

Education of Individuals Responsible for Human Research

SOP 117
Revised: February 12, 2019

Purpose and Scope

This SOP describes the education and training provided for and required by all individuals involved with the HRPP, and the HRPP material provided for Investigators, Research Staff, individuals involved in reviewing and approving human subjects research.

Procedures

HRPP Materials

The General Policy Manual (GPM) specifies education requirements for Institutional Review Board (IRB) members, IRB staff and key personnel on the research team. The Human Studies Program (HSP) works with the University of Hawai'i (UH) schools and departments and other institutions, to offer comprehensive education to the UH research community.

The HSP posts its GPM, SOPs and other policies, procedures, and guidance on the HSP [website](#); distributes them to the UH research community through presentations, training and educational sessions, and email communication via listserv or other electronic methods, in addition to the website. All IRB members will receive a copy of all SOPs and other policies and procedures during their initial training.

Required Training

- A. **For Investigators.** See the HSP website for detail in [training requirements on investigators and key personnel](#) involved in human subjects research.
 - a. Investigators must complete the required training before submitting an application for IRB review.

- B. **For HSP Staff and IRB Members.** HSP staff and IRB members must take the training The Human Subjects Research Program for IRB Administrators and for IRB Members, respectively, hosted by CITI. Additionally,
 - a. Training sessions for the HSP staff may be held during HSP staff meetings.
 - b. Training sessions for IRB members may be held during convened-IRB meetings.
 - i. Prior to assuming responsibility as a voting member of the IRB, newly appointed IRB members will:
 - 1. Attend an orientation for new IRB members,
 - 2. Receive copies of relevant policies and procedures and other documents appropriate to their role.

- C. **Continuing Education.** All investigators, HSP staff, and IRB members must complete the CITI refresher course every three (3) years. Continuing education also includes education sessions held on campus or online, or professional training opportunities on human research protections (e.g., PRIM&R).
- D. **Monitoring of Training.**
- a. The Director keeps records on training of all staff and IRB members, including completion and expiration dates.
 - b. The HSP staff checks the investigator's training when prescreening the investigator's application for review.
- E. **If Training Requirements Not Met.**
- a. If an investigator does not meet the training requirements, the IRB will not approve the investigator's applications for review.
 - b. If an HSP staff or IRB member does not meet the training requirements, the staff or member may not review any study.

Elective Training

The **PRISM Online Training** is an hour long online tutorial developed for researchers, research staff, and IRBs that include topics of readability and literacy, gain useful skills when creating or reviewing consent forms and other research participant materials. To supplement, the PRISM Readability Toolkit can be found in the Policies & Guidance section

References

- The Organization 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. (**AAHRPP Element I.1.E**)