
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 stay current with emergent issues and thinking related to their unique roles in the protection of human research participants.

This procedure outlines the requirements for the training, orientation and continuing education of such individuals involved in the design, conduct and ethical review and/or oversight of non-exempt human research including Institutional Signatory Official (IO), Human Protections Administrator, research investigators, research personnel, 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 of Human Research Protection (ORHP). Documentation of this training is kept on file by the Education and Training Manager.

Investigators and Research Staff

All researcher personnel must complete the Human Research Protection Training either by completing the Yale Human Research Protection Training 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. In addition, completion of the Yale 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 University Health Services research.

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, Director 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; FDA regulations (21 CFR 50 and 56); Federal regulations 45 CFR 164 (if applicable); emergency use; investigational drugs and devices (IND/IDE); clinical trials registration; multi-center trials; data and tissue repositories; research partners; and Certificates of Confidentiality

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 for researchers training 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 written materials to support their work, including an explanation of staff responsibilities as outlined in their job description and performance assessment, decision charts, glossaries, a copy of 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. Other materials may be included as deemed appropriate by the Chair or Director.

Continuing Education

An active, ongoing human research protection 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 are required to complete a human research protection 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 two small group administrative sessions 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 quarterly on topics affecting protocol design, conduct and review. Education topics are determined by the IRB Chairs, Directors or others or as requested by researchers, Course offerings are available through the HRPP web site www.yale.edu/hrpp.
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 medical students, Robert Wood Johnson Clinical Scholars 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, 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. These discussions may be facilitated by the IRB Chairs, Directors or staff.

4. Invitations that are extended to the human research community to attend State and regional conferences on topics of relevance, 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

Researchers who have no documentation of training are not permitted to take part in the research until such time as all required HSP training is completed.

References:

OHRP Terms of the Federalwide Assurance, #13
IRB Policy 800, Orientation and Education of IRB Members