Overview

This procedure describes the elements of the Human Research Protection Program (HRPP) Quality Assurance Program (QAP). The QAP implements quality assurance processes on an ongoing basis to ensure regulatory compliance, identify problems and seek solutions to those problems, as well as improve the quality and effectiveness of the HRPP at Yale University.

The Regulatory, Compliance, and Quality group within the HRPP is responsible for the management and monitoring of quality assurance activities. This includes the maintaining applicable records, reporting issues to the HRPP Director as necessary and appropriate, and analyzing quality assurance information for continuous improvement and to identify trends and areas of weakness that further advance the effectiveness of the HRPP at Yale University.

HRPP Quality Assurance Program Objectives

The purpose of the QAP is to assist the HRPP, institutional review board (IRB), research community, and institution in maintaining and ensuring continuing quality and standards for human subjects research protections. The QAP therefore consists of the following four primary objective components:

- Training and continuing education of the IRB staff, IRB members, and research community.
- Internal quality assurance reviews to evaluate researchers’ and their study team’s compliance with IRB approved protocols, applicable laws, regulations, guidelines, accreditation standards, policies, and local requirements.
- Quality assurance reviews of the internal and external IRB function and HRPP local oversight requirements to ensure compliance with applicable laws, regulations, guidelines, accreditation standards, policies, and local requirements.
- Provide support to, and quality review of, ancillary review committees within the HRPP to ensure appropriate approvals are in place. This includes Yale University Radioactive Drug Research Committee (RDRC) and the Human Embryonic Stem Cell Oversight Committee (ESCRO).

Training and Education

The QAP takes measures to ensure the completion of ongoing training of IRB staff, IRB members, and the research community on matters relevant to human subjects protection. Training topics covered include general training topics, issues that arise in the HRPP, topics identified as needing training by HRPP leadership, IRB staff, IRB members, or the research community, as well as topics related to new or changing laws, regulations, policies, or procedures at Yale University.

Structured training will occur as necessary and at least on a biannual basis, and may take the format of power-point lectures, workgroups, or dissemination of online self-learning programs and/or tools.
Internal Quality Assurance Reviews

For biomedical studies, the HRPP works jointly with the Yale Center for Clinical Investigation (YCCI) to conduct internal quality assurance reviews that evaluate researcher and study team adherence to IRB approved protocols, applicable laws, regulations, guidelines, accreditation standards, as well as other local requirements and policies. The HRPP conducts internal quality assurance reviews for social behavioral studies.

The goals and objectives of internal quality reviews are to:

- Continuously improve the conduct of human subjects research at Yale University
- Identify strengths and weaknesses of the research program at Yale University
- Identify needs and resources to conduct effective and compliant human subjects research
- Ensure investigator accountability and adherence to applicable requirements in the conduct of human subjects research
- Provide an internal resource for principal investigators and research teams

A. Selection of Studies

Studies approved by the Yale IRB have a risk assessment performed based on objective criteria that identifies if the study has a “High”, “Medium”, or “Low” risk assessment score, and a monthly Risk Assessment report is generated and reviewed by YCCI and the HRPP.

- A sample of **high risk protocols** generally receive a full quality review after two participants enroll in the study.
- A sample of **medium risk protocols** have a limited quality review to specifically ensure participants enrolled in the study are eligible, appropriate informed consent, and conformance with applicable regulatory standards.
- **Low risk protocols** are spot checked on an ongoing basis but otherwise no formal action is taken unless issues are discovered.

B. Internal Quality Assurance Review Method

The internal quality assurance review process for studies conducted at Yale University generally contains the following steps:

1. Introductory Meeting

   For biomedical studies, the introductory meeting is completed by the HRPP, YCCI, principal investigator, and may also include other members of the research team. For social behavioral studies, the introductory meeting typically does not include representation from YCCI.

   The purpose of the introductory meeting is to gather basic study information as well as get a preliminary assessment of PI oversight, research, and study conduct. The purpose and scope of the audit will be explained during this meeting and any initial study team questions or concerns addressed.

2. Study Review Preparation

   Individuals performing the quality assurance review prepares by reviewing relevant study materials in the applicable document management systems (COEUS, IRES, etc.). Preliminary areas of concern or for follow-up identified in this preparatory review are documented.
3. Study Review

The study review period typically occurs over the course of a few days at a time convenient for applicable parties, and efforts are made to complete the study review within a few weeks of the introductory meeting. The review is guided and documented through use of the applicable Review Worksheet. Preliminary findings are summarized and saved with the completed Review Worksheet.

For biomedical studies, areas covered in the study review typically includes confirming appropriate documentation is in place for the following:

- IRB documentation (letters, protocol and consent versions, continuing reviews, advertisements, reportable events, sponsor correspondence. Etc.)
- Local committee approvals
- Study personnel
- Facility reviews
- Specimens
- IND/IDE materials, including study drug/device
- Subject logs
- Monitoring procedures
- Study correspondence
- Protocol registrations

For social behavioral studies, areas covered in the study review typically includes confirming appropriate documentation is in place for the following:

- IRB documentation (letters, protocol and consent versions, continuing reviews, advertisements, reportable events, sponsor correspondence. Etc.)
- Local committee approvals (as applicable)
- Study correspondence

4. Exit Meeting

For biomedical studies, an exit meeting will take place upon completion of the study review to present and discuss preliminary findings with the HRPP, YCCI, Principal Investigator, and other study team members as appropriate. For social behavioral studies, the exit meeting typically does not include representation from YCCI. The study team is encouraged to provide any additional information related to the preliminary findings that provides additional context or explanation for the issues raised.

5. Final Report

A final report will be drafted by the HRPP and YCCI for biomedical studies and HRPP for social behavioral studies based on the preliminary findings and discussions from the exit meeting, ideally within two weeks of the exit meeting. The final report will identify findings from the study assessment, any information that needs to be reported to the IRB, as well as any additional recommendations or required activities of the principal investigator along with respective due date(s) for response.

Quality Assessment documentation is saved in a jointly accessible and secure space and includes the following:

- Quality Assessment Notification Letter
- Introductory Meeting Notes
- Review Checklist(s)
- Preliminary Observations any related documentation provided to the principal investigator
Findings from the Quality Assessment process will be escalated to the HRPP Director and other institutional officials at Yale University as necessary and appropriate to ensure the conduct of ethical, compliant, and safe human subjects research.

IRB Quality Assessments

The QAP takes measures to monitor internal and external IRB review of human subjects research activity conducted by Yale Investigators to confirm IRB review is done in a manner compliant with applicable laws, regulations, policy, procedures, and accreditation standards. A formal IRB Quality Assessment Review is performed at least annually and may include the following measures:

- Review of IRB minutes for internal IRBs (required annually)
- Verify completion of IRB Member evaluations for internal IRB members (required annually)
- Verify Federal Agency reporting letters are completed and sent as appropriate (required annually)
- Monitoring and performing HRPP responsibilities and obligations to research involving an external IRB of record consistent with 920 PR.4 Use of External IRBs for Review and Oversight of Research Involving Human Subjects
- IRB review and determinations associated with expedited review procedures
- IRB review and determinations associated with investigational products (e.g., drugs, devices, biologics)
- Verify the IRB incorporated ancillary review procedures into IRB review research as necessary and appropriate
- Other periodic monitoring activity as directed by the HRPP Director and/or IRB Chair(s)

Revision History

Modified: 03/13/2018 (origin)