

# Regulations for SCRO Clinical Trials and ClinicalTrials.gov

IRB/SCRO Panel Meeting  
December 13, 2011



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# Clinical Trials using Human Stem Cells

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- Adult Stem Cell Therapies
  - Bone Marrow Transplant studies
  - Adult Stem Cell Treatments
- Pluripotent Stem Cell Therapies
  - Clinical Trials using iPSC
  - Clinical Trials using hESC



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# Adult Stem Cell Clinical Trials

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- Bone Marrow Transplant Studies, looking at GVHD or BMT treatment
  - No SCRO review
- Other Clinical Trials only using adult stem cell derived therapies
  - Written Notification
- Neural Progenitor Cell therapies
  - Full Panel Review



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# Pluripotent Stem Cell Clinical Trials

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- Non-autologous iPSC and hESC require SCRO review in addition to IRB review
- CDPH has specific regulations that pertain to these clinical trials



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# CDPH Regulations for Pluripotent Stem Cell Clinical Trials

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- Researcher needs to establish there is sufficient institutional field strength to justify conducting such research, particularly with respect to first-in-human trials.
- The SCRO Committee may require the testing or screening of donors of the biological materials used to produce the covered cells prior to commencement of the clinical trial.



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# CDPH Regulations for Pluripotent Stem Cell Clinical Trials

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- IRBs shall require that informed consent include information about the biological source of the material and how they were produced.
- The language used in informed consent should not convey an unrealistic impression of the direct benefit of trial participation. This includes the use of terms like “stem cell therapy.”



# CDPH Regulations for Pluripotent Stem Cell Clinical Trials

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- Institutions conducting clinical trials are encouraged to develop methods that allow SCRO Committees and IRBs to work together to discharge these responsibilities efficiently, while bringing needed expertise in stem cell science to bear on oversight of such trials.



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# Status of hESC Clinical Trials

- Geron closed the first hESC Clinical Trial to enrollment November 14, 2011
  - Cited high cost rather than lack of therapeutic potential
- Two patients treated at Stanford, last treated November 16, 2011
  - Follow up will continue as planned
- Advanced Cell Technologies has two open clinical trials involving hESC treatment
  - A form of Juvenile Blindness and Macular Degeneration



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# ClinicalTrials.gov



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# New FDA Regulation

## 21 CFR 50.25

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(c) “When seeking informed consent for applicable clinical trials...the following statement shall be provided to each clinical trial subject in **informed consent** documents and processes. This will notify the...subject (about the)... clinical trial registry databank”



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# Informed Consent Changes

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“A description of this clinical trial will be available on <http://clinicaltrials.gov> as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search the Web site at any time.”

## Changes made to:

- Stanford Medical Consent Templates
- VA PAHCS Medical Consent Templates
- Short Form (all versions)



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# Summary

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- Effective enforcement date: March 7, 2012
- Does not apply retroactively
- Changes have been made in the:
  - Informed Consent Templates
  - eProtocol Application General Checklist
  - Website
  - Other docs (guidance docs, HRPP, etc.)
  - Staff Checklist



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# Questions?



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