

Policy 1360

Human Research Protection

Responsible Office	Office of Research Administration	Effective Date	5/21/07
Responsible Official	Associate Vice President for Research Administration	Last Revision	6/10/10

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Scope

This policy applies to all University personnel who conduct research involving human subjects and to the members and staff supporting the Yale University Institutional Review Boards.

Policy Statement

The University maintains an integrated human research protection program (HRPP) under the oversight of the Associate Vice President for Research Administration to ensure the protection of human subjects who participate in research projects conducted under the auspices of the University. The program ensures that (1) the rights and welfare of the research subjects are protected effectively, (2) the risks to subjects are reasonable when considering the potential benefits of the research, (3) the selection of subjects is equitable, and (4) informed consent will be obtained and, when appropriate, documented. Further, the program assures compliance with federal regulations and with ethical standards for research involving human subjects.

University personnel involved in human research are required to submit research protocols for review and approval to the relevant Institutional Review Board (IRB). Human research protocols cannot commence without approval or exemption determination by the IRB.

The University recognizes, however, that the protection of human subjects participating in research transcends traditional department jurisdictions and is not the sole responsibility of the IRB. The University therefore extends the HRPP to incorporate investigator and departmental oversight responsibilities to allow for an integrated program for research subject protection initiatives as they relate to the individual and the unit's core function in supporting the research enterprise. Other institutional offices and committees involved in research oversight and administration may include, but are not limited to, Grant and Contract Administration, Office of the Provost, Office of Research Compliance and Education, University Conflict of Interest and Conflict of Commitment Committee, the Yale Center for Clinical Investigation, the Yale Cancer Center, the Pediatric Protocol Review Committees and departmental representatives.

Reason for the Policy

- To ensure that the rights and welfare of human research participants are protected in all research conducted under the auspices of Yale University.

- To define the responsibilities of University investigators in conducting research involving human subjects in accordance with state and local laws, federal guidance and regulations, the University's Federalwide assurance and other University policies on ethical conduct of research.
- To define the review, approval and oversight responsibilities and authority of the University Institutional Review Boards (IRBs), the Human Subjects Protection Administrator (HPA) and the Institutional Official (IO) for the ethical conduct of research involving human subjects which the University has included in its human research protection program.
- To define the human subject protection responsibilities of other University departments, committees or individuals charged with research oversight and/or administration.

Definitions

Research

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

Human Subject

A living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information, or an individual who is or becomes a participant in research, either as a recipient of a test article or as a control.

Institutional Review Board

A University committee established in accordance with 45CFR46 which is designated by the University to protect the rights and welfare of subjects who participate in research.

Policy Sections

The Yale University Human Research Protection Program (HRPP) involves the cooperative interaction of offices and individuals within the University which are involved in research involving human subjects.

1360.1 Institutional Official

The Associate Vice President for Research Administration is the Institutional Official responsible for oversight of the human research protection program and serves as the signatory official on the Yale Federalwide Assurance filed with the Department of Health and Human Services Office of Human Research Protection (OHRP). The Institutional Official appoints members of the IRBs and ensures that the IRBs retain autonomy and remain free from undue influence on their decision making. The Institutional Official must be informed of any allegation of undue influence on the IRB or its staff. Upon learning of the allegation, the Institutional Official will assign an appropriate person, based on the nature of the allegation, to investigate and make recommendations for resolution or corrective action.

The Institutional Official maintains regular communication with the IRBs, including reports of serious or continuing non-compliance with IRB requirements and any other emergent issues. The Institutional Official shall ensure that adequate resources are provided to the components of the HRPP to perform their respective functions.

1360.2 Human Protections Administrator

The Human Protections Administrator (HPA) is responsible for oversight and day-to-day management of the HRPP. The HPA ensures that IRB policies, procedures and practices are compliant with University policies, federal regulation and state law requirements. The HPA

provides guidance to the IRBs on emergent issues and ensures consistency across the University IRBs.

1360.3 Institutional Review Boards

The University maintains Institutional Review Boards (IRBs) which are charged with the review and continuing oversight of research involving human subjects, in accordance with University policies and federal regulations. The IRBs have the authority to:

- grant exemptions from IRB review;
- determine when projects are not considered to require IRB review;
- approve, disapprove, or require modifications to research protocols;
- monitor or observe the consent process and/or conduct of the research to ensure that the rights and welfare of research participants are adequately protected; and
- suspend or terminate approval of research not being conducted in accordance with the IRB's requirements or research that is associated with unexpected serious harm to research participants.

Approval by other institutional bodies cannot substitute for IRB approval. IRB disapprovals may not be superseded by other institutional authorities although studies which receive IRB approval may be deemed inappropriate for conduct at the University by other institutional authorities.

Note: IRB membership and practices are described in the University's HRPP policies and procedures.

1360.4 Investigator Responsibilities

University faculty, staff, fellows, students and trainees involved in the design, conduct or analysis of human research are responsible for ensuring adequate subject protection in the course of their interactions with subjects and/or their data. Investigators must submit human research protocols to the IRB for approval or other determination pursuant to IRB policies and/or procedures prior to commencing the research.

Investigators shall maintain IRB approval for the lifespan of the project and shall submit continuing review documents to the IRB as necessary to maintain the approval. Research staff shall adhere to the approved protocol except when non adherence is necessary to minimize a threat to the health and safety of the participants. Performing human research in violation of the approved protocol or without IRB approval is a serious breach of conduct and is subject to disciplinary action up to and including termination.

1360.5 Role of Other Institutional Offices or Committees Involved in Research Oversight

Other offices or committees that oversee University research are responsible for considering the rights and welfare of human subjects participating in Yale studies when developing and carrying out their core functions supporting the research, including their own compliance responsibilities. These entities are responsible for integrating their core business processes and/or responsibilities into the University's human subject protection program.

Related Information

[Human Investigation Committee](#) (Biomedical IRBs)

[Human Subjects Committee](#) (Social, Behavioral and Educational IRB)

Procedure 3417 PR.01 [Human Research Study Participant Remuneration](#)

[Information Technology](#) and [HIPAA](#) Security Policies

Contacts

Subject	Contact	Phone
Institutional Official	Associate Vice President for Research Administration	203-432-0108
Biomedical IRB	Human Investigation Committee	203-785-4688
Social, Behavioral and Educational IRB	Human Subjects Committee	203-785-4688

Roles and Responsibilities

Office of Research Administration

Oversees and disseminates University requirements related to the human subjects protections program. Appoints the Chair and members of the IRBs, serves as the Institutional Official for University Federalwide Assurance and ensures that resources are appropriately allocated to the IRBs to carryout their responsibilities and authorities.

Ensures compliance with ethical principles and federal laws and guidance, state and local laws and University policy through interpretation and advice on regulatory requirements.

Office of the Provost

Provides counsel to the HRPP regarding policies, emergent issues and other matters related to academic activities and the protection of research volunteers.

IRB Leadership Committee

Provides oversight and guidance to the IRBs. Reviews and approves institution-wide IRB policies, procedures and practices. Assists in determining appropriate University responses or positions to emergent IRB issues.

University Research Compliance Committee

Facilitates coordinated responses to human research protections issues which involve multiple research compliance units.

Office of General Counsel

Interprets human subjects protection regulations and assists in ensuring that agreements between Yale and parties external to the University, which involve human subjects, require the ethical conduct of human subject research.

Office of Research Compliance and Education

Ensures University compliance with federal regulations, state and local laws, and University policy through assessments. Provides interpretation and advice on regulatory requirements, develops policy and provides educational opportunities for the community addressing sponsored project requirements.

Office of Grant and Contract Administration

Structures relationships and agreements with external parties which fund research at the University, such as federal agencies, foundations, and for-profit corporations. Ensures agreements are consistent with University requirements related to the ethical conduct of research. Ensures that research grant and contract funds are not expended for human subjects research which has not been approved by one of the Yale University IRBs. Ensures that the terms of the clinical trials agreements do not conflict with the IRB approved protocols.

Institutional Review Boards (HIC, HSC)

Reviews, approves, and provides continuing oversight of research involving human subjects. Ensures the protection of human subjects in the design and conduct of human subject research through dissemination of guidance, training and monitoring activities.

Research Personnel

Develop and submit research protocols involving human subjects to the IRB for review. Adhere to IRB requirements, federal, state and institutional rules and regulations related to research involving humans and, if applicable, to the Good Clinical Practice Guidelines as adopted by the Food and Drug Administration (FDA) for the conduct of human subjects research.

Information Security Office (ISO)

Assures appropriate technical, physical and administrative policies and safeguards are implemented to secure the creation, access, transmission and receipt of protected or restricted information, including electronic Protected Health Information (PHI). The ISO provides guidance to the research community related to compliance with University IT and HIPAA security policies.

Biological Safety Committee (Institutional Biosafety Committee, IBC)

Reviews scientific and safety aspects of research involving gene transfers, human pathogens and other biologic agents.

YNHH Radioactive Drug Research Committee (RDRC)

Oversees the use of radioactive materials to be used in human subjects prepared at the Yale Medical Center which require neither an Investigational New Drug (IND) nor Food and Drug Administration (FDA) approval

Pediatric Protocol Review Committee (PPRC)

Reviews the scientific aspects of all research conducted at the Yale School of Medicine that involves children with the exception of Pediatric Oncology, which is reviewed by the Protocol Review Committee noted below.

Protocol Review Committee (PRC)

Reviews the scientific aspects of oncology or cancer-related research trials that are conducted by researchers from the School of Medicine and, as appropriate, from the School of Nursing.

Yale Center for Clinical Investigation (YCCI)

Participates in the review of research that is fully or partially supported with YCCI funds. The scientific aspects of research supported by the YCCI may be reviewed by the YCCI's Science and Safety Committee (SSC).

Committee on Conflict of Interest and Conflict of Commitment

Collaborates with the IRB in review of protocol-specific conflict of interest disclosures to ensure that conflicts are either reduced, managed or eliminated.

Departmental Research Administrators

Responsible for departmental adherence to University policies related to human subject research and adherence to funding agency requirements.

Revision History

New Policy issued on 5/21/07. Revised on 8/20/07, 11/4/09, 2/5/10, 5/01/10, 6/10/10

A draft version was posted on the draft site on 4/20/07 for 30 day comment period.

The official version of this information will only be maintained in an online web format. Any and all printed copies of this material are dated as of the print date. Please make certain to review the material on-line prior to placing reliance on a dated printed version.
