Scope

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

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, accreditation, and funding agencies.

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.

Definitions

HRPP Leadership Group
A committee comprised of the HRPP Director, IRB Executive Chair, IRB Chairs and Vice Chairs, and HRPP senior staff. The HRPP Leadership Group provides oversight and guidance to the IRBs, reviews and approves institution-wide IRB and HRPP policies, procedures and practices and assists in determining appropriate University responses or positions to emergent IRB issues.

HRPP Partner
A University department or office whose work includes some aspect of protection of participants in human research, for example, representatives from Office of Sponsored Projects, Conflict of Interest Office, Office of General Counsel, and others as applicable.

HRPP Steering Committee
An advisory body responsible for advising the HRPP leaders in setting goals and direction for Yale’s human research initiatives and providing guidance on emergent topics of interest to the HRPP. The Steering Group is composed of representatives of the HRPP partners, or stakeholders in the Yale HRPP.
Policy 930 – Development, Review and Approval of HRPP Procedures

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.

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.

Policy Sections

930.1 Human Research Protection Policies
Yale HRPP policies and procedures are developed and maintained by the Yale HRPP under the direction of the HRPP Director and in conjunction with the HRPP Leadership Group and Steering Committee. The Steering Committee approves new HRPP policies, and substantive policy revisions.

Yale HRPP policies and procedures are reviewed every three years or when changes in regulations, laws, and institutional policies or procedures 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.

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 polices when reviewing and approving human research protocol submissions or other research related documents.

The HRPP Director, in conjunction with the HRPP Leadership Group, will determine whether or not an IRB policy or procedure requires review and/or approval by the fully convened IRB, the HRPP Steering Committee, the Institution’s Signatory Official, and/or the Office of General Counsel. The HRPP Leadership Group, with, when necessary, input as described above approves new policies and substantive policy revisions.

Policies and procedures 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 reviewed every three years or when changes in regulations, laws, and institutional policies necessitate revision.

Related Information

930 PR.01 Development, Review and Approval of HRPP Policies and Procedures
Yale University Policy 1360, Human Research Protection

Contacts

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<thead>
<tr>
<th>Subject</th>
<th>Contact</th>
<th>Phone e-mail</th>
</tr>
</thead>
<tbody>
<tr>
<td>IRB Review of Biomedical Research</td>
<td>Human Investigation Committees</td>
<td>203-785-4688  <a href="mailto:YSMhic@yale.edu">YSMhic@yale.edu</a></td>
</tr>
<tr>
<td>IRB Review of Social Science, Behavioral, Education and Humanities Research</td>
<td>Human Subjects Committee</td>
<td>203-785-4688  <a href="mailto:Human.subjects@yale.edu">Human.subjects@yale.edu</a></td>
</tr>
</tbody>
</table>

References:

45 CFR § 46.103(b) (4); 45 CFR § 103(b) (5)
45 CFR § 46.115(6)
21 CFR § 56.108
OHRP Compliance Activities: Common Findings and Guidance, July 10, 2002

Revision History

05/21/2006, 1/15/2013, 4/4/2013, 11Dec2017