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 & Assurance (ORIA) 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 the CITI Program basic training course in human subjects protection prior to conducting research using human subjects. This training requirement applies regardless of whether such research receives external funding and it applies to all academic levels. 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.

Procedures:

1. IRB Staff Training
   1. 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.
   2. IRB staff will receive initial and ongoing training in the areas relevant to their responsibilities, including all Standard Operating Policies and Procedures (SOPs).
   3. IRB staff will be encouraged to attend workshops and other educational opportunities focused on IRB functions and human subject research.

2. IRB Member Training
   1. 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.
   2. IRB members will participate in initial and ongoing training in areas relevant to their responsibilities. Training may occur online or during full board convened meetings.
   3. IRB members will be encouraged to attend workshops and other educational opportunities focused on IRB functions and human subject research.
   4. 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
   1. 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.
   2. Investigators and key study personnel may complete a human subjects protection training concurrently during the IRB review process 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.

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: http://oria.gmu.edu/research-with-humans-or-animals/institutional-review-board/human-subjects-training/

Responsibility:

Execution of SOP:
Principal Investigator
Research Study Team
ORIA 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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<tr>
<td>Aurali Dade</td>
<td>Assistant Vice President, Office of Research Integrity and Assurance</td>
</tr>
<tr>
<td>Greg Guagnano</td>
<td>IRB Chairperson</td>
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