

National Institutes of Health (NIH) Policy on Good Clinical Practice Training

The NIH requires Investigators and Clinical Trial Staff involved in NIH-funded clinical trials to complete Good Clinical Practice (GCP) training. The NIH defines a clinical trial as follows: “A clinical trial is a research study 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.”

Required GCP training is in addition to the current Human Subjects training requirements for those who are involved in human subject research and trials. Marquette university uses the GCP training program that is offered through CITI - <https://www.citiprogram.org/>. For instructions on how to register through CITI, please see <http://www.marquette.edu/orc/irb/training-education.shtml>

The NIH policy is effective as of January 1, 2017. The full policy can be found at <https://grants.nih.gov/grants/guide/notice-files/not-od-16-148.html>. Compliance with this policy is required for all applicable projects and individuals beginning with the effective date.

Faculty and staff involved in the conduct, oversight or management of clinical trials must complete training in GCP. In addition to the Principal Investigator(s) and the individuals responsible for the conduct of the clinical trial at a trial site, this policy also covers 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.

It is the responsibility of the PI to ensure that all research team members complete any training requirements as applicable and maintain documentation of the required training.

Refresher training is required at least every three years.

Some sponsors may require annual refresher training. It is the responsibility of the PI and research team member to understand these specific sponsor requirements as described in their grant, subaward, clinical trial agreement or other documents and to assure completion and appropriate documentation of this requirement.

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