
Yale University Human Research Protection Program

800 PR.1 Human Research Training, Orientation and Education

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Overview

Persons who take part in the design, conduct and reporting of human research or who are responsible for the review and oversight of human research protocols are required to understand the ethical principles and federal, state and institutional requirements related to human research and to stay abreast of emergent issues and thinking related to their unique roles in the protection of human research participants.

This procedure outlines the procedure for meeting the training, orientation and continuing education requirements of individuals involved in the design, conduct and ethical review and/or oversight of non-exempt human research including Institutional Signatory Official (IO), Human Protection Administrator, research investigators, research personnel, Institutional Review Board (IRB) Chairs, members and staff.

Initial Training and Orientation

Institutional Signatory Official/Human Protections Administrator

The Yale Institutional Signatory Official and Human Protections Administrator must complete the Human Subject Assurance training Modules I through III that are produced by the Office for Human Research Protection (ORHP) (see <http://www.hhs.gov/ohrp/education/training/introduction.html>). Documentation of this training entered into the Training Management System (TMS).

Investigators and Research Staff

All researcher personnel must complete the Human Research Protection Program (HRPP) and a Good Clinical Practice Training either by completing the Yale HRPP Training, the National Institute of Health (NIH) Protecting Human Research Participants course, or the Collaborative Institutional Training Initiative (CITI) web-based training program or an educational program deemed comparable by the Yale IRB before taking part in the conduct of human research (see <http://www.yale.edu/hrpp/education/index.html> for links to training). In addition, completion of the Yale Health Insurance Portability and Accountability Act (HIPAA) Privacy Training for Researchers or comparable program is required for all research team members conducting research within or representing the Yale School of Medicine, Yale School of Nursing, Yale Psychology Department clinics and Yale Health (see <http://hipaa.yale.edu/training>).

Institutional Review Board (IRB) Members and Staff

All new IRB members must complete an orientation regarding their roles and responsibilities in the review of research prior to their participating as a voting member of an IRB. Orientation is conducted by an IRB Chair, or designee, and encompasses the following areas and member responsibilities: ethical foundations of IRB review; application of ethical principles to IRB review; Yale IRB and Human Research Protection policies and procedures; federal regulations (45 CFR 46,) and guidance and state law; review criteria as set forth in 46 CFR 111; website information and resources; types of IRB review; review procedures and expectations; data safety and security; economic considerations related to study participation; adverse event and unanticipated event considerations; conflict of interest and protocol violations/noncompliance; secondary use of data; and organization of Yale IRBs.

For biomedical IRBs, orientation also includes information on HIPAA requirements (45 CFR 164); FDA regulations (21 CFR 50 and 56); emergency use; investigational drugs and devices (IND/IDE) (21 CFR 312 and 812); clinical trials registration; multi-center trials; data and tissue repositories; research partners; and Certificates of Confidentiality (CoC) Orientation may be scheduled individually or in groups, as necessary. Members are provided with written materials to support the learning/orientation objectives.

IRB Chairs and IRB staff are required to complete human research protection training and HIPAA Privacy training for researchers as part of their employee orientation. IRB Chairs should also complete the OHRP Human Subject Assurance

Training Modules. IRB staff are provided with an orientation which includes materials to support their work, including an explanation of staff responsibilities as outlined in their job description and performance assessment, decision charts, glossaries, 45 CFR 46, 21 CFR 50 and 56 (where appropriate), checklists to aid in review of protocols, and information on IRB submission and meeting schedules and other applicable regulations. Other materials may be included as deemed appropriate by the Chair or IRB Manager.

Continuing Education

An active, ongoing HRPP training program is maintained for the research community, offering a broad range of topics in a variety of venues so that individuals can complete their continuing education requirements.

Research personnel working on active human research studies are required to complete a HRPP and GCP training offering at least once every three years to stay current in issues and regulations regarding human research. IRB members and staff must participate in continuing education.

Investigators and Research Staff

Completion of one Yale Human Research Resource and Education Program module, one CITI module, attendance at one large group session or student group/department session, or attendance at a small group administrative session fulfill the requirement for continued education.

Examples of continuing education offerings that would satisfy the continuing education requirement include:

1. The Yale Human Subject Research Resource and Education Program, which is a seven module, web-based educational offering that outlines the ethical foundations underlying the responsible conduct of research. Learning objectives include critical points that must be considered by investigators when preparing a protocol, conducting research, and when completing or terminating a research study. The roles of the Institutional Review Board, government agencies, research sponsor, and other entities providing oversight of human research are also described.
2. Large group educational sessions that are offered by the HRPP and YCCI on topics affecting protocol design, conduct and review. Education topics are determined by the IRB Chairs, Human Research Protection Program (HRPP) Director, the Education and Training Manager or others or as requested by researchers, Course offerings are available through the [Yale](http://www.yale.edu/training/) training website, <http://www.yale.edu/training/>.
3. The Collaborative Institutional Training Initiative (CITI), which was developed by bioethicists and other human research professionals, offers a large and diverse selection of human research educational modules.
4. Small group sessions conducted twice each month on topics of administrative interest to researchers and are related to the investigators' protocol submissions and working with IRB processes.
5. On-site sessions conducted upon request for student groups, departments and others who contact the IRB. Requests may be made by emailing hrpp@yale.edu.
6. Annual sessions on conducting human research presented to undergraduates, graduate students, medical students, and Public Health students.

IRB Members and Staff

In addition to the educational opportunities for research staff, continuing education offerings are made available to IRB members and staff for completing their continuing education requirements include:

1. Educational meetings that are scheduled twice a year in months in which there is a fifth Wednesday. The sessions explore emerging issues, introduce new developments in human research protections or discuss new or potential policies. Meeting format varies depending on content of the presentation, and may include a panel discussion, video presentation, or an individual speaker. Presenters from outside of Yale and/or the IRB membership are frequently sought. As appropriate, researchers, University leadership, students, IRB staff, representatives from Yale's Research Partners and community representatives are also invited to attend.
2. Periodic review of publications (such as *IRB Ethics & Human Research*) and articles of interest and relevance from both professional publications and the popular press are distributed at the meeting or with the materials made available to members for meeting preparation, Discussion regarding the information may be led by the Chair, HRPP Director, or other appropriate staff member during the IRB meeting.

3. Expanded discussion and education regarding specific areas of regulation, law or ethics occur during IRB meetings in an effort to educate members on information required to perform their role as an IRB member. The IRB Chairs, Directors or staff may facilitate these discussions.
4. Each month an *IRB Infoshort* is presented to each committee. The Infoshort provides education for members on regulatory or IRB administrative requirements.
5. Invitations that are extended to the human research community to attend State and regional conferences on topics of relevance, webinars, and to attend the Public Responsibility in Research and Medicine (PRIM&R) annual meeting. Costs for a subset of staff to attend conferences and seminars is budgeted annually and paid for by the University.

IRB Chairs, Institutional Signatory Official, Human Protections Administrator

IRB Chairs, the Institutional Signatory Official and the Human Protections Administrator have the responsibility to remain current with developments in the field of human research protections. Attendance at local, regional and national conferences, networking with peers at other institutions, review of the literature, and review of issues presented in the lay press all serve to maintain currency. These leaders are expected to participate in conferences and peer networking on a regular basis. The University provides budgetary support for journal subscriptions and conference attendance.

Documentation

Training records are maintained in Yale's Training Management System (TMS). Completion of training is made available to the research team and verified by the IRB staff at the time of protocol submission.

Non Compliance with Training Requirements

Yale investigators on active human research studies are sent automated reminder emails prior to expiration. At the time of the next IRB submission, IRB staff verify compliance with the requirement. If the Principal Investigator is non-compliant, the submission will be rejected, and must be re-submitted once the requirement has been met. If other research personnel on the study are noncompliant, they will be removed from the protocol, and an amendment to add them must be submitted when training is complete. Those research personnel removed from the protocol will be sent an email notifying them that they must submit to the IRB a list of all research studies on which they are active, so that they may be removed from the studies, and only added back once training is complete and a personnel amendment for each study has been received.

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