

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, Broward Health policy requires that all personnel involved in human subjects research (including the principal investigator, sub-investigators, and appropriate staff such as 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 Institutional Training Initiative (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 Broward Health. This requirement is separate from other Broward Health certification requirements (e.g. Conflict of Interest Training). Recertification is required at three-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 Broward Health's 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 January 1, 2017, Broward Health 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: 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: 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 Data or Laboratory Specimen Researchers: Required for all personnel involved primarily data or laboratory specimens only, NO direct contact with human subjects.
- HSR Series for IRB Members: Required for all IRB Chairs and IRB members.

If you are involved in the conduct, oversight, or management of Clinical Trials, Humanitarian Use Devices and/or Expanded Access you are also required to take at least 1 of 4 CITI offered courses in Good Clinical Practices.

For questions or concerns related to this issue, please contact the Institutional Review Board (IRB Office) at 954-355-4941 or email irb@browardhealth.org.