



HRPP QUALITY IMPROVEMENT ACTIVITIES

1. Overview

The Human Research Protection Program (HRPP) supports a quality improvement (QI) program to promote and maintain ethical research conduct and compliance with state and federal regulations, federal guidance, institutional policies, and best practices for human subjects protections. All Ohio State University human subjects research and activities of the HRPP are included in the scope of the QI program. The HRPP QI program evaluates and improves human research protections and HRPP activities through education, training, and monitoring.

2. Definitions

Quality Improvement: A process initiated to develop/enhance a practice or procedure and to institutionalize the practice or procedure.

Audit: A systematic review, inspection, or verification, typically conducted by an independent individual or group.

Routine (Not-for-Cause) Review: An assessment or examination of something (e.g., a research practice or procedure) with the possibility or intention of instituting change if necessary.

Directed (For-Cause) Audit/Review: An audit of research and/or investigators initiated at the request of the IRB or Institutional Official to obtain or verify information necessary to ensure compliance with regulations and institutional requirements and to inform decisions about the conduct of human subjects research and/or human subjects protection.

3. Scope of QI Program

The QI program focuses primarily on review and monitoring of the activities, policies, procedures, and records for the following groups:

- Investigators and research staff participating in human subjects research
- IRBs
- Office of Responsible Research Practices (ORRP) staff supporting IRB activities
- Individuals involved in HRPP education and outreach.

Routine (i.e., “not for cause”) review and monitoring activities will be performed based on HRPP needs, as approved by the IRB Policy Committee. Various methods of review may be used, including interview, observation, and records review. The scope of review will vary based on the individual QI project. Auditing (i.e., “for cause”) of specific research and/or investigators at the request of the IRBs or Institutional Official (IO) will also be performed as necessary to support IRB review, ensure human subjects protections, and meet HRPP QI goals.



4. QI Program Goals

The purpose of the HRPP QI program is to verify and promote the following:

- Protection of the rights, welfare, and safety of human subjects participating in Ohio State research
- Compliance with federal, state, and institutional requirements governing human subjects research
- Integrity of university research and HRPP activities
- Education and training of research stakeholders, including university faculty and administrators, investigators, research staff, IRB members, ORRP staff, and students involved in human subjects research
- Evaluation and follow-up of QI initiatives and corrective actions and implementation of new quality improvement activities.

5. Development and Review of QI Initiatives

The Office of Responsible Research Practices is responsible for drafting proposals for QI initiatives after review of the regulations, guidance, and findings from previous QI projects, in consultation with the IRB Chairs and/or Office of Research Compliance. The IRB Policy Committee will review and approve HRPP QI initiatives, as applicable, based on the scope of the activity (e.g., review of HRPP policies vs. ORRP desk procedures).

Research stakeholders (as described above) may make recommendations for quality improvement and/or changes or revisions to existing HRPP policies, procedures, or practices. Feedback and suggestions can be provided to the IRB Chairs, ORRP staff, IRB Policy Committee members, and/or the IO, as described on the ORRP website.

6. Implementation of QI Activities

The Office of Responsible Research Practices is responsible for the implementation and communication of HRPP QI activities. Information and accompanying materials (e.g., self-assessment tools, guidance) will be posted and made available on the ORRP website, as applicable. Communication will be issued about new or revised QI initiatives through university communication mechanisms. The IRB Policy Committee and/or Institutional Official will set an effective date for implementation of new projects. When a QI initiative represents a significant change to existing processes or practices, the effective date will be set to allow for communication, including education and planning for operational changes.

7. QI Program Maintenance

The Office of Responsible Research Practices is responsible for maintaining the HRPP QI program. The IRB Policy Committee will review program findings and ongoing QI initiatives as needed, at least annually. Specific findings from directed reviews will be forwarded to the IRB responsible for reviewing the research and/or to the Institutional Official. Program initiatives will be developed (as described above) and/or updated as HRPP needs are recognized or change.

8. History

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