SOP 1.1.2 **Training**

General Description:

George Mason University, the Institutional Review Board (IRB) and individual investigators share a collective responsibility to ensure that research involving human subjects is guided by the highest ethical standards and is conducted in compliance with federal, state and university regulations. Regular IRB members, IRB Chairs, IRB administrators and researchers conducting human subjects research are expected to be knowledgeable in the essential aspects of ethics and regulations, and are required to meet basic training requirements.

The Office of Research Integrity and Assurance (ORIA) office maintains an institutional subscription to the Collaborative Institutional Training Initiative (CITI), a resource of online training modules that provides the Mason research community with convenient access to comprehensive and regularly updated human subjects research guidance.

All investigators (faculty, staff and students) are required to complete human subjects training prior to conducting research involving human subjects. The CITI Program basic training course in human subjects protection meets this requirement. This training requirement applies regardless of whether such research receives external funding and it applies to all academic levels. The IRB requires researchers who have active IRB protocols to complete human subjects training every four years. Four years after completing the Basic course, the CITI Refresher course will be required. The Basic and Refresher courses will alternate every four years thereafter. The CITI Program website will prompt researchers to take the appropriate required course at the time of training expiration.

Additionally, the National Institutes of Health (NIH) requires education on the protection of human research participants for all key personnel submitting NIH applications for grants or proposals for contracts or receiving new or non-competing awards for projects involving human research participants. The training is required for both exempt and nonexempt research involving human subjects. Mason faculty, staff and students who are key personnel for NIH funded human subjects research can fulfill the NIH training requirement by completing the CITI training.

If an academic department would like to propose alternate human subjects training for researchers that is specific to their department, a request can be submitted to the IRB along with a detailed description of what that training would entail, who would be eligible to take the training, and how completion of the training would be documented and forwarded to the IRB. The IRB will review this information and decide whether the described training may serve as equivalent training to the CITI training program.

Procedures:

1. IRB Staff Training

    a. IRB staff will complete training in the protection of human research subjects. IRB staff may complete any of the appropriate training options available on the CITI website.
    b. IRB staff will receive initial and ongoing training in the areas relevant to their responsibilities, including all Standard Operating Policies and Procedures (SOPs).
    c. IRB staff will be encouraged to attend workshops and other educational opportunities focused on IRB functions and human subject research as well as keep up with professional literature on human subjects research.

2. IRB Member Training

    a. IRB members will complete training in the protection of human research subjects. IRB members may complete any of the appropriate training options available on the CITI website.
    b. IRB members will participate in initial and ongoing training in areas relevant to their responsibilities. Training may occur individually (generally for new members), online or during full board convened meetings.
    c. IRB members will be encouraged to attend workshops and other educational opportunities focused on IRB functions and human subjects research as well as keep up with professional literature on human subjects research.
    d. IRB Chair(s) and IRB Vice-Chair(s) will receive additional training in areas relevant to their additional responsibilities.

3. Investigator and Study Personnel Training

    a. Investigators and key study personnel must complete the CITI human subjects basic course and any modules pertinent and applicable to his/her field of research prior to conducting any human subjects research. If any investigators or key study personnel are not affiliated with Mason, they must provide a certification of completion of the CITI basic course or the human subjects training course required by their home institution to the Mason IRB prior to conducting any human subjects research.
    b. If an academic department has developed an alternative human subjects training program that has been approved by the IRB, a researcher in that department may complete the departmental training instead of the CITI course and provide documentation of completion of the course to the IRB with any protocol submissions. Researchers should check with their specific department and/or the IRB office to determine whether or not there is an alternate training program available to them if they do not wish to complete the online CITI training.
    c. Investigators and key study personnel may complete a human subjects protection training concurrently during the IRB review of the research. The IRB coordinator will verify investigators and key study personnel have completed the required training program before the notification of final approval by the IRB Chair or designee is sent and the study is moved to an approved status in the IRBNet online system.
    d. CITI refresher courses are required by the Mason IRB every 4 years. Please note that certain funding agencies may require that researchers complete the refresher course more often in order to receive funds from that agency.

Related Forms, Guidance, and SOPs:

- 1.1.1 Definitions
- 1.6 IRB Administrative Procedures
- 2.1 Protocol Submission and Review
- Human Subjects Training; GMU ORIA Website. Available at: https://rdia.gmu.edu/topics-of-interest/human-or-animal-subjects/human-subjects/human-subjects-training/

Responsibility:

Execution of SOP:

Principal Investigator
Research Study Team
IRB Staff
IRB Members

Approval and Version History:

Please contact irb@gmu.edu if you have any questions about this policy or the version and approval history.

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Approved By	Title and Division	Date Approved
Rebecca Hartley	Assistant Vice President, Research Integrity and Assurance	January 23, 2020
Laurie Meamber	IRB Chairperson	January 23, 2020