

1. [UCI Human Stem Cell Research Oversight \(HSCRO\) website Main Page](#) – begin here
2. [Does your activity require HSCRO review?](#)
 - a. All research or clinical investigations that involve the following activities require review by the UCI HSCRO Committee:
 - **Use of human pluripotent stem cells (iPSC's)**
 - **human gametes**
 - **human embryos / embryonic cells**
 - **human fetal tissue / cells**
 - **transplantation of neural stem cells into humans**
 - b. HSCRO review is **NOT required** for the following:
 - Adult tissue-derived multipotent or unipotent stem cells
 - Mesenchymal cells (e.g., isolated from bone marrow, peripheral blood etc.)
 - Hematopoietic stem cells (HSC's)
 - Adult stem cells (for example cardiac stem cells)
 - Cord blood cells
 - Components of stem cells that are not viable and cannot be expanded (i.e., RNA / protein samples) received from a collaborator / company and NOT derived from stem cells grown in your laboratory.
 - **Additional Guidance:**
 - c. Review the current [HSCRO Policy and Standard Operating Procedures](#)
 - d. Applicable Regulations:
 - i. [CDPH Guidelines for Human Stem Cell Research](#)
 - ii. [CIRM Stem Cell Grant Regulations](#)
 - iii. [NIH Guidelines for Human Stem Cell Research](#)
 - e. Review the current UCI [Ancillary Review Chart](#)
3. **For activities that require HSCRO review**, submit a NEW Protocol via the HSCRO submission and management system called [Kuali Research Protocols \(KRP\)](#).
 - a. To access KRP:
 - i. **UCSB Researchers:** Please review the [Instructions for UCSB Researchers](#) for logging in to KRP
 - ii. **UCI Researchers:** Please follow the instructions detailed in the “Access KRP” section of the [KRP User Guide](#)
4. [How to Submit NEW Protocols for HSCRO review](#) webpage summarizes considerations when submitting your protocol for HSCRO review
 - a. **All new HSCRO Protocols require Full Committee review.**
 - i. See the [HSCRO Meetings and Deadlines page](#) for guidance.
 - ii. HSCRO Full Committee meetings usually occur on the first Thursday of the month.
 - b. Other Ancillary (IRB, IACUC, IBC) approvals may also be applicable.

- c. See the [Cell Line Provenance Policy](#) for details of submission requirements for research materials (e.g., submission requirements for adding registered pluripotent stem cell lines vs. fresh somatic cells to the protocol)

5. After HSCRO Approval you need to make changes to your protocol:

- a. See: [Amendments to HSCRO Approved Research](#) webpage.
- b. Amendments are submitted via [Kuali Research Protocols \(KRP\)](#) for HSCRO review.
- c. Full Committee review may be required if an amendment significantly changes the study aims or design, ethical considerations, or adds non-registered HSCRO covered materials / cell lines not previously verified by the Committee.

6. Your HSCRO protocol is about to expire, submitting a renewal for HSCRO review:

- a. See [Submitting a Renewal \(Renewal & Amendment\)](#) for detailed guidance.
- b. Submit 8 weeks prior to expiration if the renewal will include major amendments
- c. Submit 4-6 weeks prior to expiration for renewals with minor amendments or no amendment.
- d. **Steps:**
 - i. In KRP – select “*Renew & Amend*” - even if your renewal includes no changes!
 - ii. If **no changes** are included at renewal, in the “Amendment” section of the application - select “*RENEWAL: This is a renewal that does not require changes to the approved protocol*”.
 - iii. If **changes are included** in your renewal - select “*AMENDMENT: HSCRO*” and then specify the changes in the “Amendment” section of the application.
- e. Automated renewal reminders are sent 90, 60 and 30 days from expiration and on your expiration date. **Ensure the email: no-reply@kuali.co- is on your “Safe Senders” list.**

7. Submitting [Closing Reports](#) upon research completion:

- a. When a protocol no longer involves [activities that require HSCRO review](#), it can be closed with the [submission of a closing report](#) in KRP.
 - i. In the closing report, provide a brief summary of any results (preliminary or final) obtained in the study.
- b. The closing report will be assessed by the HSCRO Chair or designated HSCRO member at the next Subcommittee meeting. If approved, the protocol can be closed out.

HSCRO Additional Resources:

- [HSCRO Staff Weekly Office Hours](#)
- For general questions: email hSCRO staff at HSCRO@uci.edu
- Phone: (949) 824-8170 — please leave a voicemail.
- *Subscribe to the HSCRO ListServ:* Send a blank email to: or-hscro+subscribe@uci.edu