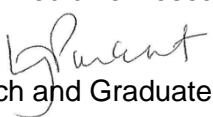


## MEMORANDUM

To: Penn State College of Medicine Researchers

From: Leslie J. Parent, MD   
Vice Dean for Research and Graduate Studies

Date: December 9, 2016

Subject: Expansion of Mandatory Good Clinical Practice (GCP) training

Well-trained investigators and research staff are key to conducting high quality clinical research. Toward that end, Penn State College of Medicine has expanded educational offerings in recent years that are essential to quality assurance and human subject protection for our research studies.

Good Clinical Practice (GCP) training has been required for several years for principal investigators (PIs) and study team members conducting FDA-regulated clinical trials. In response to a recent change in NIH policy (NOT-OD-16-148; <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-148.html>), and in conjunction with our NIH-funded Clinical and Translational Science Institute award, we are extending this GCP training requirement to all non-exempt human research studies, not just FDA-regulated trials. Effective January 1, 2017, the following investigators and staff are required to satisfy the GCP training requirement:

- Principal Investigators and all study team members on new studies
- Any new study team members added to non-exempt ongoing studies
- Study team members of ongoing non-exempt studies at the time of continuing review

GCP training is offered on-line through CITI (Collaborative Institutional Training Initiative) and takes 2 to 4 hours to complete. In addition, the Good Clinical Practice module of the eLearning training platform from The Association of Clinical Research Professionals (ACRP) will also be accepted. These courses address the international, ethical and scientific standards expected in the design, conduct, performance monitoring, auditing, recording, analysis and reporting of clinical trials.

GCP training is intended for investigators and study staff who are responsible for the conduct, oversight, and management of non-exempt human research studies, including staff who are involved in coordinating the study and collecting and managing data. The GCP training will need to be refreshed every three years in order to remain current with federal regulations, standards and guidelines.

We are committed to performing high quality, ethical clinical research at Penn State. A continual learning environment will help us maintain those high standards. Thank you for your efforts to help us meet this goal.