Research Training Certificates for Investigators and Study Staff

I. Procedure Title: Education Requirements for Investigators and Study Personnel Involved with Human Subjects Research - Certification and Recertification.

II. Issuing Date: April 1st, 2014.

III. Overview/Procedure Description:

The mission of the National Institutes of Health (NIH) is to improve human health through biomedical and behavioral research. Conducting research involving human subjects is a necessary and important part of that mission. Since October 2000, NIH has required certification and documentation of education in the protection of human research participants for all investigators and key personnel on all research projects regardless of funding source.

The Puerto Rico Clinical and Translational Research Consortium (PRCTRC) has an obligation to ensure that investigators and staff maintain continuing knowledge of, and comply with, the relevant ethical principles, federal regulations, OHRP guidance, and institutional policies for the protection of human subjects. To fulfill this obligation, the University of Puerto Rico Medical Sciences Campus (UPR MSC) Institutional Review Board (IRB) has implemented initial and ongoing web training materials through the Collaborative Institutional Training Initiative (CITI Program) at the University of Miami.

A. Purpose:

To identify the training requirements and the means by which the requirements can be met for **Human Subjects Research (HSR, the same as Human Subject Protection), Information Privacy and Security (IPS, the same as HIPAA)** and **Good Clinical Practice (GCP)** regulations for investigators, study personnel and staff conducting research at the PRCTRC.

IV. Area(s) of Responsibility: Regulatory Knowledge and Support Key Function (RKS), Investigators, study key personnel, collaborators, and PRCTRC staff.

V. Procedure Details:

1. **Who must be certified/recertified:** Research investigators, team members, students or any other individuals who work with human subjects in research or their data. The Principal Investigator is also responsible for new clinical research personnel (hired after the approval notification) that shall obtain the HSR, IPS and/or GCP training within 90 days of assignment to

the project and prior to their functioning without direct supervision. Copy of the completion report must be submitted to the RKS Core at the PRCTRC.

2. **How to obtain your completion report:** The UPR MSC is affiliated to the CITI Program to provide these online courses to faculty, students and staff of the MSC. Individuals who currently do not have human subjects' protection training, should use the CITI program to get one. Instructions for registering yourself in the CITI program can be found here https://www.**citiprogram**.org. During registration, be sure to select University of Puerto Rico Medical Sciences Campus as your institutional affiliation. Also, be sure to list your "@upr.edu" email address (if you have one) as the preferred email address.

3. **Curriculum:** After entering other information about yourself, you will be presented with several curriculum options. As part of the initial education, for the **Human Subjects Research (HSR=Human Subject Protection)**, you should select either the curriculum for *Biomedical (Biomed) or Social-Behavioral Educational (SBE)*, whichever is better aligned with your usual research. For the **Information Privacy and Security (IPS) (IPS=HIPAA)** you should select either the curriculum *IPS for Clinicians, IPS for Clinical Investigators or IPS for Students and Instructors*, whichever is better aligned with your position at the study. For the **Good Clinical Practice (GCP)** you should select either the curriculum for *GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus)*, *GCP for Clinical Trials with Investigational Drugs and Biologics (ICH Focus)*, or *GCP for Clinical Trials with Investigational Medical Devices,* whichever is better aligned with your research.

4. The CITI Program does not offer certificates. Upon course completion you are issued a completion report, which will be e-mailed to your institution and is available to print directly from your account. The completion report serves as the official document issued by the CITI Program upon completion of a course. To print or save your Completion Reports, you may do the following: From your Main Menu, in your Course list, click the "Print Report" link under Completion Report. From your My Reports page, click the "View" link under Completion Report. You may also view your expirations and scores from this page. The completion report is accessed as a PDF, so you will need Adobe Reader or similar PDF-viewing application to save or print.

5. **Research Recertification:** The UPR MSC IRB guideline that all personnel engaged in human subjects' research are required to complete continuing education with the schedule determined by the date on which the initial education was done. You will receive a reminder e-mail from CITI, this means that the course(s) you've completed for the CITI Program is soon to expire. Follow the directions in the e-mail to take the appropriate *refresher course. If you are no longer required to hold a valid CITI Program completion report you can ignore all reminder e-mails. *Please contact your institution directly for instructions on how to access the refresher course if you connect to the CITI Program website via a portal or single sign on directly from your institution.
   The ***Human Subjects Research course*** will be valid for five (5) years. Those individuals that took the course in a period longer than five (5) years have to take the "Refresher Course 101"; the completion of this refresher course will be valid for ten (10) years. After this first re-training you must take the "Refresher Course 101" again for a second re-certification. At ten (10) years of the second re-certification, you must take the ***Human Subjects Research*** course again.

Generally, it is up to each institution to determine when a "refresher" is appropriate, except where a controlling law or regulation provides a standard. Absent such a standard, or a requirement from the

institution's own policies, we recommend some kind of re-training at least every 3 to 4 years. RKS requires that researchers and research study personnel renew their HIPAA and GCP training every three years**.**

VI. References:

1. Office for Human Research Protections: http://ohrp.osophs.dhhs.gov
   45 CFR 46 (The Common Rules)
   http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm

2. Office for Human Research Protections
   http://www.hhs.gov/ohrp

3. International Conference on Harmonization, Guidance for Industry, E6 Good Clinical Practice: Consolidated Guideline http: www.fda.gov/oc/gcp/guidance.html

4. MSC-IRB Website: http://irb.rcm.upr.edu/