

DEPARTMENT: Yale University Human Investigation Committee
POLICY NUMBER: XX.BB
SECTION: Development, Review, and Approval of HIC Policies and Standard Operating Procedures (SOPs)
REVIEW RESPONSIBILITY: HIC Policy Review
ORIGINAL CREATION DATE: May 31, 2006

Yale University School of Medicine HIC Policy Regarding: Development, Review, and Approval of HIC Policies and Standard Operating Procedures

I. Introduction:

The objective of this policy is to describe the ways in which policies and SOPs are developed, reviewed, and approved in order to establish consistency in how matters are handled so as to assure subject safety and reduce errors.

II. Definitions:

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

Research Affiliate (RA): An organization for which the University has agreed to serve as the IRB of record. An organization that is approved as an RA is permitted to submit its research to the IRB so as to satisfy federal regulations for the protection of human research subjects.

Standard Operating Procedure (SOP): 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.

III. Policy:

The Yale University Human Investigation Committee (HIC) maintains written policies and Standard Operating Procedures (SOPs) for conducting research activities under its jurisdiction as required by law, regulation, and University policy.

- Approved SOPs and policies must be followed by those conducting or supporting research subject to HIC approval.
- The Deputy Director, in conjunction with the HIC Chairs, will determine whether the SOP or policy requires review and/or approval by the full HIC, HIC Chairs and Directors, the Office of the Provost, and/or Institutional Review Board (IRB) Leadership group.
- No SOPs or policies of any HIC Committee may be implemented or amended without the approval of the Chair of the Committee and/or authorized members in

accordance with HIC policy. All such documents shall contain the date of approval or the date of last revision and the authorized persons approving the SOP or policy.

- Research Affiliates that have been authorized by the University to use the HIC as their IRB of record may not change HIC SOPs or policies.

IV. Procedure:

1. Appropriate institutional officials, HIC I and HIC II members, HIC staff members, Chairs or Directors, other School of Medicine oversight committees, and investigators may recommend implementing new or modifying current SOPs and policies.
 - a. Any person wishing to suggest a new or revised SOP or policy is invited to submit the request, in writing, to the appropriate chair, along with an explanation of the need for the change.
2. Individuals with specific expertise regarding quality and compliance in human subject research develop the draft SOP or policy. Development is overseen and directed by the HIC Deputy Director and in conjunction with other departments responsible for research protection and compliance.
 - a. Resources to consult include Federal regulations, State law, institutional policies, other research institutions with permission, and other appropriate reference materials.
3. The draft SOP or policy is reviewed by the full HIC, HIC Chairs and Directors, the Office of the Provost, and/or Institutional Review Board (IRB) Leadership group, as described below.
 - a. If the draft SOP or policy is substantive or substantive and procedural, does not affect Yale University policy, and applies only to the two biomedical IRBs, the full HIC shall approve or disapprove the draft with any necessary revisions, without the draft being presented to HIC leadership, the Office of the Provost, or the University's IRB leadership.
 - b. If the draft SOP or policy is strictly procedural, does not affect Yale University policy, and applies only to the two biomedical IRBs, the HIC Chairs and Directors shall approve or disapprove the draft, with any necessary revisions, without the draft being presented to the full HIC, the Office of the Provost, or the University's IRB leadership.
 - c. If the draft SOP or policy affects Yale University policy or applies to all four IRBs, the University's IRB leadership, in conjunction with the Offices of the Provost and General Counsel, shall approve or disapprove the draft with any necessary revisions, without the draft being presented to the full HIC or HIC Chairs and Directors.
4. Upon initial approval, the SOP or policy is posted to the HIC website for ten (10) business days open to public comment. Comments and suggested revisions will be sent to the HIC.
5. HIC staff initially considers comments and suggested revisions.
 - a. If the revisions are inconsequential, meaning they will not affect the outcome

- upon implementation of the SOP or policy, and the HIC Chairs and Directors deem the revisions appropriate, then the revisions are incorporated and final approval is issued.
- b. If revisions are substantive, meaning they will affect the outcome upon implementation of the SOP or policy, the SOP or policy along with the suggested revisions will return to the body designated in Step Three of this process for final approval, approval pending revisions, or disapproval.
6. Upon final approval, the SOP or policy is posted to the HIC website, with an announcement of its posting via e-mail or other appropriate correspondence.
 7. The Institutional Official shall receive a copy of the SOP or policy in order to recommend incorporation of the SOP or policy into local IRB policy/procedure.
 8. Suggested revisions to the SOP or policy are accepted by the HIC on a continuing basis. Revisions and updates shall return to Step Five of this process for approval, approval pending revisions, or disapproval.
 - a. The HIC Education/Compliance team will routinely visit the Office for Human Research Protections (OHRP) and Food and Drug Administration (FDA) websites for issuance of guidance documents, changes in regulations, and determination letters in order to obtain suggestions and guidance for revisions of SOPs and policies.
 - b. A member of the HIC Education/Compliance team will attend HIC staff meetings and Committee meetings to obtain suggestions and guidance for revisions. The Offices of the Provost and General Counsel will discuss proposed changes and assist the HIC with interpretation of Federal, State, and local regulations affecting SOPs and policies.
 9. The HIC Education/Compliance team will provide educational sessions to the members of HIC I and HIC II and HIC staff regarding new and newly revised SOPs and policies in a timely manner.
 - a. New SOPs will be announced to the School of Medicine's research community via e-mail or other appropriate correspondence.
 - b. When appropriate, the research community will have the opportunity to comment and modify new policies and procedures prior to such policies or procedures being implemented.
 10. Administrative staff for each committee will maintain a catalogue of its approved SOPs and policies.