UTHealth Human Stem Cell Research Oversight (SCRO)

New UTHealth SCRO Policy
In November 2015, a policy for human stem cell research oversight (SCRO) went into effect.

The SCRO website at https://inside.uth.edu/scro/ provides an overview of SCRO procedures, as well as the following detailed documents for download:
- Human Stem Cell Research Oversight Policy and Procedures
- Guidelines for SCRO Review
- SCRO Committee roster

What Stem Cell Research Requires Review?
The following categories of research involving human stem cells must be reviewed and approved by the UTHealth SCRO Committee prior to initiation of the research (see the policy and guidelines linked above for more detail):
- The derivation and research use of human embryonic stem cells (hESCs)
- The research use of human induced pluripotent stem cells (hiPSCs)
- The derivation and research use of human totipotent stem cells
- The creation and research use of human gametes or human embryos

Note that research involving human somatic stem cells (including human fetal stem cells, human cord blood stem cells, and human amniotic fluid stem cells) is not required to be reviewed by the SCRO Committee; however, this research is required to be registered at the UTHealth Human Stem Cell Research Registry, information below.

What is the SCRO Application Process?
The application process begins with registration of the human stem cell protocol at the UTHealth Human Stem Cell Research Registry, information below. The SCRO office and/or the SCRO Committee Chair will review the registry submission to determine the level of review (exempt, expedited, or full committee review, as described in the Guidelines for SCRO Review).

Registration of hESC Lines and Human Stem Cell Research
UTHealth researchers are required to register hESC lines and human stem cell research at one of two UTHealth REDCap registries set up for this purpose:
- Investigators must register any hESC lines in their possession at the UTHealth Human Stem Cell Line Registry. Note that registration of hiPSC lines or somatic stem cell lines is not required.
- Investigators must register any research protocols involving hESCs, hiPSCs, human totipotent stem cells, or human somatic stem cells at the UTHealth Human Stem Cell Research Registry.

Contact
You may contact the SCRO office for assistance at scro@uth.tmc.edu or 713-500-3587.
Congratulations to Elizabeth Massey Gendel, PhD for being promoted to Senior Research Compliance Specialist. Liz joined the Clinical Trials Resource Center team in April 2014 as a Regulatory Specialist, and she will continue to be responsible for ClinicalTrials.gov administration, coordination of UTHealth’s Stem Cell Research Oversight (SCRO) program, preparation of the newsletter The Clinical Coordinator, and assistance with IRB education. In her new role, Liz will take on responsibilities for regulatory review of new clinical trials and assisting sponsor-investigators with IND and IDE submissions. Liz has previous experience in the lab (she earned her PhD in Biochemistry and Molecular Biology from UCLA and she was a Postdoctoral Scholar in UTHealth’s Department of Microbiology and Molecular Genetics), as well as in administration (she served as a Grants Specialist in UTHealth’s Sponsored Projects Administration). We wish her the very best in her new role.

Upcoming Certification Testing Dates

CCRP certification: For those interested in becoming a Certified Clinical Research Professional, the next exam in Houston is at Methodist Hospital on August 6, 2016 with a registration deadline of June 25, 2016. You can find more information here.

CCRC certification: The next exam dates for certification as a Clinical Research Coordinator (CRC) are in September and October of 2016. Applications are due by August 15, 2016, and you can find more information here.
ICMJE Proposes Data Sharing Requirements

The International Committee of Medical Journal Editors (ICMJE) already requires the registration of clinical trials as a condition of publication. ICMJE now proposes requirements for sharing of clinical trial data. Their proposal is published at this link.

Summary of the Proposal
ICMJE proposes that ICMJE member journals require as a condition of publication that authors:

- share with others the deidentified individual-patient data (IPD) underlying the results presented in the article (including tables, figures, and appendices or supplementary material) no later than 6 months after publication. The data underlying the results are defined as the IPD required to reproduce the article's findings, including necessary metadata.
- include a plan for data sharing as a component of clinical trial registration. ClinicalTrials.gov has already added an element to its registration platform to collect data-sharing plans.
- include a description of the data-sharing plan in the submitted manuscript.

ICMJE also proposes safeguards to protect the rights of investigators and trial sponsors who share their data.

Why Share Data?
In their proposal, ICMJE details the reasons for sharing clinical trial data:

- fulfill ethical obligation to share data generated by interventional clinical trials (because participants have put themselves at risk)
- increase confidence and trust in the conclusions drawn from clinical trials
- enable the independent confirmation of results
- foster the development and testing of new hypotheses
- make progress more efficient by making the most of what may be learned from each trial and by avoiding unwarranted repetition
- enhance transparency in the conduct and reporting of clinical trials by exposing when data availability following trial completion differs from prior commitments

What Does the Public Say About the Proposal?
Comments on the proposal are found at this link, and anyone can provide feedback by April 18, 2016 at this link.

NPR’s Commentary on the ICMJE Proposal
An NPR piece titled “Journal Editors to Researchers: Show Everyone Your Clinical Data” is found at this link.
Upcoming Training

**iRIS Training**

**Objective:** Provide hands-on training in the iRIS system, which is used to submit research protocols to UTHealth’s CPHS and AWC.

**Date:** April 7, 2016  
**Time:** 1:30 am – 4:00 pm  
**Location:** UCT 1155 (Parking will be validated)  
Registration is required. Register [here](#).

**Clinical Research Budgeting and Billing Training**

**Objective:** A hands-on workshop that will cover the processes for billing, coverage analysis, building a research budget, and reconciliation.

**Date:** April 26, 2016  
**Time:** 1:00 pm – 4:30 pm  
**Location:** MSB B.500  
Registration is required. Register [here](#).

**Study Coordinator Monthly Forum**

**Objective:** Discuss best practices in clinical research management and network with administrators and staff from various research groups within UTHealth.

**Date:** April 26, 2016 (Topic in Ethics)  
**Time:** 11:30 am – 1:00 pm  
**Location:** MSB 2.135  
*Lunch provided for the first 40 participants.*  
Registration is not required.

**Clinical Research Finance Lunch and Learn**

**Objective:** Provide staff members guidance on research financial topics (e.g., budgeting, billing, and coverage analysis). Also, a forum to introduce or update financial matters and to present questions or concerns for discussion in an open setting with peers.

**Date:** May 11, 2016  
**Time:** 11:30 am – 12:30pm  
**Location:** MSB 2.135  
*Feel free to bring your lunch.*  
Registration is not required.

**Orientation for Clinical Research Staff**

**Objective:** Educate new clinical research personnel on clinical trial management, as well as IRB review and Memorial Hermann study start up processes. The program will lead into the Study Coordinator Forum.

**Date:** April 26, 2016  
**Time:** 9:00 am – 11:30 pm  
**Location:** MSB G.100  
Registration is required. Register [here](#).

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**About the Clinical Trials Resource Center**

It is the mission of the Clinical Trials Resource Center (CTRC) to provide a single portal of expertise and best practices for study teams in order to facilitate efficient, compliant, and ethical study conduct and management. The CTRC office is located at UCT 790. Please visit [https://www.uth.edu/ctrc/](https://www.uth.edu/ctrc/) for more information.

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