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### 4.1 Education of Individuals Responsible for Human Subjects Research Review

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<thead>
<tr>
<th>AAHRPP Std./Element</th>
<th>Description</th>
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<tbody>
<tr>
<td>I.1.E.</td>
<td>The University of Louisville has an education program that contributes to the improvement of the qualifications and expertise of individuals responsible for protecting the rights and welfare of research participants.</td>
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</tbody>
</table>

Education and training are provided to all individuals involved with the HSPP. The HSPP Policy Manual specifies education requirements for IRB members, IRB staff, and key personnel on the research team (see Chapter 4.2).

Education is offered in many areas of research, including ethical standards, related both to research and to professional conduct, University of Louisville policies and procedures, and applicable federal, state, and local law.

The foundation of ethical training at University of Louisville is the [Belmont Report](#), which is made available at training sessions and on through the HSPPO website.

**Human Subjects Protection Program Office (HSPPO) Staff**

The HSPPO has staff dedicated to developing and providing education for IRB Chairs, IRB members, HSPPO and IRB staff, and the research community regarding human subjects’ protections.

**Evaluation of Qualifications**

In addition to receiving training on human subject research protections (described in Chapter 4.2), IRB members and IRB staff are reviewed periodically to evaluate their understanding of the HSPP (ethical principles, policies and procedures, and regulations).

IRB staff qualifications are reviewed during the hiring process and annually or as needed to ensure a high level of commitment to the HSPP.

IRB member qualifications are reviewed by the HSPPO Director or Assistant Director during the recruitment process, and IRB members are formally appointed by the Executive Vice President for Research and Innovation. IRB members, including IRB Chairs, are evaluated yearly to ensure that their service on the IRB contributes to the ethical and regulatory
review of research at University of Louisville. Feedback from these evaluations is communicated to each IRB Member and each IRB Chair. Investigators at University of Louisville are evaluated according to individual institution, school, and department policies.

Contributing to the Improvement of Expertise

New IRB members and HSPPO and IRB staff receive orientation to the University of Louisville HSPP. All IRB Chair, IRB members and HSPPO and IRB staff receive regular, ongoing training and continuing education. Opportunities for continuing education in human research protections are announced on a regular basis. IRB member and HSPPO and IRB staff attendance is encouraged at regulatory and professional meetings and conferences both locally and nationally, and for web broadcasts and seminars at University of Louisville, and in the greater community. Educational presentations and articles of interest are also presented at IRB meetings and documented in the meeting minutes. Additionally, the HSPPO supports and encourages professional certification for qualified IRB staff.

IRB staff and IRB Chairs are encouraged to take the certification examination for designation as a Certified IRB Professional. For IRB staff, job descriptions include information concerning taking the CIP exam after four years of service with the IRB.

Educational Materials and Resources

The University of Louisville research community, IRB members, HSPPO and IRB staff and other individuals responsible for the protection of human research participants have access to a wealth of educational material, available online and in printed format, or offered as courses or workshops. They include, among others:

- The HSPPO website, with links to the University of Louisville HSPP Policy Manual, instructional information, FAQs, educational material, document templates, forms, and guidances.
- Access to required training through the interactive online Collaborative Institutional Training Initiative (CITI) Course: The Protection of Human Research Subjects. This course combines human subjects protection training with HIPAA training.
- Regular and ad hoc communications from the HSPPO.
- The Research Integrity Program website.
- The IRB electronic submission system, iRIS, providing instructional text and explanation as part of the application.
- The University of Louisville Research Handbook, in particular, Chapter 9.1, Research Regulations, Human Subjects Protection Program Office.
- Access to required HIPAA training through the interactive online Collaborative Institutional Training Initiative (CITI).
- A copy of IRB: Management and Function, Robert Amdur, MD and Elizabeth Bankert, is provided to each new IRB member, and to IRB and HSPPO staff.
- A copy of Protecting Study Volunteers in Research, Cynthia Dunn, MD and Gary Chadwick, PharmD, MPM, CIP, is provided to each new IRB member, and to IRB and HSPPO staff.

Education Planning

Before the beginning of a new IRB Year (July 1), senior HSPP staff meet to design the education plan. The plan incorporates input received from IRB members, IRB staff and investigators, and from HSPPO QIP monitoring and evaluation activities. Trends in research at University of Louisville are considered, and new federal, state or local regulations (or published guidances) are integrated. Compliance activities (e.g., internal and external audits) also provide
input into the education plan, which is presented to the HSPPO Director and other senior managers for review and approval.

**Attendance at Local, Regional and National meetings**

HSPPO and IRB staff are provided the opportunity to attend a local, regional or national meeting each year. Depending upon length of service, office need, and interest, HSPPO and IRB staff may attend more than one meeting per year.

IRB Chairs and Vice Chairs and IRB members from both the Biomedical and SBE IRBs are encouraged to attend a national IRB meeting each year. Registration fees, hotel accommodations, and travel reimbursement for meals and miscellaneous expenses are provided for HSPPO and IRB staff, and Chairs, Vice Chairs and IRB members. The Executive Vice President for Research and Innovation supports attendance at these meetings.

**4.2 Required Training in Human Subjects’ Protections**

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<tr>
<th>AAHRPP Std./Element</th>
<th>Description</th>
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<tbody>
<tr>
<td>I.1.D</td>
<td>The University of Louisville has and follows written policies and procedures setting forth the ethical standards and practices of the Human Research Protection Program. Relevant policies and procedures are made available to sponsors, researchers, research staff, research participants, and the Institutional Review Board, as appropriate.</td>
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</table>

Completion of human subject training by all staff working on a research project (all investigators and other study personnel, including all persons who are responsible for the design, conduct, data analysis or reporting) is one of the requirements for protocol approval by the IRB. Principal Investigators (PIs), as part of the protocol submission process, acknowledge their obligation to protect the rights and welfare of research participants.

University of Louisville provides access to the required training through an interactive online tutorial - CITI (Collaborative IRB Training Initiative) Course in The Protection of Human Research Subjects. CITI offers a basic (initial) course and then a refresher course which must be taken every four years.

Electronic feeds of course completion information from CITI are received by University of Louisville four times per day. Training records of IRB Chairs and Members, HSPPO and IRB staff, and Institutional Officials are also maintained through the Research Integrity Program and feed into the IRB electronic submission system.

It is the responsibility of the PI to ensure 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 completion available.

**HSPPO and IRB Staff Required Training**

- **IRB Staff** = HSPPO Assistant Director (as IRB Administrator), IRB Analysts, and IRB Administrative Assistant.
- **HSPPO Staff** = HSPPO Director, HSPP education and training staff, HSPPO compliance staff, and records and documentation staff.

<table>
<thead>
<tr>
<th>Training</th>
<th>IRB Staff, HSPPO Staff</th>
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<tr>
<td>HSPPO orientation for new HSPPO staff</td>
<td>Required</td>
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<tr>
<td>HSPPO Orientation for new IRB staff</td>
<td>Required</td>
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<tr>
<td>Combined Human Subjects Protection and HIPAA Tutorial (CITI)</td>
<td>Required</td>
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<tr>
<td>Continuing HSPP education</td>
<td>Required</td>
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For newly hired HSPPO or IRB staff, **HSPP Orientation** is a process managed by the HSPPO Director or Assistant Director. **Combined CITI HSP and HIPAA training** must be completed within 30 days of employment in HSPPO, and must be renewed every four years.

### IRB Member Required Training

<table>
<thead>
<tr>
<th>Training</th>
<th>Medical IRB Members and Chairs</th>
<th>SBE IRB Members and Chairs</th>
<th>Ex-Officio IRB Members</th>
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<tbody>
<tr>
<td>HSPP orientation for new members</td>
<td>Required</td>
<td>Required</td>
<td>If needed</td>
</tr>
<tr>
<td>Combined HSP and HIPAA Tutorial (CITI)</td>
<td>Biomedical Track required</td>
<td>SBE Track required</td>
<td>Biomedical or SBE, required</td>
</tr>
<tr>
<td>Combined HSP and HIPAA Continuing education (CITI Refresher course)</td>
<td>Required</td>
<td>Required</td>
<td>Required</td>
</tr>
<tr>
<td>IRB Chair Roles &amp; Responsibilities</td>
<td>Required for Chairs</td>
<td>Required for Chairs</td>
<td>Not required</td>
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### Institutional Officials Required Training

Institutional officials at University of Louisville University must take CITI Institutional Official modules. If an institutional official is also an investigator or an IRB member, additional CITI modules would be required.

### Investigator Required HSP Training

University of Louisville requires that PIs and other key personnel involved in non-exempt research projects to provide evidence of human subjects and HIPAA training.

The IRB training requirement applies to individuals working under the auspices of University of Louisville, whether at University of Louisville facilities or at another location, and regardless of their institutional affiliation or source of funding. In the event that individuals from other institutions (“third-party” or contract employees) conduct research under the auspices of University of Louisville, they must complete human subjects’ protections training, but may do so at their home institution. A letter, certificate, or email notification by a representative from their home institution will satisfy this requirement. For example, when the University of Louisville is the IRB of Record (IOR) for another institution, and an IRB Authorization Agreement has been signed, individuals from the relying institution may provide proof of training (as noted above) to satisfy the training requirement. Similarly, new University of Louisville employees can meet the training requirement if they have completed human subjects’ protections training at their prior institution within the applicable timeframe. Third-party individuals and new University of Louisville employees may also take the University of Louisville CITI modules, if desired.

Key personnel are research personnel who are directly involved in conducting the research with human subjects through an interaction or intervention for research purposes, including participating in the consent process by either leading it or contributing to it; OR who are directly involved with recording or processing identifiable private information, including protected health information, related to those subjects for the purpose of conducting the research study.