Overview
This procedure outlines the process for the development, approval and maintenance of policies and procedures under the jurisdiction of the Yale University Human Research Protection Program (HRPP) and Institutional Review Boards (IRB).

Review and Maintenance of HRPP and IRB Policies

Investigator Responsibilities:

a) The Investigator should be knowledgeable of HRPP and IRB policies and procedures as part of his/her training for conducting human research at Yale University. Current policies and procedures are located on the HRPP website.

b) It is the responsibility of the Investigator to routinely view the HRPP website for new or revised HRPP and/or IRB policies and procedures.

c) The Investigator will contact an IRB Office or the HRPP Compliance Manager for clarification of policies and procedures, when needed or to suggest areas where new or revised policies, procedures, guidance or forms may be warranted.

HRPP and IRB Administration Responsibilities:

a) The HRPP Director, Education and Compliance Managers and the IRB Committee Manager will routinely view the OHRP and FDA websites for issuance of guidance documents, changes in regulations, and determination letters and stay current on Yale policies that may affect the protection of research participants.

b) The IRB Committee Manager and HRPP Education and Compliance teams are responsible for identifying when guidance on necessary revisions of policies and procedures may be required.

c) The HRPP/IRB and the Office of the General Counsel will collaborate on changes and assist with interpretation of Federal, State and local regulations or other Yale policy and procedures affecting IRB policies and procedures.

d) The HRPP Education/Compliance teams will provide educational sessions to the IRB Committee members and staff regarding IRB policies and procedures, as well as updates or revisions, in a timely manner.

e) The HRPP Education team is responsible for reviewing policies and procedures to ensure they remain current.

IRB Staff Responsibilities:
a) The IRB Regulatory Analyst will use the IRB policies and procedures posted on the IRB website when processing research activities.

b) The IRB Regulatory Analyst may consult with the IRB Chair or other knowledgeable member of the IRB or HRPP staff for guidance in applying the IRB policies and procedures.

c) If an IRB staff member notices that a policy or procedure is inaccurate or out of date, the staff member should bring it to the attention of their manager or the HRPP Director who will communicate to the HRPP Leadership Group when necessary. It is all IRB staff’s responsibility to keep the IRB policies and procedures current and applicable to the daily processes.

Development or Revision of Policies and Procedures

Institutional officials, IRB chairs, members and staff, researchers and members of other University departments and oversight committees responsible for the protection of Yale’s research participants are considered among the stakeholders in Yale’s HRPP. As such, representatives from these groups are welcome to propose a new or revised policy or procedure at any time. The proposal should be submitted in writing to the Director of the responsible HRPP area, (e.g. IRB, GCA), or his/her designee, along with an explanation of the reasons supporting the proposal.

Suggested changes to HRPP or IRB policies should be submitted to the HRPP Director who will review and coordinate any changes with the HRPP Leadership Group, which is responsible for the development and maintenance of HRPP policies and procedures.

Policies and procedures will be drafted or modified when deemed necessary due to new guidance, changes in regulations or other documents published by federal agencies, or when necessary due to changes in Yale policy, procedure or practice.

The development or modification of policy and/or procedure is overseen directly by the Director of the responsible HRPP area, (e.g. IRB, GCA), or other person(s) and, when necessary, in conjunction with other departments responsible for research protection and compliance.

Resources used to support the development of policies and procedures may include federal regulations, state law, institutional policies, other research institutions, consultants (with permission), and other references deemed appropriate.

Review and Approval of Draft HRPP and IRB Policies and Procedures

The draft policy or procedure is initially reviewed by the HRPP Leadership Group. A final draft of the proposed policy or procedure is then disseminated to all HRPP staff for review and comment. Further approval may be sought, determined by the complexity and impact of the proposal. If the draft proposal substantively changes the manner in which the IRB considers and evaluates research protocols, or is drafted in response to newly released guidance or law from federal agencies, the proposal will be reviewed by the fully convened IRBs, the HRPP Leadership Group, the HRPP Steering Committee, the Institutional Signatory Official, Office of General Counsel or other University leadership as required.

The HRPP Steering Committee, with, when necessary, input as described above, approves new HRPP policies and substantive policy revisions.

The HRPP Leadership Group, with, when necessary, input as described above approves new policies and substantive policy revisions.
Deployment of New and Revised Policies

Educational sessions for IRB members and staff will be conducted in a timely manner when new or newly revised policies and procedures that affect the responsibilities of the IRB or designated reviewers are being considered.

The HRPP Education team is responsible for disseminating to the research community new and revised policies and procedures related to the protection of human research participants in a timely manner.

New policies are retained in a database, noting the date of implementation. The policies are available for public reference on the HRPP web site. In addition, a broadcast email is sent to the research community, announcing the release of the new policy, providing the website location where the policy can be reviewed and inviting comment from the research community, where appropriate.

Revised policies are also retained in a database noting the date of implementation. The revisions are posted for public reference on the HRPP web site. Depending on the scope and content of the revision, a broadcast email describing the revision may be sent to the research community.

Responding to Feedback

Suggested revisions to policies and procedures are accepted on a continuing basis. Suggestions are reviewed by the HRPP Education and Community Outreach Manager who is responsible for assessing the recommendation with the HRPP Director.

Ongoing Review of Policies

The HRPP Director is responsible for ensuring review and revision of policies when there are changes in regulation, law, policy or practice that affect policies. The Director is also responsible for ensuring the periodic comprehensive review of all policies and procedures.

Recordkeeping

HRPP and IRB policies and procedures contain the initial date of approval and the date(s), if any, of revision along with the name of the responsible office.

Revision History