**CITI Training**

Required Training for Investigators and Research Personnel

1. Training is required for all investigators and research personnel every three (3) years. Once the CITI training has been initially completed, there is a recertification option for maintenance of certification. You may be required to complete one or both of the following training(s) depending on the type of research—please complete those courses which are most relevant to you.
   1. For study team members involved in interventional drug, biologic, or device studies, studies involving invasive procedures, retrospective chart/existing data review, specimen collection studies, or research involving patients, please complete the CITI Biomedical Research (Stage 1 - Basic Course);
   2. For study team members involved in research not involving patients' (i.e. staff or community members) 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).
   3. Although not required, it is highly recommended that all Principal Investigators take the Responsible Conduct of Research (RCR) course, which overviews research misconduct and questionable research practices; data management – i.e., data acquisition, record-keeping, retention, ownership, analysis, interpretation, and sharing; scientific rigor and reproducibility;  
      responsible authorship and publication; peer review; conflicts of interest in research; mentor/mentee responsibilities and relationships; collaborative science; civility issues in research environments, including but not limited to, harassment, bullying, and inappropriate behavior; policies regarding laboratory safety, biosafety, and human and animal research subjects; views about scientists as responsible members of society; social and environmental impacts of research; and contemporary ethical issues in biomedical research.
2. If the research is sponsored (funded from entities such as pharmaceutical companies, NIH, NSF, or PCORI) the investigator and research personnel must complete two or three of the following in addition to the CITI Biomedical and/or Social and Behavioral courses above:
   1. All study team members involved in sponsored research of any kind must take the Responsible Conduct of Research (RCR) course.
   2. For study team members involved in interventional drug, biologic, or device studies, studies involving invasive procedures, retrospective chart/e reviews or specimen collection studies, complete the GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus) and ;
   3. For study team members involved in research not involving patients' (i.e. staff or community members) survey data, questionnaires, participant observation, or non-invasive physical measurements to study human attitudes, beliefs, or behaviors, complete the GCP – Social and Behavioral Research Best Practices for Clinical Research.
3. 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.
   1. 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**

*Creating a CITI Account*

1. Visit the Login link here: [CITI Registration](https://www.citiprogram.org/login).
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
   1. 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.
2. Scroll down to the section entitled “Learner Tools for Lakeland Regional”
   1. Select “Add a Course”
      1. Question 1 – Human Subjects Research
         1. If Biomedical CITI is needed, select the first checkbox
         2. If Social/Behavioral CITI is needed, select the second checkbox
      2. Question 2 – Institutional/Signatory Officials
         1. Leave blank if it does not apply to you.
      3. Question 3 – IRB Administration
         1. Select “Not at this time” if this does not apply to you.
      4. Question 4 – Good Clinical Practice (GCP)
         1. If Biomedical GCP is needed, select the first checkbox
         2. If Social/Behavioral GCP is needed, select the 4th checkbox
      5. Question 5 – Information Privacy Security
         1. Select “I am not required to complete the IPS course at this time”
      6. Questions 6 – Responsible Conduct of Research
         1. Select “Not at this time”, if this does not apply to you.
      7. Question 7 – Conflict of Interest (COI)
         1. Select whether or not you would like to take the COI course.
      8. Question 8 – Clinical Research Coordinator (CRC)
         1. Select whether or not you like to take the CRC course.
   2. 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.