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 employees or agents of the UR 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. Employee or Agent – An individual who: (1) acts on behalf of the institution; (2) exercises institutional authority or responsibility; or (3) performs institutionally designated activities, including but not limited to staff, students, contractors, and volunteers, regardless of whether the individual is receiving compensation.

4. References

4.1. Policy 504 IRB Reliance and Collaborative Research

4.2. Human Subject Protection Training for External Research Personnel
OHSP Training Framework
UR HRPP Educational Forum and Materials

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 educational programs, opportunities, and 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:

5.1.1. Administers and monitors Human Subject Protection (HSP) training requirements conducted through the Collaborative Institutional Training Initiative (CITI). This includes:

5.1.1.1. Collaborating with University Information Technology (IT) to ensure CITI training information for employees or agents of the UR is documented in the online Institutional Review Board (IRB) review system.

5.1.1.2. Ensuring employees or agents of the UR are notified of pending HSP training expiration.

5.1.2. Implements additional training opportunities/resources designed to supplement HSP training requirements. This includes, but is not limited to:

5.1.2.1. In-person and online training seminars, workshops and classes intended for employees or agents of the UR that are engaged in human subject research (e.g., OHSP Training Framework, UR HRPP Educational Forum and Materials).

5.1.2.2. Educational programs and resources for OHSP staff and RSRB members.

5.1.2.3. Information and resources provided via the OHSP website.

5.2. Employees or agents of the UR are responsible for:

5.2.1. Completing and maintaining HSP training, including documentation of such training, as described in section 6.0 below.

5.2.2. Complying with any additional internal training requirements set forth elsewhere within the UR (e.g., departmental training requirements), board-requested training requirements, and external research training requirements (e.g., sponsor training requirements, professional certification maintenance, etc.), as applicable.

6. Requirements

6.1. The Institutional Official (IO) is required to:

6.1.1. Complete the 'Institutional Official' training within the UR's HSP curriculum in CITI.[1]

6.1.2. Complete and maintain the either the 'IRB Member' *or* 'Biomedical Researcher' training within the UR's HSP curriculum. Refresher training is required every 3 years.

6.2. RSRB Board Chairs and Vice Chairs are required to:

6.2.1. Complete the 'IRB Chairs' training within the UR's HSP curriculum in CITI.[1]

6.2.2. Complete and maintain the 'IRB Member' training within the UR's HSP curriculum. Refresher training is required every 3 years.

6.3. OHSP Staff and RSRB Members are required to:

6.3.1. Complete and maintain the 'IRB Member' training within the UR's HSP curriculum in CITI. Refresher training is required every 3 years.[1]

6.4. Employees or agents of the UR engaged in human subject research are required to:

6.4.1. Complete and maintain HSP training through the UR's CITI subscription *prior* to engaging in any human subject research. Refresher training is required every 3 years.

[1] Onboarding (initial) training requirements are only applicable to new IOs, RSRB Board Chairs, RSRB Vice Chairs, RSRB Members, and OHSP Staff appointed on or after the policy effective date.

6.4.1.1. Acceptable courses within the HSP curriculum for internal research personnel include 'Biomedical Researcher', 'Social-Behavioral-Educational Researcher', and 'IRB Member'. Coursework should be selected based on the type of research being conducted and/or the role in the research/institution.

6.4.1.2. In limited circumstances, and at the discretion of the OHSP/RSRB, HSP training completed via an alternate training platform or another institution's CITI subscription may be accepted for adjunct faculty, based on the individual's role in the research.

6.4.2. 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.

6.4.3. 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.

6.5. External collaborators and unaffiliated researchers:

6.5.1. Individuals who are *not* employees or agents of the UR are required to successfully complete HSP training *prior* to engaging in human subject research when their engagement in the research falls under the purview of the RSRB. E.g., single-site research when an external collaborator is engaged in the research on behalf of the UR; or multi-site research when the RSRB serves as the Reviewing IRB (as described in Policy 504 IRB Reliance and Collaborative Research).

6.5.1.1. External collaborators/unaffiliated researchers associated with an institution that has HSP training requirements in place (e.g., another academic medical center or university), should complete the HSP training required by their institution.

6.5.1.2. External collaborators/unaffiliated researchers that are associated with an institution that does not have HSP training requirements in place, may complete:

6.5.1.2.1. The UR's HSP training through CITI; or

6.5.1.2.2. Another similar HSP training (see HSP Training for External Research Personnel).

Originator/Authors:

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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.

8/2024: Updated definitions in Section 3 to be consistent with the remainder of the policy and all other OHSP policies; Updated applicable references; Clarified Section 5.1.1.1 regarding the documentation of CITI training in the IRB review system; Updated the type of required HSP training for the IO, RSRB Board Chairs and Members and OHSP Staff members in Sections 6.1-6.3; Added alternative training options accepted on a limited basis for adjunct faculty in Section 6.4.1.2; Clarified HSP training requirements for external collaborators in Section 6.5.1; Additional editorial revisions.

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Approved By:

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