GUIDELINE FOR OHSP EDUCATION & TRAINING FRAMEWORK

The purpose of this guideline is to assist Researchers, Department Chairs, Administrators and other Senior Leadership within the University of Rochester (UR) in navigating the research training requirements, opportunities and framework set forth by the Office for Human Subject Protection’s (OHSP) Division of Research Education & Training.

As described in OHSP Policy 201 Education Program, all research personnel are required to complete and maintain basic human subjects training through the Collaborative Institutional Training Initiative (CITI) prior to conducting any human subject research at the UR.

The OHSP Division of Research Education & Training, in collaboration with other UR Human Research Protection Program personnel, also provides additional training opportunities in the form of Orientation, Boot Camp, Core Training and Advanced Training courses (as described in Table 1). These courses are meant to provide a framework of training for research personnel to use as necessary, based upon their study team role. While OHSP provides training recommendations regarding these additional courses, there is no requirement to complete these courses. Department Chairs, Center Directors, Administrators and other UR Senior Leadership may use these courses and training recommendations as necessary, based upon their group’s needs.

All courses within the OHSP Education & Training Framework will be available to UR employees free-of-charge and enrollment will not be restricted by role or experience. (Note: OHSP has provided a recommended timeframe for completion in Table 1. Having a certain level of experience for the advanced courses will be of benefit to participants.)

Boot Camp, Core Training and Advanced Training courses conducted in-person, are open to external research personnel. Contact Kelly Unsworth at (585) 275-5244 or kelly_unsworth@urmc.rochester.edu for the fee schedule.

Registration for courses that fall within the framework is required. Please visit the OHSP Division of Research Education & Training website for information on registration.

Consultation is available for Department Chairs, Administrators and other Senior Leadership wishing to institute additional training requirements within their jurisdiction by contacting Kelly Unsworth at (585) 275-5244 or kelly_unsworth@urmc.rochester.edu.
<table>
<thead>
<tr>
<th>Design</th>
<th>CITI Training</th>
<th>Orientation</th>
<th>Boot Camp</th>
<th>Core Training</th>
<th>Advanced Training</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Online Modules <a href="http://www.citiprogram.org">www.citiprogram.org</a></td>
<td>1 Hour Online Course</td>
<td>½ Day Workshop (offered quarterly)</td>
<td>10 Learning Modules (combo of classroom &amp; online training)</td>
<td>1 Day Workshop (offered annually)</td>
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<tr>
<td>Goal</td>
<td>Understand general basics of human subjects research</td>
<td>Understand basics of conducting research at UR</td>
<td>Apply basics identified in CITI &amp; Orientation to research at UR</td>
<td>Cultivate advanced understanding of research topics</td>
<td>Augment topics addressed in Core Training</td>
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</tbody>
</table>
| Content         | • Per CITI – general review of human subject protections based on selected training  
• 4 levels of training: GTMR – Biomedical  
GTMR – Behavioral  
Minimal Risk  
IRB                                                                 | • Describe the HRPP at UR  
• Introduce UR policies and required review processes concerning human subject research  
• Provide resources available within UR                                                                 | • Elements of a research protocol & basic protocol development  
• Informed consent process  
• RSRB/WIRB review process  

**Completion Requirements/ Recommendations**

Based on Study Team Role

- All Study Team Members
- All Study Team Members
- All Study Team Members
- Pls (Modules 2, 3, 6, 7, 8 & 10) Research Nurses Study Coordinators
- Pls Research Nurses Study Coordinators

**Recommended Timeframe for Completion**

- New Hires & Current Faculty/Staff: Required prior to conducting any human subject research
- New Hires: Complete within 2 months of start date  
Current Faculty/Staff: Anyone with ≤ 1 yr exp

- New Hires: Complete within 6 months of start date  
Current Faculty/Staff: Anyone with ≤ 1 yr exp

- New Hires: Begin within 1 year of start date; complete by 3 years of start date  
Current Faculty/Staff: Anyone with ≤ 3 yr exp

- New Hires: Within 4 years of start date  
Current Faculty/Staff: Anyone with ≤ 5 yr exp

**Competency Check**

- Per CITI – Online test
- Informal competency check within video (responses are not collected)
- Group competency check

- Written and/or group competency check (when applicable) within module  
Comprehensive written competency check with completion of all modules

- Written competency check

**Documentation of Completion**

- Course Completion Certification Letter
- Certificate of Course Completion
- Certificate of Attendance

- Certificate of Attendance (individual modules)  
Certificate of Course Completion (with successful competency check)

- Certificate of Course Completion (with successful competency check)

**Maintenance Requirements**

- Course refreshers required every 3 years through CITI Program
- None
- None
- None
- None

$ Except CITI Training, completion requirements and their corresponding time frames are recommendations only. Department Chairs, Center Directors, Administrators and other UR Senior Leadership may institute course completion requirements that override OHSP recommendations as they see fit.

# All study members are welcome at any/all courses (including individual modules within Core Training); enrollment will not be restricted based on role.

% Except CITI training refreshers, maintenance requirements will not be required by OHSP. Department Chairs, Center Directors, Administrators and other UR Senior Leadership may institute maintenance requirements that override OHSP recommendations as they see fit.