

HOWARD UNIVERSITY

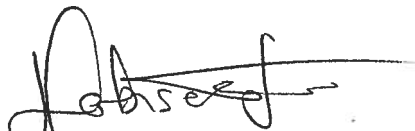
Office of Regulatory Research Compliance

March 26, 2015

MEMORANDUM

TO: Howard University Researchers

FROM: Thomas O. Obisesan, MD. MPH
Associate Vice President for Regulatory Research Compliance and
Designated Institutional Official



RE: Good Clinical Practice (GCP) training

To ensure a well-trained professional workforce in clinical research and enhance our human subject protection program, the Howard University's (HU) Office of Regulatory Research Compliance (ORRC) now mandates the Good Clinical Practice (GCP) course for relevant research personnel.

Effective July 1, 2015, Principal Investigators (PIs) and Study Personnel conducting human subject research that meets the FDA definition of Clinical Trial*, will be required to complete the GCP training. Inherent in the GCP training are the standards for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of the results clinical trial. An enhanced GCP provides the assurance that study-related data and reported results are credible and accurate; and that the rights, integrity and confidentiality of the subjects enrolled in clinical trials are protected.

**A clinical trial is "A research study in which one or more human subjects are assigned to one ore more interventions (which may include placebo or other control) so researchers can evaluate the effects of those interventions on health-related biomedical or behavioral outcomes"*

To avoid delays in the approval of research protocols by the IRB, PI must ensure that study personnel complete the required trainings: Human Subjects Protection (Biomedical or the Social & Behavioral), HIPAA Research, and Conflict of Interest (COI) and Responsible Conduct of Research (RCR) (all human subject study personnel); and Good Clinical Practice (GCP) for those conducting clinical trials.



You may access the training materials by logging on to the CITI portal at <https://www.citiprogram.org>) and add the GCP to your training portfolio. For additional questions, you may call the ORRC at 202-865-8597.

CC: Edward Cornwell MD, Interim Dean College of Medicine
Department Chairs