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# Yale University Human Research Protection Program

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## HRPP Policy 930 Development, Approval and Maintenance of Human Research Protection Program Policies and Procedures

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Responsible Office	Office of Research Administration	Effective Date:	5-21-2006
Responsible Official:	Human Protections Administrator	Last Revision	11-21-2009

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**Policy Sections** ..... 1

    930.1 Human Research Protection Policies ..... 1

    930.2 Institutional Review Board (IRB) Policies ..... 2

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### Scope

This policy describes the ways in which Yale Human Research Protection Program (HRPP) policies and procedures are developed, approved and maintained.

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### Policy

Written policies and procedures describing the requirements and practices related to the conduct and review of human research and the protection of research participants are developed and maintained by the Yale HRPP in congruence with Federal regulations, State and local laws, University policy and standards of regulatory, accrediting, and funding agencies.

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### Reason for the Policy

University policies and procedures establish consistency in how matters are handled and help ensure compliance with applicable laws, regulations and Yale’s commitment to the protection of its research participants. The purpose of this policy is to identify the review that is necessary to approve policies and procedures, given their complexity and scope.

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### Definitions

#### Policy

A general statement reflecting and describing principles established by an institution, usually with the intent of reaching a long-term goal.

#### Procedure

A set of instructions written in standardized format, describing a course of action to be followed in a consistent manner under similar conditions or situations to help ensure conformance with University policy.

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### Policy Sections

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#### 930.1 Human Research Protection Policies

Yale HRPP policies and procedures are developed and maintained by the Yale HRPP Steering Committee under the direction of the HRPP Director and in conjunction with the Executive Institutional Review Board (IRB) Chair.

Yale HRPP polices and procedures are to be reviewed every three years or when changes in regulations, laws, and institutional policies necessitate revision.

Each HRPP Partner is responsible for developing HRPP policies within their own departments and for ensuring their department’s continued compliance with their policies.

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### 930.2 Institutional Review Board (IRB) Policies

The Yale University Institutional Review Boards (IRB) develop and maintain written policies and procedures for the conduct, review and approval of human research activities under its jurisdiction as required by law, regulation, and University policy.

Approved policies and procedures must be known to those conducting or supporting research subject to Yale IRB approval.

IRB members, Chairs/Vice Chairs and staff must be knowledgeable of policies when reviewing and approving human research protocol submissions or other research related documents.

The HRPP Director, in conjunction with the IRB Chairs, will determine whether or not an IRB policy or procedure requires review and/or approval by the fully convened IRB, IRB Chairs and Vice Chairs, the Institution's Signatory Official, and/or the Institutional Review Board (IRB) Leadership.

Policies and procedures shall contain the date of approval or the date of last revision and the title of the person authorized by Yale to maintain and communicate the policy and subsequent revisions.

IRB policies and procedures are to be reviewed every three years or when changes in regulations, laws, and institutional policies necessitate revision.

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### Related Information

930 PR.01 Development, Review and Approval of HRPP Policies and Procedures

Yale University Policy 1360, Human Research Protection

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### Contacts

Subject	Contact	Phone e-mail
IRB Review of Biomedical Research	Human Investigation Committees	203-785-4688 YSMhic@yale.edu
IRB Review of Social Science, Behavioral, Education and Humanities Research	Human Subjects Committee	203-436-3650 Human.subjects@yale.edu

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### Roles and Responsibilities

#### Human Research Protection Program Steering Committee

The HRPP Steering Group is a policy and decision making body that is responsible for overall development of the HRPP. The Steering Group is composed of representatives that are considered partners, or stakeholders in the Yale HRPP.

#### Institutional Review Board Leadership Group

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.

**Institutional Signatory Official (IO)**

A senior official named in the FWA who has the authority to commit the entire organization, as well as all of the components listed in the FWA, to a legally binding agreement. The IO also has the authority to assure compliance of the organization and all of its components to the Terms of the FWA.

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**References:**

45 CFR 46.103

45 CFR 46.115 (6)

21 CFR 56.108

OHRP Compliance Activities: Common Findings and Guidance, July 10, 2002

Vanderbilt University, Institutional Review Board Policies

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**Revision History**

05/21/2006