	University of Puerto Rico Medical Sciences Campus Human Research Subjects Protection Office	Effective: 9/1/2008
		Rev. 07/01/2014

HUMAN SUBJECTS PROTECTION AND HIPAA TRAINING REQUIREMENTS

Purpose:

To establish the training requirements for research staff under the UPR MSC.

Applicability:

All investigators and research teams

Policy:

All investigators and research team members involved in the conduction of research involving human subjects, shall document they have received training in human research subjects protection regulations and the HIPAA law.

Procedure:

The Principal investigator and all research team members responsible of the design and conduct of the human research part of any project, regardless of the funding source, must be trained in Human Subjects' Protection and HIPAA law prior to project initiation.

The research staff must show evidence of Human Subjects Protection and HIPAA training when applying for an IRBWISE account. The research staff must insert an electronic copy of the training certificates under the investigator's account profile.

UPR MSC is affiliated with the "Collaborative Institutional Training Initiative (**CITI program**) for the provision of online training for our faculty, students and staff. (http://citiprogram.org).

IRB allows the following trainings to satisfy this policy:

- Web-based online training http://citiprogram.org
    - Biomedical Research and/or Social/Behavioral Research Courses
    - CITI Health Information Privacy and security (HIPS)

Who needs to take the CITI Program Training?

All Investigators and "Key Personnel" who are "engaged in" research with living human beings, human tissue samples or identifiable private information, are required to take the CITI Training Program.

Key Personnel who are "engaged in research with human subjects" are MSC faculty, staff or students who:

-enroll individuals,

-obtain subjects' informed consent by doing more than handing out or collecting forms or telling subjects how to get in touch with the Investigators;

-intervene or interact with subjects by performing invasive (e.g., drawing blood) or non-invasive (e.g., survey) procedures on them,

-collect data directly from or follow-up directly with participants

-collect identifiable private information from participants or

-have access to information that links participants' names or other identifiers with their data, or

-act as authoritative representatives for the investigators.

As of **May 16, 2011** if the Biomedical Research and/or Social /Behavioral Research certificate is more than 5 years old at the time of IRB submission, study team members will be required to take the "Refresher Course 101"Course provided by CITI program.

For study team members (investigators and others listed on a study) who are not affiliated with the UPRMSC, the IRB will accept research compliance training certifications from their local institution.