



## Investigator Guidance: Understanding CITI Certification Requirements

Federal regulations and guidelines require documented evidence that all personnel involved in the design or conduct of human subjects research have received (and continue to receive) training and education in human subject protection. Pursuant to this requirement, University of Miami policy requires that all personnel involved in human subjects research (including the principal investigator, co-investigators, collaborators and appropriate staff such as 'study contacts' or 'key personnel') receive and maintain 'certification' in human subject protection prior to their involvement in such research. This applies to existing and new personnel.

Training for certification is provided through the **Collaborative IRB Training Initiative Program (CITI Program)**. Completion of the **CITI Course in the Protection of Human Research Subjects (HSR Series)** is required to become certified to conduct human subject research at the University of Miami. This requirement is separate from other University certification requirements (e.g. Conflict of Interest Training). Recertification is required at two-year intervals. *Principal Investigators are required ensure that all study team members hold current CITI certification. Failure to maintain such certification shall be considered noncompliance with University requirements for the conduct of human subject research.*

Please know that the CITI Program offers excellent courses for new certifications; all personnel involved in human subject research must complete at least one of the following courses to become 'CITI-certified'. Effective June 17<sup>th</sup>, 2016, the University of Miami has reviewed the basic and refresher modules required for each group and revised the required training to include the following tracks:

- **HSR Series for Biomedical Researchers:** [formerly Groups 1, 2 & 3] Required for all personnel involved primarily in biomedical research; and for all personnel performing both biomedical and social/behavioral research.
- **HSR Series for Social-Behavioral-Educational Researchers:** [formerly Group 4] Required for all personnel involved primarily in social and behavioral research. The IRB reserves the right to make this course a requirement for research personnel involved in both biomedical and social/behavioral research.
- **HSR Series for IRB Members and HSRO Staff:** [formerly Group 5] Required for all IRB Chairs, IRB members and alternate members and HSRO staff. HSRO staff and others who are Certified IRB Professionals (CIP) are exempt from the CITI certification requirement.

For questions or concerns related to this issue, please contact the Human Subjects Research Office at 305-243-3195 or email our Help desk at [hsro@med.miami.edu](mailto:hsro@med.miami.edu).