentiation and integration of the human cells into the animal central nervous system. Please address the concern for development of human traits.**

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**viii) Evaluate the probable pattern and effects of differentiation and integration of the human cells into other animal tissues.**

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**ix) What is the likelihood of gamete production?**

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**x) If any human pluripotent cells are introduced into a non-human animal, how are you guaranteeing that the animals will not breed? Please include plans for any accidental pregnancies.**

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**xi) Describe your expertise, experience or training in the use of human or non-human stem cells in animal models.**

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**5. Human pluripotent stem cell use in humans**

**a) Y/N Will the research involve introduction of embryonic or pluripotent**

**stem cell lines or their cellular derivatives into humans?**

**i) Provide scientific rationale for the introduction of stem cells or cellular**

**derivatives into humans.**

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**ii) Evaluate the probable pattern and effects of differentiation and integration of**

**the human cells into human tissues.**

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**iii) What are the possible side effects of introducing embryonic or pluripotent stem cell lines or their cellular derivatives into humans?**

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**iv) Provide a copy of the IRB approved informed consent forms in the Attachment section.**

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**6. Compliance Approval**

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| **Committee** | **Protocol Number** | **Protocol Director** | **File Date** | **Approval Date** | **Expiration Date** |
| **IRB**  **IACUC**  **Biosafety** |  |  |  |  |  |

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**7. Reserved for Future Use**

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**8. Attachments**

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| **Attachment Name** | **Attached Date** | **Attached By** | **Submitted Date** |
| consent |  |  |  |
| IRB protocol |  |  |  |

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**Obligations**

*Any change in the research protocol must be submitted to the SCRO for review*

*prior to the implementation of such change. Inasmuch as the SCRO Panel includes faculty, staff, legal counsel, public members, and students, protocols should be written in language that can be understood by all Panel members.*

*SCRO approval of any project is for a maximum period of one year. For continuing projects and activities, it is the responsibility of the investigator(s) to resubmit the project to the SCRO for review and re-approval prior to the end of the approval period. A Notice to Renew Protocol is sent to the Protocol Director 7 weeks prior to the expiration date of the protocol.*

*Department Chair must be aware of faculty and staff research that is not part of a*

*sponsored project. VA applicants may require Division Chief or Ward Supervisor*

*approval.*

*By signing this document, I indicate that the information provided on this form is*

*complete, accurate and true to the best of my knowledge. I agree to abide by my*

*responsibilities under Federal, State, and University policies, including MTAs,*

*purchase agreements, or other contracts with respect to my use of human stem*

*cells.*

PLEASE NOTE: List all items (verbatim) that you want to be reflected in your

approval letter in the box below.

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**Y The Protocol Director has read and agrees to abide by the above obligations.**