210.1 Education and Training of Individuals Responsible for Human Research

Education and training are provided to all individuals involved with the human research protection program. This policy manual details the education requirements for IRB members and HSP staff. Education requirements for Investigators and key personnel on the research team are specified in the GUIDE 601: Investigator's Handbook and the Human Studies Program Learning Commons website. The HSP works with the UH campuses and departments, John A. Burns School of Medicine, and other institutions, to offer comprehensive education to the UH research community.

Education Unit (EU)

The HSP and the ORC has full- and part-time staff, responsible for developing and providing education for IRB members, HSP staff, and the research community regarding human research protections.

Evaluation of Qualifications

In addition to receiving training on human participant research protections, the IRB members and HSP staff are reviewed periodically to evaluate their understanding of the HRPP (i.e., ethical principles, policies and procedures, and regulations and requirements).

HSP staff qualifications are assessed at least annually or as needed to ensure a high level of commitment to the HRPP.

IRB member qualifications are reviewed by the HSP Director during the recruitment process, and IRB members are officially appointed by the IRB Chair and HSP Director. IRB members, including IRB Chairs, are evaluated annually to ensure that their service on the IRB contributes to the ethical and regulatory review of research at UH. Feedback from these evaluations is communicated to each IRB Member and each IRB Chair. Investigators at UH are evaluated according to individual institution, school, and department policies.

The Quality Improvement Unit (QIU) evaluates the effectiveness of the education provided. Results of the QIU assessments are used to revise the content of educational materials, improve delivery methods and identify appropriate audiences, and to communicate with the other components of the HRPP about updating their education and training.

See SOP 110: Quality Improvement Activities for the human research protection program.
Contributing to the Improvement of Expertise

New IRB members and HSP staff receive orientation to the UH HRPP, including written and electronic IRB reference material. All IRB members and HSP staff receive regular, continuous training and education. Opportunities for continuing education in human research protections are announced on an ongoing basis. IRB member and HSP staff attendance is encouraged at regulatory and professional meetings and conferences, and for web seminars at UH and in the greater community. The HSP also supports and encourages professional certification for qualified HSP staff.

Educational Materials and Resources

The UH research community, IRB members, HSP staff and other individuals involved in the protection of human research participants have access to a plethora of educational material, available online and in printed format, or offered as lectures or workshops.

They include, among others:

- The HSP website, with links to the UH Human Studies Program General Policy Manual, the Investigator’s Handbook, instructional information, FAQs, educational material, document templates, forms and guidance.
- Access to required and elective training through the interactive online Collaborative Institutional Training Initiative (CITI) Course: Human Subjects Research, GCP, working with vulnerable populations, and Information Privacy and Security/ HIPAA.
- The ORC website
- The eProtocol electronic protocol submission system, providing instructional text and explanation within the application.
- eProtocol training
- Links to pertinent federal regulations, codes of ethics, policies and procedures of collaborating non-UH research institutions.
- Past presentations on human research protection.

Additional education and training are provided through seminars, workshops, classes and training courses offered by the HSP and other HRPP components.

210.2 Required Training in Human Research Protections

Completion of human subject training by all staff working on a research protocol or proposal (all Investigators and other study personnel, including all individuals who are responsible for the design, conduct, data analysis or reporting) is one of the requirements for research approval by the IRB. Principal Investigators, as part of the protocol submission process, acknowledge their obligation to protect the rights and welfare of research participants. See APP 04: New Research for Initial Approval, Non-Exempt Application “Obligations” section.

UH provides access to the required training through an interactive online tutorial - CITI (Collaborative Institutional Training Initiative) Course. CITI offers a basic (initial) course and then a refresher course, which must be taken every three years. The required training has been customized for different learner groups (biomedical and social & behavioral sciences Investigators, Investigators conducting exempt research, IRB members, and HSP staff).
Once required courses are completed, a certificate of completions for each completed course can be saved or printed from the CITI website. Individual Investigators must maintain their own records or training. It is the responsibility of the Principal Investigator to ensure the completion of the required training by all study personnel, including all persons who are responsible for the design, conduct, data analysis or reporting, and to have all certificates of completions available for audits.

The HSP Director maintains record on training of all staff and IRB members, including completion and expiration dates. CITI sends an email reminder to CITI subscribers of upcoming expiration on their training.

### IRB Member and HSP Staff Required Training

<table>
<thead>
<tr>
<th>CITI Training</th>
<th>Biomedical/Cooperative IRB Members and Chairs</th>
<th>Social &amp; Behavioral Sciences IRB Members and Chairs</th>
<th>HSP Reviewing Staff (HSP Director, IRB Coordinators, Compliance Specialist)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Human Subjects Research – basic/refresher</td>
<td>Cooperative and Biomedical IRB Members</td>
<td>Social and Behavioral IRB Members</td>
<td>IRB Administrators</td>
</tr>
<tr>
<td>Supplemental Modules</td>
<td>Optional, but encouraged:</td>
<td>Optional, but encouraged:</td>
<td></td>
</tr>
<tr>
<td>• Children (Biomed Focus)</td>
<td>• Children (Biomed Focus)</td>
<td>• Children (Social &amp; Behavioral Focus)</td>
<td>• Children (Biomed Focus)</td>
</tr>
<tr>
<td>• Prisoners (Biomed Focus)</td>
<td>• Prisoners (Biomed Focus)</td>
<td>• Prisoners (Social &amp; Behavioral Focus)</td>
<td>• Prisoners (Biomed Focus)</td>
</tr>
<tr>
<td>• Pregnant Women, Fetuses, and Neonates (Biomed Focus)</td>
<td>• Pregnant Women, Fetuses, and Neonates (Biomed Focus)</td>
<td>• Pregnant Women, Fetuses, and Neonates (Biomed Focus)</td>
<td>• Pregnant Women, Fetuses, and Neonates (Biomed Focus)</td>
</tr>
<tr>
<td>• Children (Social &amp; Behavioral Focus)</td>
<td>• Working with Elementary &amp; Secondary Schools</td>
<td>• Working with Elementary &amp; Secondary Schools</td>
<td>• Children (Social &amp; Behavioral Focus)</td>
</tr>
<tr>
<td>• Prisoners (Social &amp; Behavioral Focus)</td>
<td></td>
<td></td>
<td>• Prisoners (Social &amp; Behavioral Focus)</td>
</tr>
<tr>
<td>• Working with Elementary &amp; Secondary Schools</td>
<td></td>
<td></td>
<td>• Working with Elementary &amp; Secondary Schools</td>
</tr>
<tr>
<td>Information Privacy and Security (IPS)</td>
<td>Cooperative and Biomedical IRB Members</td>
<td>Social and Behavioral IRB Members</td>
<td>IRB Administrators</td>
</tr>
<tr>
<td>Good Clinical Practice (GCP)</td>
<td>Good Clinical Practice Course, US FDA Focus</td>
<td>N/A</td>
<td>Good Clinical Practice Course, US FDA Focus</td>
</tr>
</tbody>
</table>

Supplemental human research protection training sessions for the HSP staff are held during HSP staff meetings, and held during convened-IRB meetings for IRB members. These training sessions are not required, but are mainly conducted to enhance better understanding of regulations and policies on human research protection.
If an HSP staff or IRB member does not meet the CITI training requirements, the staff or member may not review any study.

**Investigator Required Training**

UH requires that Principal Investigators and other key personnel involved in the design or conduct of a project, including those projects that may be deemed exempt under 45 C.F.R. 46, provide evidence of training and qualifications by submitting relevant documentation as requested by the sponsor, IRB, or regulatory authorities.

Investigators must complete the required training before submitting an application for IRB review. The HSP staff checks the Investigator’s training when prescreening the Investigator’s application for review. If an Investigator does not meet the training requirements, the IRB will not approve the Investigator’s application.

PIs must submit to the IRB the names of all key research personnel (i.e., individuals involved in the development of the research design, collection of participant consent, participant data, and analysis of identifiable research data) with their training completion information in the eProtocol system. PIs must submit a modification for new personnel acquired during active review period and secure IRB approval before the new personnel can be involved in the research.

See the HSP website for detail in [training requirements on Investigators and key personnel](#) involved in human participant research.