A Guide for the Combined IRB/SCRO

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Welcome to Stanford's IRB/SCRO Panel

Why a combined IRB/SCRO model?

- More comprehensive review of all regulatory, scientific, and ethical issues, while avoiding unnecessary overlap or inefficiencies
- Greater expertise, including stem cell research expertise, available to both IRB & SCRO
- Streamlining of review as science increasingly moves into clinical research
- NIH does not require institutions to have a SCRO, but California law still requires this oversight and supports methods that allow IRBs and SCROs to work together.
- CIRM may revise requirements—another need for flexibility

Legal Considerations

- **IRB and SCRO** retain distinct oversight responsibilities under applicable federal and state laws and regulations

- **IRB** oversees human subjects research
  - Some required SCRO reviews are **NOT human subjects research** (e.g., research using anonymous or indirectly identifiable embryos, animal research, etc.)
  - With a combined IRB/SCRO, RCO can **channel appropriate studies** for combined review, while channeling others for only SCRO or only IRB consideration, as appropriate

Legal Considerations, continued

SCRO reviews are not subject to **federal agency jurisdiction**

- **OHRP** oversees only human subjects research and has jurisdiction only over IRB activities
- **NIH** does not require SCRO oversight
- **FDA** may or may not have reason to review SCRO records

Legal Considerations, continued

- All **applicable federal and state** requirements will be followed
- Requirements are **combined in the Charge** to the panel:
    - Common Rule
    - FDA regulations
    - NIH Stem Cell Guidelines
    - CIRM regulations
    - California law, with consideration of the State Advisory Committee Guidelines
    - ISSCR and NAS Guidelines for stem cell research and clinical trials

Practical Considerations

- The SCRO and IRB panels are composed of the same individuals, with one chair
- For each IRB/SCRO protocol, SCRO issues are usually discussed first, then IRB issues are addressed
- IRB/SCRO members fulfill the requirements of a quorum
- Minutes of the combined IRB/SCRO meeting can be separated for regulatory purposes, if required

Stanford's IRB/SCRO

- Convene as one Panel, but carry out responsibility for SCRO oversight and criteria for IRB review
- Take one vote on combined IRB/SCRO protocols
- Each individual brings different expertise and contribution—collective not individual review
- Each Regular protocol has a minimum of two reviewers, with one presenting

You are providing a great service to the University and its research mission

The SCRO and IRB panel managers, the Research Compliance Office, the Dean of Research and the OGC all thank you—and are always available to answer your questions.