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# Yale University Human Research Protection Program

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## HRPP Policy 800 Human Research Protection Orientation, Training and Education

Responsible Office	Office of Research Administration	Effective Date	
Responsible Official	HRPP Director	Last Revision	11/10/09

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### Scope

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

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### 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, 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 help to ensure that knowledge is obtained and practiced by maintaining an orientation, training, and education program which provides for the initial as well as continuing education on matters relevant to human research.

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### 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.

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### 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**

A living individual (1) about whom an investigator (whether professional or student) conducting research obtains either (a) data through intervention or interaction with the individual; (b) identifiable private information; or (2) who is or becomes a participant in research involving drugs or devices, either as a recipient of a test article or as a control. Note that both human subject and human participant are used interchangeably in IRB policies and procedures. While the term “participant” conveys the voluntary nature of an individual's agreement to participate in the research, it also can convey a sense of partnership which is not reflected in all types of research. In some cases, the research volunteer is in fact more acted upon than truly having any sense of partnership in the research. Hence the term subject is considered more appropriate in such cases.

## **Research**

A clinical investigation or a systematic investigation, including research and development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

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## **Policy Sections**

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### **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.

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### **800.2 Continuing Human Research Education**

Continuing education is required at least every three years for individuals involved in the design and conduct of non-exempt human research 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.

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## **Related Information**

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

800 PR.1 Human Research Education Procedure

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## Contacts

Subject	Contact	Phone
Training and Education	Education and Community Outreach Manager	203-785-4688
Oversight of Training, Education, Orientation and Continuing Education	IRB Chair/Director	203-785-4688

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## 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/Directors and HRPP administrators. 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/Directors and HRPP administrators.

### **IRB Chair/Director:**

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.