Human Subject Protection Training (CITI)

https://www.ttuhsc.edu/research/divisions/integrity-office/education/citi-training.aspx

All investigators and research study personnel are required to complete training regarding the protection of human subjects **prior** to beginning any human subject research-related activities. Initial study submissions will be halted until the required training for all study personnel has been completed and documented in the Cayuse system. This training will be verified prior to access to Cayuse Human Ethics module being granted, and MUST be completed and documented with the IRB **at least every three years**.

The web-based training course required by TTUHSC is the **"Biomedical Investigator Course"**, accessed through the <u>Collaborative Institutional Training Initiative (CITI)</u> Program. The course takes approximately 2-4 hours to complete. TTUHSC requires an overall score of **at least 85%** in order to successfully complete the course. Upon successful completion of the course, you will be able to download a course transcript (for your records).

IMPORTANT NOTE: If you have completed the CITI "Biomedical Investigator Course" training at another institution, you will need to transfer those course credits over to TTUHSC in order to meet TTUHSC requirements (this includes TTU training). See instructions below. **Contact** <u>Jennifer Board</u> to see if your training can be used as a substitute.

FOR CRAs and PIs: In special circumstances, Clinical Research Coordinators and Principal Investigators may be permitted to substitute pre-approved CITI courses and/or recognized certifications in place of the CITI Biomedical Investigator Training course. **Contact** <u>Jennifer Board</u> for more information.

CITI ACCOUNT ACCESS

Logging in to an existing CITI account

Go to <u>www.citiprogram.org</u> and click the **'Log In'** button (upper right corner). On the next screen, enter your CITI Username and Password. **NOTE:** If you have forgotten your Username and/or Password, use the '*Forgot?*' option provided by CITI. **Do NOT set up a new account.**

The page should default to the '*Courses*' tab. Under '*Institutional Courses*', click on the '*View Courses*' button for '*Texas Tech University Health Sciences Center*'.

The required course you are looking for is the **"Biomedical Investigator Course"**. Scroll down the page until you find this course title. **NOTE: There are <u>NO other CITI courses required</u> by the TTUHSC IRB.**

Click on the '*Start Now*' (or '*Continue Course*') button for the course. You will need to complete each module before moving on to the next one.

TTUHSC requires an overall score of **at least 85%** in order to successfully complete the course. Once you have completed the course, you can go to the *'Records'* tab in your CITI account to access the completion report/certificate.

Creating a new CITI account

Go to <u>www.citiprogram.org</u> and click on the '*Register*' button (upper right corner). Under '*Select Your Organization Affiliation'*, type in '*Texas Tech University Health Sciences Center'*. Continue setting up your account by following the Registration steps #1-7 below.

Steps 1-6: Answer the questions regarding '*Personal Information*'. **NOTE:** Register with your TTUHSC or TTU email address unless you do not have either (i.e. you are an Outside Collaborator). **NOTE:** If you are interested in CEU credit, make sure you answer the questions in Step 5 accordingly.

Step 7: It is very important that you answer these questions correctly, as they determine which course(s) you will receive access to. Please answer as instructed below:

- Question #1 Select 'Biomedical Investigator Course: Research Investigators, Research Personnel, and IRB members'.
- Question #2 Answer this question based on whether or not you have previously completed the Biomedical Investigator Course (whether at TTUHSC or another institution).
- Question #3 Select 'Not at this time'.
- All other questions can be skipped (unless you have been asked to complete another course by your department).
- COVID-19 Question the very last question on the list is required to be answered (by CITI). It is information about COVID-19 and remote contact tracing. Please note that it is <u>NOT</u> required by TTUHSC.
- When you are done adding courses, click 'Complete Registration'.

The 'Biomedical Investigator Course' (and any others you have selected) will now show in your CITI account under the 'My Courses' tab. Click on the 'Start Now' button for the course. You will need to complete each module before moving on to the next one.

TTUHSC requires an overall score of **at least 85%** in order to successfully complete the course. Once you have completed the course, you can go to the '*My Records*' tab in your CITI account to access the completion report/certificate.

Transferring CITI credits from another institution

Go to <u>www.citiprogram.org</u> and click the **'Log In'** button (upper right corner). On the **'My Courses**' tab, click on **'Add** *Institutional Affiliation*' (found in the blue horizontal tab at top of page). Type in **'Texas Tech University Health Sciences Center'**. Continue setting up your account by following the Registration steps #1-7 below.

Steps 1-6: Answer the questions regarding '*Personal Information*'. **NOTE:** Register with your TTUHSC or TTU email address unless you do not have either (i.e. you are an Outside Collaborator). **NOTE:** If you are interested in CEU credit, make sure you answer the questions in Step 5 accordingly.

Step 7: It is very important that you answer these questions correctly, as they determine which course(s) you will receive access to. Please answer as instructed below:

- Question #1 Select 'Biomedical Investigator Course: Research Investigators, Research Personnel, and IRB members'.
- Question #2 Answer this question based on whether or not you have previously completed the 'Biomedical Investigator Course' (whether at TTUHSC or another institution).
- Question #3 Select 'Not at this time'.
- All other questions can be skipped (unless you have been asked to complete another course by your department).
- **COVID-19 Question** the very last question on the list is required to be answered (by CITI). It is information about COVID-19 and remote contact tracing. Please note that it is **NOT** required by TTUHSC.
- When you are done adding courses, click 'Complete Registration'.

CITI Training Instructions

The **'Biomedical Investigator Course'** (and any others you have selected) will now show in your CITI account under the '*My Courses*' tab. Click on the '*Start Now*' button for the course. You will see a complete list of the TTUHSC required modules.

NOTE: The only modules you will need to complete are those that were NOT required by your other institution. These will be the ones showing 'Incomplete'. Those that you have already completed will show a completion date and a % score.

TTUHSC requires an overall score of **at least 85%** in order to successfully complete the course. Once you have completed all of the modules, you can go to the '*My Records*' tab in your CITI account to access the completion report/certificate.

CITI ADDITIONAL INFORMATION

Accessing a Course Completion Report / Certificate

- Log in to your CITI account (see instructions above if needed).
- The page should default to the '*My Courses*' tab, so click on the '*My Records*' tab to start. You will see a complete list of all the CITI courses you have completed.
- At the top of the 'My Records' page is a drop down titled 'Show Records for:'. If you are affiliated with more than one institution, you can look at each individually, or all of your institutions together.
- Scroll down until you find the course you need the completion certificate/report for.
- Click on the 'View-Print-Share' link under 'Completion Record'.
- You will see two options 'Completion Report' and 'Completion Certificate'. The report is the detailed version of the course, while the certificate is the overall view. The certificate is what most people ask for.
- Under each of these will be the option to 'View/Print' as well as 'Copy Link'. 'View/Print' is best for when you want to look at the certificate and save it. 'Copy Link' works well when you need to send the certificate to someone else.

That's all there is to it. Just make sure you choose the most current dated certificate if you have more than one for that course.

Other Human Subject Research Related Courses offered by TTUHSC

TTUHSC offers several other courses pertaining to human subject research that may also be required by your department, funding agencies, and/or research sponsors. The courses are available at no charge to TTUHSC research users through TTUHSC's CITI subscription.

These courses can be found under the '*My Courses*' tab in your CITI account.

- Clinical Research Coordinator (CRC)
- Responsible Conduct of Research (RCR)
- GCP for Clinical Trials with Investigational Drugs / Medical Devices (U.S. FDA Focus)
- Essentials of Public Health Research
- Revised Common Rule
- Institutional/Signatory Official: HSR
- Mental Health for Higher Ed and Healthcare
- COVID-19 series

NOTE: The ONLY course REQUIRED by TTUHSC is the "Biomedical Investigator Course".

CE Credits Information

Users have the option to purchase CE/CME credits for CITI courses they have completed.

The first step is to make sure that you have registered for CE credits, which is done under the '*My CE/CMEs*' tab in your CITI account. Once registered, you can purchase credits for courses you have already completed AND/OR for courses you are getting ready to take. All of the key information you need, including instructions for payment, will show on the first page of each course. **NOTE: Any cost associated is your responsibility.**

CME credits ARE available for:

- Biomedical Investigator Training course
- Clinical Research Coordinator (CRC)
- Biomedical Responsible Conduct of Research (RCR)
- GCP for Clinical Trials with Investigational Drugs and Devices (U.S. FDA Focus)
- Revised Common Rule

CME credits ARE NOT available for:

- Essentials of Public Health Research
- Clinical Trial Billing Compliance (CTBC)

For any and all questions related to CE/CME credits, contact <u>CITI Support</u>.

Jennifer Board Research COI & CMP Chief Analyst 806.414.9934 jennifer.board@ttuhsc.edu

CITI "Biomedical Investigator Course" Modules

REQUIRED MODULES (10)

- Populations in Research Requiring Additional Considerations and/or Protections
- Avoiding Group Harms U.S. Research Perspectives
- History and Ethics of Human Subjects Research
- Basic Institutional Review Board (IRB) Regulations and Review Process
- Informed Consent
- Records-Based Research
- Genetic Research in Human Populations
- FDA-Regulated Research
- Research and HIPAA Privacy Protections
- Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research

OPTIONAL MODULES (22)

- Humanitarian Use Devices (HUDs)
- Research with Older Adults
- Research with Persons who are Socially or Economically Disadvantaged
- Research with Decisionally Impaired Subjects
- Students in Research
- The IRB Member Module 'What Every New IRB Member Needs to Know'
- Phase I Research: Understanding Phase I Research
- Phase I Research: Protecting Phase I Subjects
- Introduction To Community-Engaged Research (CEnR)
- Introduction to Community-Based Participatory Research (CBPR)
- Consent in the 21st Century
- Consent and Biobanks and Associated Databases
- Consent and Subject Recruitment Challenges: Therapeutic Misconception
- Consent with Subjects Who Do Not Speak English
- Informed Consent and Incidental Findings in Research with Human Subjects
- Data and Safety Monitoring in Human Subjects Research
- Conflicts of Interest in Human Subjects Research
- Human Subjects Considerations and Big Data Research
- Research Involving Children
- Research Involving Pregnant Women, Fetuses, and Neonates
- International Studies
- Vulnerable Subjects Research Involving Workers/Employees