Review Types for New SCRO Protocols & Phone Scripts and Waivers of Documentation of Consent

IRB/SCRO Education
January 10, 2012
SCRO Review Categories Flow Chart

The SCRO Review Categories Flow Chart is a general guide. The IRB/SCRO panel may review any project involving human stem cells or their derivatives as they see necessary.

Designated review is used for revisions to existing protocols.

For more information on how to submit a SCRO protocol, please go to http://scroprotocol.stanford.edu.

- **Will your research involve:**
  - Human stem cells or any kind?
  - Human neural progenitor cells in animals or humans?
  - Human tissues and/or fetal tissues for use in deriving pluripotent stem cells?

  - **No**
  - **Yes**

- **Research creating or using induced pluripotent stem cells without introducing the cells or their derivatives into animals:**
  - **No**
  - **Yes**

- **Non-pluripotent human stem cells such as hematopoietic or mesenchymal stem cells:**
  - **No**
  - **Yes**

- **Purely in vitro research using human pluripotent stem cells from acceptable sources:**
  - **No**
  - **Yes**

- **Research linked to the creation of human pluripotent stem cell lines from human embryos or gametes:**
  - **No**
  - **Yes**

- **Introduction of human pluripotent stem cell lines, their derivatives or human neural progenitor cells into animals or humans:**
  - **No**
  - **Yes**

- **Human gametes or embryos used for human stem cell research:**
  - **No**
  - **Yes**

**Written Notification Only**

**Full Panel Review**

**Contact SCRO Office**

Email scrostaff@lists.stanford.edu or call (650) 724-3868

Please contact the SCRO office at (650) 724-3868 for additional questions.
Written Notification

- Research creating or using induced pluripotent stem cells without introducing the cells or their derivatives into animals
- Non-pluripotent human stem cells such as hematopoietic or mesenchymal stem cells (excluding neural progenitor cells)
- Purely in vitro research using human pluripotent stem cells from acceptable sources. See Stem Cell Matrix.

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Full Panel Review

- Research limited to the creation of human pluripotent stem cell lines from human embryos or gametes
- Introduction of human pluripotent stem cell lines, their derivatives or human neural progenitor cells into animals or humans
- Human gametes or embryos used for human stem cell research

http://researchcompliance.stanford.edu
Phone Scripts and
Waivers of Documentation of Consent

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Phone Scripts and Waivers of Documentation of Consent

The IRB reviews phone screening scripts that are approved with a waiver of documentation of consent to ensure the scripts do not contain language involving greater than minimal risk.

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For research subject either to OHRP or FDA regulation, the IRB finds:

That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

OHRP 45 CFR 46.117(c)(2); FDA 21 CFR 56.109(c)(1)

…the more sensitive and personal the information…the more likely the screening would not meet the definition of "minimal risk."
Sensitive information includes:

- potentially embarrassing/damaging info
- questions concerning illegal drug use
- attempts at suicide
- psychiatric conditions
- sexual orientation/practices
- contagious illness (e.g., HIV or hepatitis C)
- experiencing/committing any reportable event (e.g., child/elder abuse)

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Questions?