GOOD CLINICAL PRACTICE (GCP) TRAINING REQUIREMENTS

[GCP = Good Clinical Practice. Definition: A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected. ICH E6 1.24]

In the interest of maintaining a quality research program and compliance with federal regulations, Ochsner has requirements for training in Human Subject Protection and Good Clinical Practices (GCP) for all investigators and staff involved in human research at Ochsner. All investigators who wish to conduct research at Ochsner must complete the CITI required human subject protection courses. Individuals will not receive a username and password for the IRB electronic system, eIRB, until completion of the CITI required courses is confirmed.

In addition, ongoing educational requirements have been established as a mechanism to support the best and safest care to Ochsner's research subjects, to fulfill our obligations under Ochsner's Federal Wide Assurance and other federal regulatory guidance, and to assist members of the Ochsner research community in honing their GCP skills. The initial CITI training requirement will expire 3 years after the initial course was completed. For example, if the Basic CITI required course is completed on March 1, 2021, the training certificate will expire on March 1, 2024. Within the 3-year approval period, investigators must obtain recertification.

During the 3-year period, investigators can remain certified by doing one of following:

- Retake the full initial CITI course prior to your certification expiring
- Take the GCP* or RCR courses
- Take the CITI refresher course
- Take 12 hours of GCP credits approved by the IRB. There are at least 8 hours offered each year, and these are detailed in the annual GCP Education Brochure. CME and CNE credit are provided.

***Many external Sponsors and agencies require GCP training. If you are or will be involved in investigational drug or device trials, it is highly recommended to take CITI GCP course to meet the 3-year requirement or to take the GCP course at the same time as the initial required basic course.**

All education training data is maintained in eIRB. eIRB accounts will be marked as inactive if the above training requirements are not met. Only those who have met the defined requirements will be allowed to initiate any new research and continue established research. You should not participate in any clinical research unless you have an active eIRB account. For research staff members that do not require eIRB

access, your supervisor through performance evaluations may determine the appropriate consequences for not maintaining the Ochsner GCP Education Requirements.

Features in eIRB to track training compliance include the following:

- Users can access and download training records from their profile page. The profile page also contains a tab displaying the user's associated studies
- A Training Tab on the study workspace displays all team members listed on a study and their education compliance status
- A display on the study workspace showing the overall study education compliance
- Inactive study team members (those with expired training) can no longer be added as study team members.
- If a study team member becomes non-compliant, the overall study will display as non-compliant. If the study is in pre-submission and is not compliant, the study cannot be submitted to the IRB. The non-compliant member must be removed from the study but can be added at a later date once the training requirements are met
- Automatic training expiration notification reminders are sent 60 & 30 days prior to expiration. A final notification will be sent the day after expiration and the IRB office will also be notified.
- The eIRB system receives automatic updates from CITI when a user completes a course. The automatic update can take 24-48 hours to post in eIRB. If you need immediate eIRB account activation or re-activation, contact the IRB staff office at irb@ochsner.org to update your account immediately

Our goal is to provide education and training that will support ongoing quality research and growth in individual competence in our research staff. This will allow us to do what is most important, protect our patient volunteers.

Revision history for auditors:

March 2021	Added section recommending GCP course completion for those involved in investigational drug and device studies
December 2020	Updated to include new features in eIRB for tracking compliance. Phase out of 3 year cohorts. Education date is now calculated 3 years after the specific date when the CITI course is completed. Added section on GCP and RCR course options
December 2018	Minor updates for clarification
December 2015	Guidance published