



MCW Office of Research Standard Operating Procedure

HUMAN SUBJECT RESEARCH PROTECTIONS TRAINING REQUIREMENTS

Unit: Human Research Protections Program (HRPP), Office of Research

Applies to: Faculty and Staff involved in human research

PURPOSE:

All individuals involved in the design, conduct, or analysis of human subjects research are required to be certified in completing human subjects research protections (HSRP) training via Collaborative IRB Training Initiative (CITI) Program. Depending upon the type of human subject research, additional MCW HSRP training course may be required.

The purpose of MCW Human Subject Research Protections (HSRP) training is threefold:

1. **Responsible Conduct in Research** - to assure a thorough and universal foundation in the ethical and legal principles guiding human participant research.
2. **Scientific Integrity** - to enhance the awareness of and sensitivity to research integrity issues such as conflict of interest.
3. **Public Duty** - to demonstrate to project subjects, the community, and research sponsors that we have the training and expertise necessary to protect the rights and welfare of research subjects.

DEFINITIONS:

N/A

PROCEDURE:

Human Subject Research Educational Requirements for MCW, Froedtert Health (FH) or Versiti Investigators

1. All Investigators and project team members must complete required training prior to submission of a research project for review and approval by the MCW IRB. Principal Investigators and project team members are required to remain current with required training to continue to conduct research.
2. Additional human subject protection education is required each year for investigators and coordinators. Investigators and coordinators must obtain three hours of human subject protection education annually. Non MCW members of the research team must obtain one hour of human subject protection education annually.

The following training opportunities may be used to satisfy training requirements, but are not required:

- HSR Grand Rounds (monthly)
 - Research Connection Series (monthly modules)
 - Core Curriculum: Education for Human Research Team Members
3. To maintain ongoing HSRP training certification, completion of identified courses every three (3) years after initial certification is required.

4. Investigators and project team members are expected to maintain their own certification records. Individuals may print out their completion reports or notifications of completed courses.
 - a. Completion of required HSRP trainings (CITI, DoD or Banking) will be displayed within the eBridge system available under the “Researcher Profile” tab within eBridge.

HSRP Training Opportunities and Offerings:

The following training is required for Principal Investigators and all project team members:

1. CITI

- **Initial** - Investigators involved in the design, conduct, or review of human research at any MCW, FH or Versiti location or reviewed by the MCW IRB or reviewed by an external IRB of record must obtain CITI certification. CITI certification is obtained by completing the required online modules with an overall score of 80%.

2. Research Banks at MCW and Froedtert Hospital: IRB Training for Bank Personnel (if applicable)

- Required for Bank Custodians who have access to the bank database, solicits subject consent for banking, or has record-keeping or administration responsibility for a bank.
- This training is available via online module or in person training by registering for Research Connection Series – Banking module.

3. For research supported by or required to follow the Department of Defense directives (if applicable)

- For initial and continuing research, ethics education must be completed by all personnel who conduct, review, approve, oversee or manage human subject research. In support of this requirement Investigators and project team members must complete the online MCW DoD human research module.
- This training is available via online module only.

Research Educational Requirements for non-MCW, FH or Versiti Investigators

For projects where MCW is serving as the IRB of Record for another institution outside of MCW, FH or Versiti, the MCW HRPP office may accept HSRP training from another institution provided either of the following conditions are met:

- The institution has current AAHRPP accreditation, or
- The institution is a part of a CTSA-awarded consortium

If the above requirements are satisfied, the deferring institution point of contact must provide a statement that the local Principal Investigator and project team members are current with the institution’s human subject training requirements.

If an institution does not meet the above criteria, project team members must complete MCW-specific HSRP training requirements through CITI.

REFERENCES:

N/A

SUPPORTING DOCUMENTS:

N/A

Effective Date: 07/01/2023
Version number: 4.0
Previous Version/date: 3.0; 06/15/2018
Responsible Office: HRPP Office
Approval Date: 05/29/2023

Approved By
HRPP Authorized Official: Ryan Spellecy, PhD, Director, HRPP
Human Research Protections Program (HRPP)
Office of Research
Medical College of Wisconsin