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, ERSA, 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 year the course was completed. For example, if the CITI course is completed in March 2013, the training certificate will expire on December 31, 2016. Within the 3 year approval period, investigators must obtain 12 credits of GCP training.

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 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.

Only those who have met the defined requirements will be allowed to initiate any new research and continue established research. Every Dec. 31, those in the cohort to be checked for compliance will have their GCP continuing education reviewed. Each person will be checked for compliance once every 3 years. Those in that year’s cohort who do not meet the requirement on 12/31 will be locked out of ERSA until the requirements are met. You should not participate in any clinical research until you have been recertified and ERSA access granted. For research staff members that do not require ERSA access, your supervisor through performance evaluations may determine the appropriate consequences for not maintaining the Ochsner GCP Education Requirements.

The IRB staff office manages the GCP education program. GCP education completion dates are maintained in a database. The database is used to send out quarterly emails to the cohort that will be checked at the end of a specific year. The emails note the number of credits earned and the number of credits needed to meet the 3 year renewal requirement. Only the cohort that will be checked at the end of
the year receives quarterly email notifications that year, so for the first 2 years of certification investigators will not receive notifications.

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.