

University of Rochester	Office for Human Subject Protection		
	Research Education & Training	Effective Date: 12/11/2020	
	Education Program	Policy 201	Version: 2.1

POLICY

1. Purpose

Describe the institutional training requirements and educational opportunities for individuals involved in the University of Rochester's Human Research Protection Program (UR HRPP) to ensure that the rights, safety and welfare of subjects are protected during the conduct of research.

2. Scope

This policy applies to all individuals responsible for protecting the rights and welfare of human subjects under the UR HRPP. This includes, but is not limited to: all research personnel engaged in human subject research, the Institutional Official (IO), Office for Human Subject Protection (OHSP) staff and Research Subject Review Board (RSRB) members.

3. Definitions

- 3.1. Internal Research Personnel – An employee or agent of the UR engaged in human subject research (as defined by Policy 102 University of Rochester's Human Research Protection Program and Policy 301 RSRB Scope and Authority).
- 3.2. External Research Personnel – An individual engaged in human subject research not acting as an employee or agent of the UR (as defined by Policy 301 RSRB Scope and Authority and Policy 102 University of Rochester's Human Research Protection Program).

4. References

- 4.1. [Policy 102 University of Rochester's Human Research Protection Program](#)
[Policy 301 RSRB Scope and Authority](#)
[Policy 302 RSRB Membership and Composition](#)
- 4.2. [Guideline for OHSP Education and Training Framework](#)
[Guideline for Professional Certification Reimbursement](#)
[Guideline for Determining Engagement in Research](#)
[Guideline for Listing Study Team Members on a Study Application](#)

5. Responsibilities

- 5.1. The OHSP Division of Research Education & Training is responsible for assisting researchers in protecting the rights, welfare and safety of human subjects by providing programs and educational resources in research ethics and human subject safety, with an emphasis on proper conduct of research. To accomplish this, the Division of Research Education & Training:

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- 5.1.1. Administers and monitors basic human subject protection training requirements conducted through the Collaborative Institutional Training Initiative (CITI). This includes:
 - 5.1.1.1. Maintaining internal research personnel training information.
 - 5.1.1.2. Ensuring internal research personnel are notified of pending training expiration.
- 5.1.2. Implements additional training opportunities designed to supplement the basic human subject protection training requirements. This includes, but is not limited to:
 - 5.1.2.1. In-person and online training seminars, workshops and classes intended for study team members engaged in human subject research (see *Guideline for OHSP Education & Training Framework*).
 - 5.1.2.2. Educational programs for OHSP staff and RSRB members.
 - 5.1.2.3. Information and resources provided via the Division website.

5.2. Employees or Agents of the University of Rochester are responsible for:

- 5.2.1. Completing and maintaining the required basic human subject protection training, including documentation of such training, as described in section 6.0 below.
- 5.2.2. Maintaining documentation of completed human subject protection training (e.g., CITI Course Completion Report).
- 5.2.3. Complying with any additional internal training requirements set forth elsewhere within the UR (e.g., departmental training requirements), any board-requested training requirements, and any external research training requirements (e.g., sponsor training requirements, professional certification maintenance, etc.).

6. Requirements

6.1. Institutional Official & OHSP Staff

- 6.1.1. The IO and OHSP staff must successfully complete and maintain the “IRB Member” basic human subject protection training through CITI, as required by their job responsibilities. Refresher training is required every 3 years.
 - 6.1.1.1. Existing human subject protection training of a different type (e.g., “Biomedical” or “Social-Behavioral-Educational”) will be accepted for an IO or OHSP staff member entering into their role; however, “IRB Member” training must be completed with each refresher training while acting as IO or employed by OHSP.

6.2. RSRB Members

- 6.2.1. All RSRB members must successfully complete and maintain the “IRB Member” basic human subject protection training through CITI. Refresher training is required every 3 years.

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- 6.2.1.1. Existing human subject protection training of a different type (e.g., “Biomedical” or “Social-Behavioral-Educational”) will be accepted for any RSRB member entering into their role; however “IRB Member” training must be completed with each refresher training while serving as a RSRB member.
- 6.2.1.2. Alternate RSRB members are required to maintain training as described in Section 6.3 below.
- 6.2.2. All RSRB members must comply with the initial and ongoing training and education policies set forth in *Policy 302 RSRB Membership and Composition*.
- 6.3. Internal Research Personnel
 - 6.3.1. All internal research personnel must successfully complete basic human subject protection training through CITI prior to conducting any human subject research.
 - 6.3.1.1. Acceptable courses within the human subject protection curriculum for internal research personnel include “Biomedical”, “Social-Behavioral-Educational”, and “IRB Member”. Coursework should be selected based on the type of research being conducted and/or the role within the research study.
 - 6.3.1.1.1. At the discretion of the OHSP/RSRB, additional training may be required based on the nature of the research, an individual’s role in conducting the research, prior incidents of non-compliance, or other similar circumstance.
 - 6.3.1.1.2. Internal research personnel who also serve as a RSRB Member are only required to maintain the training described in Section 6.2 above throughout their board service.
 - 6.3.2. All research personnel must successfully complete basic human subject protection refresher training through CITI every 3 years.
 - 6.3.2.1. Personnel with a lapse in training must cease all involvement in human subject research activities until refresher training is completed. At the time of continuing review, the RSRB may withhold study renewals in cases where training for key research personnel has lapsed.
- 6.4. External Research Personnel
 - 6.4.1. External research personnel who collaborate with the UR on human subject research and are considered engaged in research per the *Guideline for Determining Engagement in Research*, must meet basic human subject protection training requirements prior to conducting research activities.
 - 6.4.1.1. If external research personnel are associated with an institution with existing human subject protection training requirements (e.g., another academic medical center or university), OHSP will recognize the external institution’s training.
 - 6.4.1.2. If an external research personnel’s associated institution does not set forth human subject protection training requirements, individuals may complete:

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- 6.4.1.2.1. The UR's basic human subject protection training through CITI; or
- 6.4.1.2.2. Another similar human subject protection training.

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Appendices:

None

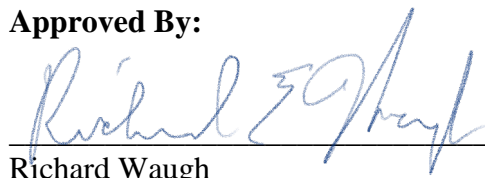
Revision History:

- 06/2016: Hyperlinks added; Clarifications to Sections 6.2.1, 6.3.1.1 and 6.4.1; editorial changes
- 10/2018: Removed the requirement for OHSP to provide certification and re-certification letters to research personnel in Section 5.1.1; Updated type of human subject protection training required in Sections 6.1, 6.2 & 6.3; Added the requirement for Internal Research Personnel to maintain training documentation; Eliminated appendices that are no longer applicable/necessary; Additional editorial/administrative changes
- 11/2020: Clarified the definitions in Section 3 to reference engagement in human subject research; clarified acceptable coursework for Internal and External Research Personnel in Sections 6.3.1.1 and 6.4.1.2; Additional editorial changes

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Institutional Official and Senior VP for Research

12/11/20
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12/15/2020
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Director of Research Education & Training, OHSP

12/15/2020
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