



Clinical Research News You Can Use

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Clinical Research Education

Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that

The Clinical Research Education course shares best practices on managing clinical trials.

involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety, and well-being of trial subjects are protected,

consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible.

The Clinical Research Education course is designed to share best practices for managing clinical trials based on the principles outlined in the GCP guidelines.

This educational program is designed and conducted by experienced clinical trial research professionals from within UTHealth. The program examines the entire clinical trial process, from study feasibility to trial close-out activities, and provides practical recommendations for increasing the efficiency of clinical trial conduct. This course combines didactic

presentations and interactive group sessions. Specific topics include human subject protections, GCP principles, institutional compliance, the informed consent process, study initiation, study conduct, FDA inspection, source documentation, investigational devices and drugs, and reporting requirements, among others.

To get the most from this course, it is highly recommended that participants complete CITI Humans Subjects Research (HSR) and CITI Good Clinical Practice (GCP) training. For information on how to take CITI training, see [this link](#).

This course is geared towards new research nurses, clinical research coordinators, and clinical research assistants; however, many experienced research staff have attended in the past to refresh their knowledge and to network with other research staff. This workshop has been offered at UTHealth since 2007 and has received positive feedback from participants.

Dates: October 22 – 23, 2019
Location: Cooley University Life Center
7440 Cambridge St, Houston 77054
Fees: \$100
Register here: [Clinical Research Education](#)

For more information, contact the Clinical Trials Resource Center at clinicaltrials@uth.tmc.edu.

Specialized IRB Panel for Comparative Effectiveness Research

The UTHealth Committee for Protection of Human Subjects has 4 IRB panels, each meeting once a month. Starting September 2019, Panel 3, which meets on the second Friday of each month, will be designated as a comparative effectiveness research (CER) panel. CE research involves generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat, and monitor a clinical condition or to improve the delivery of care. The [department review form](#) has been amended to include additional questions for CE research. If the question 5.a “Is this comparative effectiveness research” is

answered yes, then IRB staff will assign the protocol for review by Panel 3.

The review process for these projects would be facilitated by additional department input (via the department review form) to determine whether all the interventions being studied are part of usual care, as well as the reasonably foreseeable risks for the interventions being evaluated.

If you have questions about this process, please contact CPHS at cphs@uth.tmc.edu.

Department Review Process - Clarification

The department review process provides the IRB with information to help determine if the proposed research meets all the regulatory criteria for approval. The department review should assess scientific validity of the proposed research, with particular attention to the feasibility of meeting enrollment targets.

There is no change in the process for protocols from School of Dentistry, Cizik School of Nursing, School of Public Health, School of Biomedical Informatics, Graduate School for Biomedical Sciences, and others (not from McGovern Medical School). As usual, new protocols should be [routed](#) within iRIS for departmental representative signature.

New submissions from McGovern Medical School that meet the criteria for review at a convened IRB meeting must undergo department review. CPHS does not require the department review form to be submitted with initial submissions for protocols that:

- qualify for [exemption](#);
- qualify for review [by expedited procedure](#); or
- have received federal funding (attach evidence of funding in lieu of the completed department research review form).

- will be reviewed by commercial IRBs.

Each department at McGovern Medical School has established its own procedure for department review of clinical research. Please consult within your department to determine the appropriate process. Refer to this [list of Department Reviewers](#) to find the person to contact within your department.

If the department reviewer provides comments and suggestions on the department review form, then you are highly encouraged to incorporate these comments and suggestions into the study protocol before submitting to the IRB for review. If there are issues that you are unable to resolve with the department reviewer, then you are encouraged to prepare and submit a cover letter that explains the differences and provides your justification. Submit the signed department review form in the “Other Study Documents” section of the initial iRIS application under the Departmental Research Review category.

If you have questions about this process, please contact CPHS at cphs@uth.tmc.edu.

Consent Documentation

It is often said that informed consent is not just a form but a process. The informed consent document must be signed and dated personally by the study participant, unless CPHS has approved consent by a legally authorized representative. The person obtaining consent must also sign and date the consent document. In addition to obtaining signatures on the consent document, it is also very important to document the consent process in the source documents.

According to the FDA GCP regulations (21 CFR 312.62(b), “the case history for each individual shall document that informed consent was obtained prior to participation in the study.” This requirement can be met by documenting the consent process in the source documents or by documenting the consent process within the case report form.

We recommend that the investigator or the study staff write a progress note about the consent process that includes how and when the consent

discussion occurred. Some study teams have developed template language that they include in the medical records. Here is an example of language that can be used to document the consent process in the progress notes:

15 May 2014

Discussed the TRYAL study with Mr. John Doe. Explained the study procedures and went over the consent document and answered his questions. I offered that he could take the consent document home and discuss with his family, but Mr. Jones said he would like to discuss with his wife. Mr. Doe returned in an hour and indicated interest in participating in the study. Mr. Doe and I signed the consent document. I gave a copy of the signed consent document to Mr. Doe.

A. Smith, RN

Remember the oft-repeated mantra in compliance circles: “if it is not documented, it didn’t happen.”

You can read more about the informed consent process and documentation [here](#).

Test your Good Clinical Practice Knowledge

True or False?

1. A legally authorized representative (LAR) may be asked to sign the consent only if CPHS has approved a consent document that includes a signature line for LAR signature.
2. The participant must personally sign and date the consent form before any study procedures.
3. If the participant is not able to sign the informed consent form due to injuries, then it is okay to have the participant’s friend sign the consent form instead.
4. If the participant forgot to date the consent, then the study coordinator should write the date in the consent form.

Answers: 1. True, 2. True, 3. True, 4. False

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 and Time: 8/27/19 - 1:30 – 4:00pm

Location: UCT 1155 (parking will be validated)

Registration is required. [Register here.](#)

Study Coordinator Monthly Forum

Objective: Discuss best practices in clinical research management. More information [here](#).

Date: September 25, 2019

Topic: UTHealth Biomedical Informatics Group (BIG) services, including REDCap, Data Requests (for hypothesis validation), Subject Recruitment, and the ACT Network, by Susan Guerrero

Time: 11:30 am – 1:00 pm

Location: MSB B.645

Lunch will be provided for the first 40 participants.

Registration is not required.

TMC – SoCRA METS

Objective: Monthly training and educational event for clinical research professionals.

Date: Sep 4, 2019

Time: 3:30 pm – 4:30 pm

Topic: Best Practices for Clinical Trial Sites

Speaker: Stuart Horowitz, PhD, MBA

Location: Third Coast Restaurant, 6th Floor Room II, 6550 Bertner Avenue

Registration is required. [Register here.](#)

Clinical Research Education

Objective: Good clinical practice guidelines and clinical trial management.

Date: October 22-23, 2019

Time: 8:30 am – 4:00 pm

Location: Cooley Life Center (parking will be validated). Lunch will be provided.

Registration is required. [Register here.](#)

IRB Office Hours

If you would like help submitting an iRIS application or writing a protocol or consent form, or if you want to learn more about IRB reciprocity agreements, then consider taking advantage of IRB office hours.

MSB hours: 2nd and 4th Thursdays from 1:00 pm – 4:00 pm at MSB B.640

SOD hours: 1st Thursdays from 1:00 pm – 4:00 pm at SOD 4416 (Research Office conference room).

An appointment is not necessary

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 suite 1840. Please visit <https://www.uth.edu/ctrc/> for more information.

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We would love to hear from you.

Please send your comments, suggestions and feedback to clinicaltrials@uth.tmc.edu