

CITI Training Guidance/Instructions

The section provides instructions for obtaining CITI training. For ease of future submission to IRB, please name the documents based on the naming convention table below:

Biomedical Basic Course	LastName_BiomedBasic
Biomedical Good Clinical Practice	LastName_BiomedGCP
Social Behavioral Basic Course	LastName_SocialBasic
Social Behavioral Good Clinical Practice	LastName_SocialGCP

For example, if John Smith was on the study team and needed to upload the Biomedical Basic Course to IRBNet he would label the training document as: Smith_BiomedBasic

CITI Training Requirements

- For the most up-to-date training requirements, please see “Research: Investigator, Research Personnel, IRB Member, IRB Administrator, and Institutional Official Training-AD.0161” in PolicyStat. Summarized below.
- Residents will need to complete the CITI Biomedical Research AND GCP for Clinical Trials (US FDA Focus). If there is a need for the other CITI trainings (social-behavioral), we will let you know on a case-by-case basis.
 - o For study team members involved in interventional drug, biologic, or device studies, studies involving invasive procedures, retrospective chart/existing data review or specimen collection studies, please complete the **CITI Biomedical Research (Stage 1 - Basic Course)**;
 - o For study team members involved in research reviewing survey data, questionnaires, participant observation, or non-invasive physical measurements to study human attitudes, beliefs, or behaviors, please complete the **CITI Social and Behavioral Research (Stage 1 - Basic Course)**.
 - o If the research is sponsored (funded from entities such as pharmaceutical companies, NIH, NSF, or PCORI) the investigator and research personnel must complete one or both of the following in addition to the CITI Biomedical and/or Social and Behavioral courses above:
 - ❑ For study team members involved in interventional drug, biologic, or device studies, studies involving invasive procedures, retrospective chart/e reviews or specimen collection studies, please complete the **GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus)**;
 - ❑ For study team members involved in research reviewing survey data, questionnaires, participant observation, or non-invasive physical measurements to study human attitudes, beliefs, or behaviors, please complete the **GCP – Social and Behavioral Research Best Practices for Clinical Research**.
 - o For research involving populations or circumstances that are not adequately covered by the Biomedical Course, the IRB may request additional training on a specialized topic.
 - ❑ For **clinical use** of a Humanitarian Use Device (HUD) – only the **CITI HUD** module is required.

- ② For **investigational use** of a Humanitarian Use Device (HUD) – The **CITI HUD** module is required, in addition to other relevant required training listed in this policy.

How to Register for CITI Courses

IF YOU ALREADY HAVE A CITI ACCOUNT, LOG INTO IT and skip to “Adding Courses to Your CITI Account”

Creating a CITI Account

1. Visit the Login link here: [CITI Registration](#).
2. Click the “Register” tab.
3. Enter “Lakeland Regional Medical Center Inc” into the text box and select Lakeland Regional from the dropdown menu.
4. Click the checkbox indicating that you AGREE to the Terms of Service and Privacy Policy.
5. Click the checkbox affirming that you are an affiliate of Lakeland Regional Medical Center Inc.
6. Click the blue “Create a CITI Program account” button.
7. Enter your personal information
 - a. Be sure to use your myLRH email address when signing up.
8. Click the blue “Continue to Step 3” button.
9. Choose your username and password and enter them into the text boxes.
10. Select your Security Questions and enter your Security Answer into the provided text boxes.
11. Click the blue “Continue to Step 4” button.
12. Enter your Country of Residence and indicate whether or not you would like communication from CITI.
13. Click the blue “Finalize Registration” button.

Adding Courses to your CITI Account

1. Once logged into your CITI Account, navigate to the “My Course” tab.
 - a. Please ensure you have added Lakeland Regional Medical Center Inc to your affiliated institutions (see Step 3 under “Creating a CITI Account” above).
2. Scroll down to the section entitled “Learner Tools for Lakeland Regional”
 - a. Select “Add a Course”
 - i. Question 1
 1. If Biomedical CITI is needed, select the first checkbox
 2. If Social/Behavioral CITI is needed, select the second checkbox
 - ii. Question 2
 1. Leave blank if it does not apply to you.
 - iii. Question 3
 1. Select “Not at this time” if this does not apply to you.
 - iv. Question 4
 1. If Biomedical GCP is needed, select the first checkbox
 2. If Social/Behavioral GCP is needed, select the 4th checkbox
 - v. Question 5
 1. Select “I am not required to complete the IPS course at this time”
 - vi. Questions 6
 1. Select “Not at this time”, if this does not apply to you.
 - vii. Question 7

1. Select whether or not you would like to take the COI course.
 - b. Click the blue “Submit” button.
3. You will return to the homepage and see your newly added CITI courses under “Courses Ready to Begin”.
4. Click “Start Now” to complete the training.

How to Download CITI Certifications

1. Click on the “My Records” tab.
2. Scroll to the desired completed CITI Training.
3. Select “View-Print-Share”.
4. Scroll to the section titled “Completion Certificate” and select “View/Print”
5. Download and save the certification for upload with the IRB Package.