# IRB
# Education Requirements

All Principal Investigators and research personnel are required to receive training regarding the protection of human research subjects ***prior*** **to beginning any human research-related activities.** This training will be verified prior to iRIS access being granted.

## Required Training

**Human Subjects Research (HSR)**

***Each person conducting or assisting in the conduct of a research project that involves human participants is first required to complete training on ethical and regulatory issues.***

The course approved by TTUHSCEP is the web-based *Course in the Protection of Human Research Subjects—Human Subjects Research* administered by the University of Miami through the *Collaborative IRB Training Initiative* (CITI).
Training must be completed every 3 years. The ability to submit new projects or continuing reviews of ongoing projects will be limited if more than 3 years elapse between completion of the course. Renewal training is identical to the initial CITI course.

**Conflict of Interest (COI)**

Training regarding financial conflicts of interest in research is required of all investigators and research personnel and applies to all research, regardless of funding. Training must be completed every 4 years. The ability to submit new projects or continuing reviews of ongoing projects will be limited if more than 4 years elapse between completion of the course. Renewal training is identical to the initial CITI course.

**Clinical Research Coordinator (CRC)**

The CRC course provides clinical research professionals with basic training tailored to the conduct of clinical trials. It includes the planning aspects of clinical trials, including the overall clinical trial process, associated activities, and the roles and responsibilities of the clinical team members. The CRC training is required of all research coordinators, and investigators/other research personnel who are performing the duties of a research coordinator.

**Good Clinical Practice (GCP)**

NIH guidelines now require Good Clinical Practice (GCP) training for NIH funded investigators and clinical trial site staff who are responsible for the conduct, management and oversight of NIH-funded clinical trials.

All TTUHSC El Paso research personnel involved with drug and/or device studies will also be required to complete GCP training, regardless of funding. For existing studies, this new requirement will be enforced at continuing review.

**Clinical Trial Budget Course**

This in-depth course provides practical knowledge on how to develop, negotiate, and implement a clinical trial budget from the perspective of the clinical site. It details what goes into budget planning and reviews criteria for measuring direct and indirect costs. The course outlines how to assess clinical trial feasibility and calculate procedural costs, while offering a primer on negotiating study budgets in ways that produce fair and mutually acceptable outcomes.

If you are a Principal Investigator, Research Director, or Clinical Research Coordinator conducting industry-sponsored clinical trials, this course is now required. This training will need to be completed prior to submitting a clinical trial budget for review through Research Contracts and Agreements. Please visit https://www.citiprogram.org/ and use the "Add a Course" option under the TTUHSC El Paso affiliation; the course is listed as question number 10 on the enrollment page.

**Informed Consent Training (ICF)**

As part of the ongoing process to ensure proper informed consent procedures are being followed, all TTUHSC El Paso research personnel involved with research studies that will involve obtaining informed consent, will also be required to complete Informed Consent Training. For existing studies, this new requirement will be enforced at continuing review.

Information and access to the training is available online at: https://elpaso.ttuhsc.edu/research/compliance/Training.aspx. Please contact Josh Cardoza, the Research Compliance Officer at josue.cardoza@ttuhsc.edu with any training related questions. Certificates should be retained as proof that the training was completed.

**CITI Instructions**

**Registration**

To begin the on-line course, go to the following web site: www.citiprogram.org and select "Register." Next, enter "Texas Tech University Health Sciences Center-**El Paso**" as your organization affiliation. Continue through the multiple step process to establish your Username and Password. You do not need an eRaider account to complete the training. TTUHSCEP personnel must use their TTUHSCEP email address for registration. You may include a secondary email as well. On the CITI registration page you will need to select "Human Subjects Research Course" **and** "Conflict of Interest Course," and any other training (as indicated previously) that may be required for the research that is being done. *Research personnel (investigators and staff) who are performing duties in a coordinator role will also need to complete the "Clinical Research Coordinator" course.

To add a course to an existing account, log in, click on "View Courses" under Texas Tech University Health Sciences Center-El Paso, scroll down to the bottom of the page, and click on "Add a Course." Respond with a "yes" to the questions related to the course you need to complete, and follow the prompts.

**NOTE: PLEASE USE YOUR TTUHSCEP EMAIL ADDRESS FOR REGISTRATION AT WWW.CITIPROGRAM.ORG**

**Course Completion**

Upon successful completion of the course, you will be able to download a course transcript and print a certificate. Please keep for your records. TTUHSCEP is also notified of your successful completion of the course, but we are not provided with a copy of it. You will be required to achieve an overall score of at least 80% to successfully complete the course. You can also log back in at any time to print your completion report by clicking on "View previously completed coursework."

**CITI Accounts Previously Affiliated with another Institution**

All TTUHSC El Paso research personnel must affiliate their CITI account with the El Paso campus. Go to the CITI website at www.citiprogram.org and from the main menu, select "Add Affiliation" and follow the prompts. Select Texas Tech University Health Sciences Center-El Paso as your institution. Proceed with completing required training as indicated above.

**Research Financial Disclosure:**

TTUHSC EP OP 73.09 requires that Investigators and research personnel update their Research Financial Disclosure forms on at least an annual basis, or within 30 days of a change in significant financial interests. The annual disclosure form may be accessed through iRIS via the Conflict of Interest Module under "My Workspaces" at the top left of the iRIS dashboard.

**Checklist:**

**In order to request an iRIS user account, complete the training below as applicable to your research:**

1) Human Subjects Research course at www.citiprogram.org
2) Conflict of Interest (COI) course at www.citiprogram.org
3) Clinical Research Coordinator (CRC) course at www.citiprogram.org

4) Good Clinical Practice (GCP) course at www.citiprogram.org
5) Clinical Trial Budget Course at www.citiprogram.org
6) Informed Consent Training information: http://elpaso.ttuhsc.edu/research/compliance/Training.aspx
**7) When training is complete, an iRIS user account can be requested at: https://ttuep.imedris.net.**
*8) The research financial disclosure form will need to be submitted through iRIS once an account is obtained.*

For account requests, include current contact information as well as the purpose for the request. For requests from non-TTUHSCEP employees/staff/students, please provide information regarding your current status i.e. research volunteer, non-Tech employee, non- salaried clinical faculty, etc., and provide documentation that verifies this information.