
Yale University Human Research Protection Program

HRPP Policy 800 Human Research Protection Orientation, Training and Education

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Responsible Official	Director, Human Research Protection Program	Last Revision	12/11/17

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Scope

This policy defines the orientation, training, and/or education programs required for Institutional Review Board (IRB) members, staff, and research personnel. The policy applies to all individuals who serve as members of the research team and/or who participate in the design, conduct, ethical review and/or oversight of Yale human research.

Policy Statement

All individuals who serve as members of the research team and/or who participate in the design, conduct or ethical oversight of non-exempt human research as described in *IRB Policy 100, IRB Review of Research Protocols*, are required to demonstrate knowledge of the relevant ethical principles and federal, state and institutional requirements related to such research, appropriate to their role and obligations in human research.

The University's Human Research Protection Program will facilitate awareness and understanding of human research obligations by maintaining an orientation, training, and education program, which provides for the initial as well as continuing education on matters relevant to human research.

Reason for the Policy

A sound understanding and working knowledge of the relevant ethical principles, legal and regulatory requirements, professional standards, and University policies, procedures and guidance, is needed by persons involved in the design, conduct, review and/or oversight of human research conducted or supported by Yale University. Such individuals also are obligated to stay current with evolving issues related to the conduct of human research and the protection individuals who choose to participate in such research. This policy helps to ensure that research personnel, IRB members and staff and other persons charged with the protection of research participants receive and maintain the training and education necessary to fulfill their obligations in the research enterprise.

Definitions

Engagement in Research

An individual is considered engaged in human research when he/she for the purposes of the non-exempt research project, obtain: (1) data about the subjects of the research through intervention or interaction with them; (2) identifiable private information about the subjects of the research; or (3) the informed consent of human subjects for the research. An institution is considered engaged when its employees or agents conduct the above activities, or when the institution receives a direct federal award to conduct human subject research, even when all activities involving human subjects are carried out by a subcontractor.

Human Research

Projects that meet the definitions of both "research" and "human subject".

Human Subject or Human Participant

45 CFR 46 (Common Rule definition) –

“A living individual about whom an investigator (whether professional or student) conducting research obtains either (1) Data through intervention or interaction with the individual; or (2) identifiable private information.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction includes communication or interpersonal contact between investigator and subject.

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

21 CFR 50.3(g) and 21 CFR 56.102(e) (Food & Drug Administration definition) –

An individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient.

Research

45 CFR 46.102(d) (Common Rule – Subpart A) –

“A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities, which meet this definition, constitute research for purposes of this policy, whether or not they are conducted or supported under a program, which is considered research for other purposes.

21 CFR 50.3(g) and 21 CFR 56.102(e) (Food & Drug Administration) –

Any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act, or is not subject to requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The term does not include experiments that are subject to the provisions of part 58 of this regulation, regarding nonclinical laboratory studies.

Policy Sections

800.1 Initial Human Research Protection Training

All individuals who serve as members of the research team and/or who participate in the design, conduct or ethical oversight of non-exempt human research shall complete training relevant to their role, as described in IRB Procedure 800 PR1 Human Research Protection Training, Orientation and Continuing Education. Training must be completed prior to their participating as a research team member. To ensure IRB members and staff have the knowledge, skills and ability required to carry out their responsibilities, training or orientation is required prior to participating in IRB review and/or any other IRB activities.

800.2 Continuing Human Research Education

Continuing education is required at least every three years for individuals involved in the design and conduct of active, non-exempt human research studies and every year for IRB chairs, IRB members and IRB staff. Appropriate continuing education is described in IRB Procedure 800 PR1, Human Research Protection Training, Orientation and Continuing Education.

800.3 Department of Defense (DoD)-funded Studies

Specific educational requirements or certification may be required by the DoD for investigators conducting studies they fund.

The DoD may evaluate Yale education policies to ensure researchers working on DoD-funded studies are qualified to perform the research, based on the complexity and risk level of the study.

Related Information

HRPP Policy 900: Recruitment, Appointment, Terms and Evaluation of IRB Members and Chairs

800 PR.1 Human Research Education Procedure

Contacts

Subject	Contact	Phone
Training and Education	Education and Community Outreach Manager	203-785-4688
Oversight of Training, Education, Orientation and Continuing Education	Education and Community Outreach Manager Institutional Review Board (IRB) Chair(s)	203-785-4688

Roles and Responsibilities

Education and Community Outreach Manager:

Responsible for the identification, creation, and maintenance of orientation and other materials used for initial training, in consultation with IRB Chairs and HRPP Director and HRPP managers. Responsible for the development and implementation of continuing education programs for the research community and for IRB members and staff in consultation with IRB Chairs and HRPP Director and HRPP managers.

[Human Research Protection Program \(HRPP\)](#)

The Human Research Protection Program is responsible for oversight of human research protection through ongoing education, monitoring, and evaluation of all parties involved in the conduct of human research.

Human Investigation Committee (HIC)

The HIC I-Oncology, HIC II, HIC III and HIC IV serve as the four Institutional Review Boards or IRBs for biomedical human research conducted at Yale University.

Human Subjects Committee (HSC)

The HSC serves as the Institutional Review Board for social, behavioral and educational human research at Yale University.

IRB Chair:

Responsible for conducting or ensuring the appropriate orientation of new IRB members and the availability of continuing education for IRB members and staff. Responsible for conducting education on issues arising during IRB review of specific protocols. Responsible for overseeing the training and orientation program.

Revision History

Modified 3/4/2013, 12/11/17