UCSD Human Research Protections Program

# SCRO Project: Standard Application for Review

This form can be used for paper-based submissions to the IRB and also for electronic submissions.
Please follow the instructions that apply to your submission type:

## Instructions for submitting

1. Complete all pages of this form. **To do this, open the form using your Web Browser** to fill in the form (requires Acrobat Reader or plug- in).
2. Click the **Print button** on the last page to make a copy for signatures.
3. Click the **Submit button** on the last page to submit the data from the Facesheets to the HRPP Office via the Internet.
4. When you submit the Facesheets, the HRPP system will give you a Temporary Project ID (a "T-number"). Once your information has been imported into the HRPP database, usually within 1-2 working days, the project will receive a HRPP project number. You will then need to log into your "My Protocols at a Glance" through eIRB services. Click on the link for your "new" project and you may begin to upload the Research Plan, consents/assents, and other documents, as appropriate. The template for the Research Plan is available on the website in Word format.
5. The Principal Investigator and Department Chair must sign where indicated on the last page of the Facesheets.
6. Mail one copy of the **signed Facesheets** to HRPP Office, mail code 0052.

## Section 1: PROJECT TITLE

## Section 2: KEY PERSONNEL

| | | | | | | |
|---|---|---|---|---|---|---|
| Principal Investigator | Last name | | First name | | Degree | |
| | Title | | Department | | Mail code | |
| | E-mail | | Phone | | Fax | |
| | Principal Investigator is salaried UCSD employee (check Yes or No): Yes ☐ No ☐ | | | | | |
| | | | | | | |
| Contact | Last name | | First name | | Degree | |
| | Title | | Department | | Mail code | |
| | E-mail | | Phone | | Fax | |

## Section 3: PROJECT CHARACTERISTICS

| Yes | No | | | | | |
|---|---|---|---|---|---|---|
| ☐ | ☐ | This is a **renewal of a previous project** | If **yes**, the IRB number for the **previous project** is | | | |
| ☐ | ☐ | Involves human embryonic stem cells ***in vitro*** | | | | |
| ☐ | ☐ | Involves human embryonic stem cells ***in vivo*** | | | | |
| ☐ | ☐ | Involves somatic cell nuclear transfer (SCNT) | | | | |
| ☐ | ☐ | Involves parathenogenesis | | | | |
| ☐ | ☐ | Is a clinical trial (If yes, what phase?) | Phase I ☐ | Phase II ☐ | Phase III ☐ | Phase IV ☐ |
| ☐ | ☐ | Use of **human oocytes** for hESC research | | | | |
| ☐ | ☐ | Use of **human embryos** for hESC research | | | | |
| ☐ | ☐ | Proposing to **derive** new human pluripotent stem cell lines | | | | |
| | | **If yes, what methods** of stem cell derivation do you plan to use (Please specify methods in Research Plan and check all that apply) | | | | |
| | | ☐ hESC ☐ iPSC ☐ Other – specify: | | | | |
| ☐ | ☐ | Proposing to use **existing** human pluripotent stem cell lines (if yes, list all pluripotent stem cell lines below) | | | | |
| | | | | | | |
| | | | | | | |
| ☐ | ☐ | Human cells or tissues to be obtained from **living donors** | | | | |
| ☐ | ☐ | Human pluripotent stem cells or neural progenitor cells to be introduced into **human subjects** | | | | |
| ☐ | ☐ | Human pluripotent stem cells or neural progenitor cells to be introduced into **animal subjects** | | | | |
| | | If yes for animal subjects, which vivarium will be used for housing: | | | | |

## Section 4: FACILITIES WHERE STUDY WILL BE CONDUCTED/CELLS STORED

| Yes | No | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| ☐ | ☐ | Non-UCSD facilities | | | | | | |
| | | If yes, please describe: | | | | | | |
| ☐ | ☐ | UCSD facilities. If yes, list all buildings and room numbers in which stem cells will be used or stored | | | | | | |
| | | Building | | Room #(s) | | Used ☐ | Stored ☐ | |
| | | Building | | Room #(s) | | Used ☐ | Stored ☐ | |
| | | Building | | Room #(s) | | Used ☐ | Stored ☐ | |

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## Section 5: FUNDING

| | | |
|---|---|---|
| **Funding Source** (check all that apply) | ☐ Unfunded | ☐ Departmental or ORU funding |
| | ☐ HHS | ☐ Academic Senate |
| | ☐ NSF | ☐ Not for profit foundation |
| | ☐ CIRM | ☐ Other funding source – specify: |
| **Funding Mechanism** | ☐ Grant | ☐ Gift ☐ OCGA Research Agreement (RA) |
| | ☐ Contract | ☐ Internal |
| | ☐ Other funding mechanism - specify: | |
| **Funding Status** | ☐ Awarded | ☐ Pending |
| | Name of Sponsor | |

| | | | | |
|---|---|---|---|---|
| **Other project Identifiers** | UCSD OCGA proposal number | | Investigator-initiated or RA number | |
| | Sponsor's ID (e.g., NIH grant Nr) | | Other project identifiers | |

## Section 6: OTHER PERSONS ASSOCIATED WITH THIS PROJECT*

| Role | Last name | First name | Degree | Department | Institution |
|---|---|---|---|---|---|
| Co-Investigator | | | | | |
| Co-Investigator | | | | | |
| Co-Investigator | | | | | |
| Co-Investigator | | | | | |
| Co-Investigator | | | | | |
| Co-Investigator | | | | | |
| Other role: | | | | | |
| Other role: | | | | | |

*If more persons are involved with this study than can be listed here, submit a separate list providing this information

## Section 7: SIGNATURES

By signing below, you certify that the information provided about this study is accurate to the best of your knowledge, that before any derivation or use of human embryonic stem cells (hESCs) or induced pluripotent stem cells (iPSCs), each researcher will have been adequately trained to conduct the proposed research including all applicable ethics training requirements**; that before the use of human gametes or embryos for derivation of hESCs, each researcher will have completed an approved course in hESC derivation; and that you agree to conduct the study in compliance with applicable federal, state and University policies including MTAs, purchase agreements, or other contracts with respect to the use of stem cells and to contact the appropriate administrative office with any questions regarding my responsibilities on these matters.

| | | | |
|---|---|---|---|
| Principal Investigator | | Date: | |

By signing below, you provide assurance regarding the PI's qualifications and adequacy of resources to ensure compliance with applicable federal, state, and University policies.

| | | | |
|---|---|---|---|
| Department Chair | | Date: | |

**See http://sdrec.ucsd.edu for training requirements and training options.

- **Click the Print button** to make copies for signatures and for your records.
- **Click the Submit button** to submit the data from the application to the HRPP office via your web browser; you will receive an acknowledgement page back with your assigned Temporary project identifier (your "T-number"). Once your information has been imported into the HRPP database, usually within 1-2 working days, the project will receive a HRPP project number. You will then need to log into your "My Protocols at a Glance" through eIRB services. Click on the link for your "new" project and you may begin to upload any accompanying documents, such as the Research Plan, consents/assents, etc.

**Click Here to Print** **Click Here to Submit Data via Web**