

## Memorandum

- To: University Research Community
- From: Roberto M. Gutierrez Assistant Vice President for Research Office of Research and Economic Development

Christopher Grayson Director, Research Integrity Office of Research and Economic Development

Subj.: NIH Policy on Good Clinical Practice Training for NIH Awardees Involved in NIH-funded Clinical Trials

Date: December 19, 2016

Effective January 1<sup>st</sup>, 2017 the NIH has enacted a policy that requires all NIH funded investigators and staff who are involved in the conduct, oversight, or management of clinical trials to be trained in Good Clinical Practice (GCP).

The NIH defines a clinical trial as "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."

The principles of GCP help assure the safety, integrity, and quality of clinical trials. GCP provides a standard for ensuring clinical trial compliance, implementation, data collection, monitoring, and reporting (e.g., safety data, accrual reports, study status, protocol deviations, unanticipated problems, or final data), and outline the responsibilities of Institutional Review Boards (IRBs), investigators, sponsors and monitors. GCP addresses elements related to the design, conduct and reporting (e.g., safety data, accrual reports, study status, protocol deviations, unanticipated problems, or final data) of clinical trials.

In order to meet this sponsor requirement, all NIH funded clinical trial personnel who are engaged in clinical trial research will need to take an online GCP course either offered by the CITI Program or the National Institute on Drug Abuse (NIDA) Center for Clinical Trials (CCTN) Clinical Trials Network (CTN).

GCP training is valid for three years. The Office of Research Integrity will be reaching out to currently funded personnel to remind them to complete the GCP course no later than February 28, 2017. As new NIH clinical trial projects are funded, engaged personnel will need to provide verification of GCP training prior to conducting research with human subjects.

Additional details about GCP training is available at http://research.fiu.edu/irb/training-requirements.

Additional information about the NIH GCP training requirement is available at <u>https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-148.html</u>.

If there are any additional questions, please feel free to contact your ORED representative (http://research.fiu.edu/ored/staff-directory/) at 305-348-2494 for further assistance.

OFFICE OF RESEARCH AND ECONOMIC DEVELOPMENT

Modesto Maidique Campus • MARC 430 • Miami, FL 33199 • Tel 305-348-2494 • Fax 305-348-4117 • www.fiu.edu Florida International University is an Equal Opportunity/Access Employer and Institution • TDD via FRS 1-800-955-8771