

Policy 1360 Human Research Protection

Responsible Office	Office of the Provost	Effective Date	5/21/07
Responsible Official	Associate Vice President, Research Administration	Last Revision	11/4/09

Policy Sections	2
1360.1 Institutional Official.....	2
1360.2 Human Protections Administrator	2
1360.3 Institutional Review Boards	2
1360.4 Investigator Responsibilities	3
1360.5 Role of Other Institutional Offices or Committees Involved in Research Oversight.....	3

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, Research Administration to ensure the protection of human subjects who participate in research projects conducted under the auspices of the University. The program ensures (a) 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 subject research are required to submit research protocols for review in accordance with the relevant Institutional Review Board (IRB) policies and/or procedures. 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 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, the Office of Grant and Contract Administration, Office of Research Administration, Office of Research Compliance and Education, University Conflict of Interest and Conflict of Commitment Committee, the General Clinical Research Center, the Yale Cancer Center, Pediatric Protocol Review Committees, Yale Center for Clinical Investigation, 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, University's federal-wide 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 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 the 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 Deputy Provost for Biomedical and Health Affairs is the Institutional Official responsible for oversight of the human research protection program and serves as the signatory official on the Yale Federalwide Assurance with the Department of Health and Human Services Office of Human Research Protection (OHRP). The Institutional Official shall appoint members of the IRBs. 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 the University IRB Operations Manual and federal regulations. The IRBs have the authority to grant exemption from review, determine when projects are not considered to require IRB review, approve, disapprove, require modification in research protocols and to monitor research to ensure that the

rights and welfare of research participants are adequately protected. 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. IRB membership and practices are described in the University IRB Operations Manual and Policies.

1360.4 Investigator Responsibilities

University faculty, staff, fellows, students and trainees involved in the design, conduct or analysis of human subject research are responsible for ensuring adequate subject protection in the course of their interactions with subjects and/or data. Investigators may not commence such research activities prior to review and approval or granting of exemption of the project by the appropriate University IRB. 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 in instances which pose a threat to the health and safety of the participants. Conduct of human subjects 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

Responsible for providing ethical consideration for the rights and welfare of human subjects participating in Yale studies when developing and conducting formal business processes relating to their core function in supporting the research, including their own compliance responsibilities. Ensure that core business processes or responsibility integrate into the University's human subject protection program.

Related Information

[Human Investigation Committee](#) (YSM)

[Human Subjects Committee](#) (FAS, Schools of Forestry and Environmental Studies, Management, Law, Divinity, Art, Architecture, Drama and Music)

[Human Subjects Research Review Committee](#) (YSN)

Procedure 3417 PR.01 [Payment to Research Study Subjects](#)

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

Contacts

Subject	Contact	Phone
Institutional Official	Deputy Provost for Biomedical and Health Affairs	203-432-4446
YSM IRB	Human Investigation Committee	203-785-4688
FAS IRB	Human Subjects Committee	203-436-3650
YSN IRB	Human Subjects Research Review Committee	203-737-2371

Roles and Responsibilities

Office of the Provost

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

IRB Leadership Committee

Provides oversight and guidance to the IRB's. 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 Administration

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 Grant and Contract Administration

Responsible for structuring relationships and agreements with external parties who fund research at the University, such as federal agencies, foundations, and for-profit corporations. Ensure agreements are consistent with University requirements related to the ethical conduct of research. Ensure 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. Ensure that the terms of the clinical trials agreements do not conflict with the IRB approved protocols.

Institutional Review Boards (HIC, HSC, HSRRC)

Responsible for the review, approval, and continuing oversight of research involving human subjects. Ensure the protection of human subjects in the design and conduct of human subject research through dissemination of guidance, training and monitoring activities.

Research Personnel

Responsible for the development of research protocols involving human subjects, submission of such protocols to the IRB for review and for adhering 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)

Responsible for assuring that 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 PHI. The ISO provides guidance to the research community related to compliance with University IT and HIPAA security policies.

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

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 research trials conducted at the Yale Cancer Center.

General Advisory Committee (GAC)

Reviews the scientific aspects of all research conducted at the General Clinical Research Center.

Committee on Conflict of Interest and Conflict of Commitment

Collaborates with IRB in review of protocol specific conflict of interest disclosures and development of conflict management plans

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. Modified on 8/20/07. Policy first issued on 5/21/07. 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.
