GUIDELINE ON HUMAN SUBJECT PROTECTION (HSP) TRAINING FOR EXTERNAL RESEARCH PERSONNEL

As defined in Office for Human Subject Protection (OHSP) Policy 201 Education Program, basic human subject protection training is required for individuals engaged in the conduct of human subject research. This includes individuals that are internal to the institution (e.g., University of Rochester [UR] faculty/staff/students), as well as those who are collaborating with UR researchers and are external to the institution. To determine engagement, see OHSP’s Guideline for Determining Engagement in Research.

When human subject protection training is required, internal research personnel are required to complete their human subject protection training through the UR’s affiliation with the Collaborative Institutional Training Initiative (CITI). External research personnel may complete human subject protection training through a variety of mechanisms, as identified in the policy. The purpose of this guideline is to provide additional direction concerning what human subject protection training is most appropriate for external research personnel, based on the nature of the research and/or their role in research conduct.

NOTE: As stated in OHSP Policy 901 Investigator Responsibilities, it is the responsibility of the Principal Investigator (PI) to oversee the conduct of all research activities, including the training and education of all study staff. Human subject protection training is only meant to act as a baseline training requirement; completing the training alone does not necessarily prepare study team members to adequately carry out their role. Additional role and protocol-specific training are routinely required to ensure data integrity and compliance.

HSP Training for External Research Personnel Affiliated with another Academic, Healthcare, or Research Institution/Organization

When external research personnel collaborate with the UR on human subject research and are affiliated with another academic, healthcare, or research institution/organization (e.g., another academic medical center or another university), OHSP recommends that the individual complete human subject protection training in accordance with their affiliated institution’s training requirements. Most of these types of institutions already have human subject protection training requirements in place. **External research personnel do not need to duplicate training efforts and complete both the UR’s and their affiliated institution’s human subject protection training.**

In the rare event that an individual is affiliated with another academic, healthcare or research institution/organization, and their affiliated institution does not have human subject protection
training requirements in place, OHSP recommends the individual complete the training through the UR’s CITI subscription (see instructions for registering for and completing training here).

**HSP Training for Community Research Partners**

External research personnel who collaborate with the UR on human subject research and are not affiliated with an institution/organization that has existing human subject protection training requirements, i.e., individuals who are members of the community or are affiliated with a community-based organization or agency (hereinafter referred to as Community Research Partners) should complete human subject protection training through either:

- The UR’s CITI subscription; or
- The University of Illinois Chicago’s CIRTification training platform.

The training offered through the CIRTification platform was developed specifically for Community Research Partners. The content reviewed within the training is similar, but not identical, to the content provided via CITI. Based on the differences in content described in CIRTification’s content comparisons summary, OHSP recommends that Community Research Partners:

- Complete human subject protection training via CIRTification (instructions provided below) when their role is limited to:
  - Recruitment, enrollment, consent, and/or data collection activities in minimal risk research;
  - Recruitment and/or minimal risk data collection activities in greater than minimal risk research; or
  - Advisement activities related to study design and/or the development of consent and recruitment materials, subject education/instructional materials, or subject-completed measures (regardless of risk level).

- Complete human subject protection training via CITI (instructions are available here) when their role involves:
  - Enrollment, eligibility verification, consent, and/or greater than minimal risk data collection activities in greater than minimal risk research;
  - Research with a prisoner population (regardless of risk);
  - Research oversight responsibilities typically designated to a Principal Investigator or Co-Investigator;
  - Research oversight responsibilities related to the identification and management of study-related risks and/or data and safety monitoring; or
  - Research regulated by the Food & Drug Administration.

**CIRTification Instructions**

1. Click on the following hyperlink to access the CIRTification training website: http://training.ccts.uic.edu/
2. Select the ‘Register’ option in the upper right corner and then select the ‘I am not from UIC’ option.
3. Complete the registration form.  *When asked to identify your site, select University of Rochester from the dropdown menu.* Click ‘Register’ when complete.
4. Click the ‘Course Catalog’ option in the green box.
5. Select ‘Learn More’ in CIRTification description box and then select ‘Enroll’.
6. Complete the enrollment and demographic information and click ‘Submit’.
7. Following enrollment confirmation, select the ‘My Courses’ option in the upper right corner.
8. Select your language preference to initiate the course. The training platform will walk you through completing the training modules thereafter. You may log in and out of the course as many times as you need to in order to complete the training.
9. Once the training has been completed, and you have passed the quiz at the end, the system will generate a certificate with a date of completion on it. Save a copy of this certificate as a PDF; a copy must be provided to your Principal Investigator. You can also log back in to the system at a later time with your email and password to obtain a copy of the completion certificate.

**Alternative HSP Training for External Research Personnel**  
In lieu of the training options described above, [OHSP Policy 201](#) further permits external research personnel to complete ‘another similar human subject training’ in order meet the training requirement. OHSP recommends that this option be used under very limited circumstances. In the event an alternative training option is used (i.e., options other than what is described above), should be reviewed by the [OHSP Director of Research Education & Training](#) prior to use to ensure the appropriateness of the content.

**Training Documentation & IRB Review**  
To demonstrate adherence to OHSP Policies 201 and 901, as referenced above, Principal Investigators should maintain human subject protection training documentation for all study team members. Human subject protection training documentation may further be required by Sponsors, Funding Agencies, and Reviewing IRBs per their respective policies and procedures.

When the Research Subjects Review Board (RSRB) is the Reviewing IRB:

- **Single-Site Research:** When a Community Research Partner (as described above) is engaged in research conduct, the individual must be identified in the ‘External Team Member Information’ field in the Click IRB Submission (on the ‘Local Study Team Members’ page); this process involves uploading documentation of the individual’s human subject protection training. Step-by-step instructions for doing so are available in the [Click IRB Study Staff Manual](#) (see the instructions for ‘Create and Submit a Study’). To facilitate the RSRB review process, study teams are strongly encouraged to identify the
external study team member’s role as described in the instructions. **Note:** If the external individual is engaged in the research on behalf of their role/position at a non-UR research location or facility and the research is federally funded, the non-UR facility is considered a separate research site, requiring a Federalwide Assurance and IRB site approval (see OHSP Policy 504 IRB Reliance and Collaborative Research). External research personnel would then be managed as described below (multi-site research).

- **Multi-Site Research:** In accordance with SMART IRB recommendations, the Relying IRB (i.e., the IRB that delegates the responsibility of IRB review and approval to the RSRB) is responsible for ensuring their local site research staff have ‘adequate education, training, and qualifications to perform the research’. External research personnel should only be identified in the Click IRB submission as a ‘Local Study Team Member’ when they are engaged in the research as part of the local UR site. Study team members engaged in the research at other participating sites (e.g., investigators or study coordinators from other sites engaged in the research) should not be identified in the Click IRB submission.

When the Research Subjects Review Board (RSRB) is the Relying IRB:

- External research personnel should only be identified in the Click IRB submission as a ‘Local Study Team Member’ when they are engaged in the research as part of the local UR site. See above under “Single-Site Research.” Study team members engaged in the research at other participating sites (e.g., investigators or study coordinators from other sites engaged in the research) should not be identified in the Click IRB submission. Note: The ‘Basic Study Information’ page of the Click IRB submission requests the identification of a lead PI. This field can be skipped when the local PI is not acting as the lead PI (overseeing all participating sites).