Do You Need hSCRO Review?

V 1.0 April 2024

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:**

   - Generation of new lines of human pluripotent stem cells from whatever source and by whatever means.
   - Use of:
     - human gametes
     - human embryos
     - human induced pluripotent stem cells (iPSC)
     - human fetal tissue and/ or human fetal stem cells
     - human embryonic stem cells
   - Transplantation of stem cells into humans (not including Mesenchymal or Hematopoietic stem cells).
   - Activities involving the introduction of human adult pluripotent, human fetal tissue, human fetal stem cells, human embryonic stem cells, or their neural derivatives into nonhuman animals at any stage of embryonic, fetal, or postnatal development.
   - Activities in which the identity of the donors of blastocysts, gametes, or somatic cells from which human stem cells were derived is readily ascertainable or might become known to the investigator.

   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
   - Non-UCI collaborator/site/ Sponsor will create pluripotent stem cells from biospecimens collected at UCI. For example, skin biopsy samples are collected at UCI and sent to a non-UCI sponsor to genetically manipulate to obtain induced pluripotent stem cells.
   - In vitro generation or use of human iPSC derivatives, that is, differentiation of human iPSCs already approved on an existing hSCRO protocol in the PI's laboratory into a new multipotent or unipotent cell lineage, unless they meet one of the other requirements above (e.g., in vivo transplantation of neural stem/progenitor cells of any origin).
   - 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 **UCI** 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

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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. **See Amendments to hSCRO Approved Research** for detailed information related to when subsequent changes to your hSCRO Approved Protocol required submission.
    a. **Amendments** are submitted via **Kuali Research Protocols (KRP)** for hSCRO review.
    b. Amendments may require **Administrative, Subcommittee or Full Committee review.** Please review the online guidance.
    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. See **Submitting a Renewal (Renewal & Amendment)** for detailed guidance on how to submit **your yearly renewal application to hSCRO**.
    a. Must be **submitted yearly - 8 weeks prior to expiration** if the renewal will include major amendments that **require Full (Convened) hSCRO Committee review otherwise** 4-6 weeks prior to expiration for renewals with no or minor amendments.
    b. **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** — will send you straight to voicemail.
  Please be assured that although we are not answering this phone line, all messages are being listened to in real-time and forwarded to the appropriate colleague for follow-up.
- ***Subscribe to the hSCRO ListServ:*** Send a blank email to: or-hscro+subscribe@uci.edu