Good Clinical Practice (GCP) Training for Clinical Trials: FAQs

What is GCP Training?

GCP training aims to present "best practices" to clinical trials research teams. It covers all aspects of a study's timeline, including: study design; participant recruitment, consent and retention; privacy and confidentiality; participant safety and adverse event reporting; quality control and assurance; bias and data integrity; and research misconduct.

What studies qualify as a "clinical trial"?

NIH has broadened the definition of "clinical trial" to include all research studies "*…in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes*." (See NIH policy on GCP training, **effective January 1, 2017**: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-148.html.)

Who must take the training?

All clinical trial staff must take the training. "Clinical trial staff" is defined as: "*Individuals, identified by the investigator, who are responsible for study coordination, data collection and data management. The central focus of clinical trial staff is to manage participant recruitment and enrollment, to maintain consistent study implementation, data management, and to ensure integrity and compliance with regulatory and reporting requirements. These individuals may also seek informed consent from prospective participants, enroll and meet with research participants, and collect and record information from research participants. Clinical trial staff may also be called the research coordinator, study coordinator, research nurse, study nurse or sub-investigator."*

What GCP training is appropriate for my study?

Principal investigators must ensure that co-investigators, students, and study staff who meet the definition of "clinical trials staff" complete the GCP course appropriate for the type of study they will be working on. There are two course offerings for JHSPH researchers:

- **Drug and Device Clinical Trials:** The *GCP (CITI) course*, available directly through the JHSPH institutional account at CITI, is the "traditional" GCP course covering topics related to clinical trials involving drug or device products. When you access your CITI account, click "Add a Course" and go to the "Select Curriculum" page. Scroll down to Question 2 and select the first option, "***Investigators, study staff, and students involved in drug or device clinical trials*.**" You may complete this course OR any other GCP course approved by NIH as satisfying the policy requirement.
- **Social/Behavioral Clinical Trials:** MyLearning has added a new GCP course specifically designed by NIH for Social/Behavioral clinical trials called *Good Clinical Practice (GCP) for Social and Behavioral Research*. If you are not already logged in to the JHU portal, you will have to log in with your JHED ID and JHED password. To take the course, click on the "Add to Dev Plan" link located above the course description. Then click on the "Home" link at the top of the page. Click on "My Plan" on left, and find the course listed under "Self-Enrollments". Click on the course link, scroll down and click on Module 1 to start the course.

Note: If you may work on both drug studies and Social/Behavioral studies, complete the GCP course for drug and device clinical trials. The Social/Behavioral course is appropriate only for non-drug/device clinical trials.

What do I do with my GCP Training Completion Certificate?

For all JHSPH investigators registered in PHIRST, you may log into PHIRST and upload your GCP certificate of completion into your Profile Page, and record the date of completion. This record will serve as the IRB's documentation of your successful course completion.

For study staff not registered in PHIRST: The definition of "clinical trial staff" includes more people than are listed in the PHIRST research application. The Principal Investigator will be responsible for ensuring that all the people on the study who meet that definition complete the training and must retain copies of the GCP training certificate in the study records.