Stem Cell Research Oversight (SCRO)

Regulatory Services for Clinical Trials

ClinicalTrials.gov, FDA INDs and IDEs

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HOOP 200 – Review of Research

H. Human Stem Cell Research Oversight (SCRO) Committee

All research involving human embryonic stem cells (hESCs) or human induced pluripotent stem cells (hIPSCs) conducted at the university by its employees and/or involving use of its facilities or resources must be reviewed and approved by the Human Stem Cell Research Oversight (SCRO) Committee before it is initiated. Some research involving hESCs or hIPSCs may require additional approval by the AWC, IBC and/or CPHS. For more information on the application process, please contact the SCRO office at scro@uth.tmc.edu.

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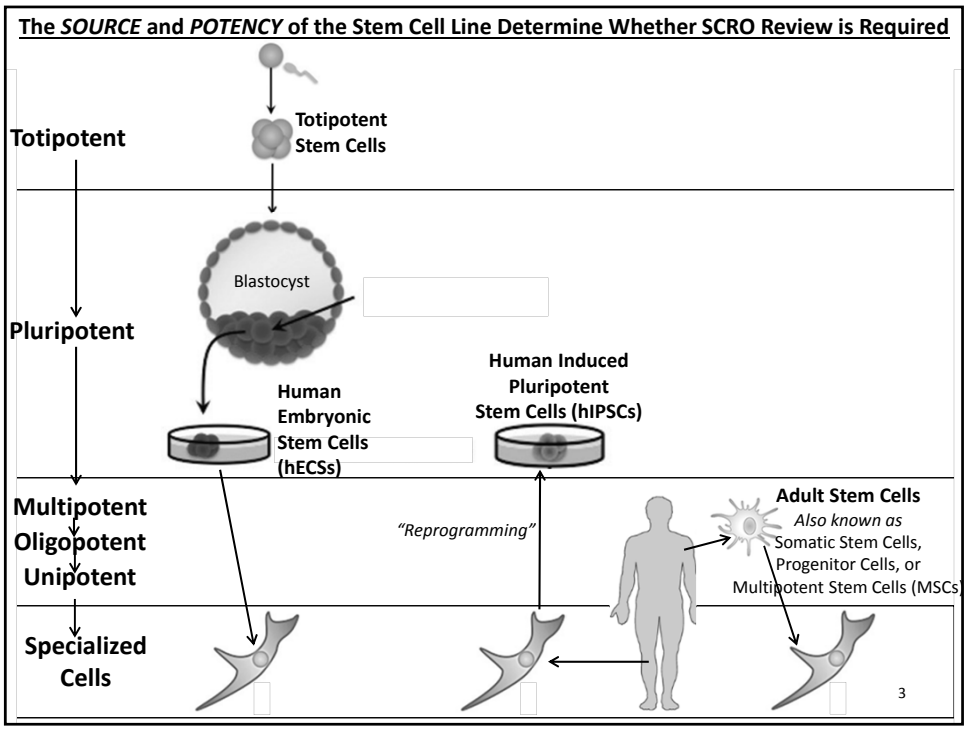

What Requires SCRO Review at UTHealth?

	Creation for Research Purposes	Research Use
human embryonic stem cells (hESCs)	**YES**	**YES**
human induced pluripotent stem cells (hIPSCs)	*No*	**YES**
human totipotent stem cells	**YES**	**YES**
human gametes	**YES**	**YES**
human embryos	**YES**	**YES**
adult stem cells	*N/A*	*No*

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SCRO Website

https://inside.uth.edu/scro/

- SCRO Application
- Document “SCRO Policy and Procedures”
- Document “Guidelines for SCRO Review”

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SCRO contact information

- *SCRO Office*
  - SCRO@uth.tmc.edu
  - *(*713) 500-3587
- *Elizabeth Gendel*
  - Elizabeth.M.Gendel@uth.tmc.edu
  - (713) 500-3587

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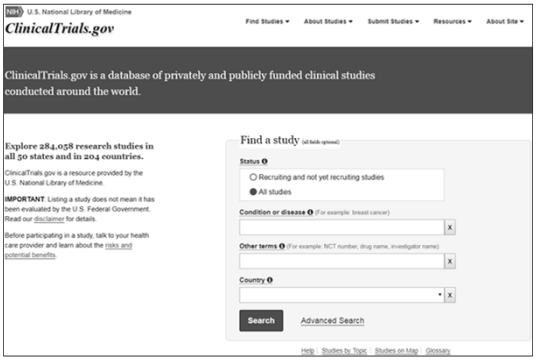
Regulatory Services for Clinical Trials

- **I review all IRB submissions that go to the full board to determine:**
  - If the study must be registered at ClinicalTrials.gov
  - If the study might need FDA approval before it begins (*via an IND or IDE*)
- **Either CTRC or IRB will notify your study team**
- **CTRC can assist with:**
  - Registration and Results Entry at ClinicalTrials.gov
  - Preparation and Submission of Application to FDA for Approval to Study an Investigational Drug or Device *(that is, an IND or IDE application)*

What is ClinicalTrials.gov?

- Online database of clinical trials
  - Protocol info, results, recruitment status, and contact info
  - Free, public resource
  - Anyone can search the database



Once a Trial is Registered, it is Assigned an NCT

NCT # stands for National Clinical Trial #

NCT00000000

Why Register and Report Results at ClinicalTrials.gov?

- It's the **law**! *enforceable by fines*
- **NIH** funding can be terminated or withheld
- It can affect the ability to publish in a medical **journals**
  - ICMJE = International Committee of Medical Journal Editors
- An NCT # is required by **CMS** for claims for research-related procedures
- Required per UTHealth's **HOOP 186**
- Can serve as a **recruiting** tool

Which Studies are Required to Be Registered at ClinicalTrials.gov?

- Most basically,
  - **Interventional studies with a health-related outcome**
    - Interventional = Subjects assigned to an intervention as part of a study protocol (*and not as part of routine medical care*)

Who Registers the Study?

- **If the study is initiated by a UTHealth PI**,
  - then the **UTHealth PI** is responsible
- **If the study is NOT initiated by a UTHealth PI**,
  - then the **industry sponsor** or **lead site** usually registers

When to Register at ClinicalTrials.gov?

- Per **FDAAA**, the **Final Rule**, and the **NIH policy**, require registration no later than 21 days after enrollment of the first participant
- BUT, **ICMJE journals** require registration at or before the time of first patient enrollment

THE BOTTOM LINE:
It's best to register after IRB approval but before enrollment begins.

How to Register at ClinicalTrials.gov?

- Contact Elizabeth Gendel to get an Account
  - *713-500-3587, Elizabeth.M.Gendel@uth.tmc.edu*
- You May Set Up an Appointment with Elizabeth Gendel to Register Together
  - *NCT # typically available 2–5 business days after submission*

Results Entry at ClinicalTrials.gov

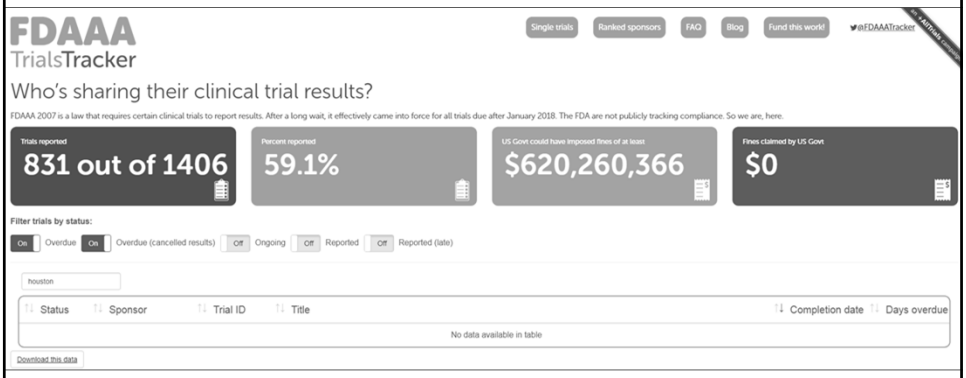
- Work with Elizabeth Gendel
- Results are due 1 year after the trial's "Primary Completion Date"
  - "The date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the pre-specified protocol or was terminated."

FDA Fines for Late ClinicalTrials.gov Results

- FDA fines of **$10,000** plus **$10,000 per day thereafter**
- FDA performs audits of ClinicalTrials.gov records

Public Shaming Website

https://fdaaa.trialstracker.net/



THANK YOU!

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