1. What are the panel meeting dates & deadlines? [1]

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3. Does research on human cancer stem cells require a SCRO protocol?

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5. Does research involving other human stem cells, progenitor cells or mesenchymal cells require SCRO review?

6. What is Written Notification?

7. Does research involving the derivation of induced pluripotent stem cells (iPSC) require a SCRO review?

8. My research does not involve stem cells at this time, but I am collecting tissues or samples that may result in human pluripotent stem cells. Do I need to submit a SCRO Protocol?

9. My research involves using human embryonic stem cells (hESC). What do I need to establish provenance?

10. My research involves iPSCs or their derivatives. What do I need to establish provenance?

11. Does my human stem cell research also require an IRB review?

12. Which organizations does the Stanford IRB/SCRO Panel serve?

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1. What are the panel meeting dates & deadlines?

For a current schedule, refer to the Panel meeting dates & deadlines [2].

2. What is the IRB/SCRO Panel?

The IRB/SCRO Panel responsible for overseeing the protection of human participants in research and overseeing scientific and ethical considerations for human stem cell research. The IRB/SCRO Panel is a part of the Research Compliance Office and derives its authority from the Office of the Vice Provost and Dean of Research. The Panel reviews both IRB protocols and SCRO protocols. The IRB and SCRO review follow separate processes, however, they may be conducted concurrently.

3. Does research on human cancer stem cells require a SCRO protocol?
The IRB/SCRO Panel does not review protocols when research involves only human cancer stem cells, unless it is required by the sponsor or if the Panel has specific concerns about the research.

4. Do hematopoietic stem cell transplants require a SCRO protocol?

Research focusing on the characteristics of the stem cell itself requires SCRO review. Research on treatment issues such as pre-transplant medications or GVHD (Graft Vs Host Disease) does not require review. California Institute for Regenerative Medicine (CIRM) funded hematopoietic research requires SCRO review.

5. Does research involving other human stem cells, progenitor cells or mesenchymal cells require SCRO review?

You will need to submit a SCRO protocol. However, much human adult stem cell research is eligible for a process called Written Notification. Once you submit a SCRO protocol, the Panel determines whether your research is eligible for Written Notification.

6. What is Written Notification?

Research that is eligible for Written Notification will not be reviewed on an annual basis, unless there is a change in the research that requires IRB/SCRO Panel approval. Written Notification is a SCRO review type whereby the Panel acknowledges that a researcher has submitted his or her research aims. The Panel determines whether the research meets the eligibility for written notification under the regulations at 17 CCR § 100070 or the CDPH Guidelines for Human Stem Cell Research, §5 (a)(3).

7. Does research involving the derivation of induced pluripotent stem cells (iPSC) require a SCRO review?

Research with iPSCs may require SCRO review. We encourage you to submit a SCRO protocol and/or contact IRB/SCRO staff if you have questions about whether a review is required. Any iPSC work that involves placing the cells or the derivatives of the cells into animals or humans will require full convened Panel review.

8. My research does not involve stem cells at this time, but I am collecting tissues or samples that may result in human pluripotent stem cells. Do I need to submit a SCRO Protocol?

No, a SCRO protocol is not necessary at this time; however, an IRB protocol is required. We advise you to use informed consent language that will permit you to use these samples for stem cell research in the future.

9. My research involves using human embryonic stem cells (hESC). What do I need to establish provenance?

For Federally funded research, acceptable provenance is met by checking to see if the hESC (human embryonic stem cell) line is listed on the NIH Registry. For research funded from sources other than the Federal government, any of the following serves to establish acceptable provenance of the cell line:

- listed on the NIH registry
- listed on CIRM registry
- deposited or approved by the United Kingdom Human Fertilization and Embryology Authority
- approved by the Canadian National Stem Cell Oversight Committee
- derived in accordance with Japanese Guidelines
- listed on the Stanford Stem Cell Matrix

10. My research involves iPSCs or their derivatives. What do I need to establish provenance?

- Documentation that there are limitations to payments made to individuals who are not tissue donors for CIRM
funded research

- If CIRM-Funded and identifiable, establishing provenance requires one of the following:
  - IRB or IRB-equivalent approval letter for original collection of the tissues, or
  - Informed consent that allows the somatic cells to be used for research, or
  - Assurance from the Principal Investigator or organization responsible for the collection of somatic cells that all applicable laws were followed in the collection of the tissue for research purposes.

11. Does my human stem cell research also require an IRB review?

IRB review is only required if human subjects are involved. If you have questions about whether human subjects are involved, we may ask that you fill out a short Determination of Human Subjects Form [5], which will help us determine if IRB review is necessary.

12. Which organizations does the Stanford IRB/SCRO Panel serve?

The Stanford IRB/SCRO Panel reviews research for Stanford and its affiliates. This includes:

- Stanford University
- Stanford Hospital and Clinics (SHC)
- Lucile Packard Children’s Hospital at Stanford (LPCH)
- Veterans Affairs Palo Alto Health Care System (VAPAHCs)
- Palo Alto Veterans Institute for Research (PAVIR)

13. Who can I contact for more information?

Email the SCRO staff [6]
eProtocol HelpDesk:
(650) 724-8964

Source URL: https://researchcompliance.stanford.edu/panels/scro/resources/faqs

Links
[1] https://researchcompliance.stanford.edu/../../rco/meetings
[4] https://stanfordmedicine.box.com/shared/static/1qy7nqodmv3hdhz78f0lw3pnyifdm7k2.xlsx
[6] mailto:scrostaff@lists.stanford.edu
[7] https://stanford.service-now.com/services?id=get_help&cmdb_ci=591219d013556200e71d3d576144b0a2