

The IRB Chair and Institutional Official (IO) are consulted when ORIC receives requests for this type of arrangement. Investigators should contact the ORIC for questions regarding reliance agreements.

G. Quality Assurance and Quality Improvement Activities

It is important to recognize that some Quality Assurance (QA) or Quality Improvement (QI) activities conducted at the Institution may be classified as human subject research. Most QA and QI activities are assessments developed and initiated with the intent of assuring or improving the process, outcome, and/or efficiency of complex systems of health care. However, if the primary goal is to produce generalizable knowledge as defined in section B above, the activities are subject to the regulations governing the protection of human research subjects and require prior IRB review. Further guidance about requirements for QA/QI projects can be found in Section 7 Guidance on Quality Improvement and Assurance Projects of this manual. Investigators are also encouraged to contact ORIC staff for assistance in this area.

1.3 HUMAN RESEARCH PROTECTION PROGRAM (HRPP)

The Institution's Human Research Protection Program (HRPP) includes all persons and departments of the Institution engaged in the planning, design, review, conduct, or administrative support of any research involving human subjects. The Institution's HRPP is guided by the ethical principles outlined in this policy and is committed to the education of the research community and outreach to collaborating institutions.

A. HRPP Quality Improvement:

The Institution will routinely evaluate the resources needed for the HRPP, including but not limited to:

- Space
 - Personnel
 - IRB membership, education and training, and submission metrics
 - Legal counsel
 - Financial conflict of interest review and management
 - HRPP routine monitoring and auditing programs (e.g. Post-Approval Monitoring Program)
 - HRPP educational, training, and outreach programs
- i. IRB Membership, Training, and Submission Metrics Quality Improvement Activities
- Review of IRB Membership

ORIC will routinely evaluate IRB membership and qualifications to ensure that composition is in compliance with federal regulations. IRB Metrics

ORIC tracks key IRB metrics (i.e., time from complete submission to approval for new studies submitted for all review types) and evaluates for ongoing process improvement. The HRPP is committed to maintaining IRB approval times to be in the top 50th percentile as compared to the Association for the Accreditation of Human Research Protection Programs (AAHRPP) annual HRPP metric reports. If approval times are lagging, investigation into causes will be initiated by ORIC administration and solutions to address delays will be designed and implemented.

- IRB Member education and training

The HRPP is committed to ensuring the IRB members and Chair(s) are equipped with the necessary knowledge and tools to conduct robust and ethical reviews of human subjects research. The IRB members are routinely provided continuing education in the form of: presentations at convened meetings, discussion of issues related to human subjects research, relevant articles, guidance documents, and opportunities for attendance at local/virtual educational events.

- ii. Routine Monitoring of the HRPP

The Institution conducts routine post-approval monitoring to assess compliance of the HRPP with organizational policies and procedures, applicable laws, regulations, codes and guidance. Objectives include, but are not limited to: improving compliance in the proper conduct of the informed consent process, monitoring the maintenance of regulatory documentation, and reviewing the documentation of inclusion/exclusion criteria. Random monitoring is conducted each month to review the specified objective for assessing compliance. Feedback and recommendations for improvement are directly provided to investigators and research staff. When recurring errors are identified, policies are revised for clarification. In addition, “global” e-mails to investigators and research staff are sent out weekly to highlight such issues and educate the entire research community. If necessary and appropriate, it may also become a topic for a research town hall meeting or other applicable means of targeted education.

Annual trends are monitored to evaluate the effectiveness of the post-approval monitoring process and related recommendations, education, etc. Additionally, data from routine monitoring will combined with patterns and trends identified during for-cause audits or investigations so that education and training of the research enterprise is disseminated accordingly.

- iii. Needs Assessments

The continuing education and training needs of the HRPP investigators, and research staff are an integral part of the Institution’s research mission. Under the leadership of the ORIC Education staff, the HRPP conducts a periodic needs assessment survey to identify gaps in education, training and competency related to the conduct of human subjects research. The results of each needs assessment are shared with HRPP Leadership which will then assist with developing the goals for training and education. Any deficiencies will be specifically addressed with the support of leadership in that identified area.

- iv. **HRPP Educational, Training, and Outreach programs**

ORIC Education staff provide ongoing education related to the protections of human subjects research and training related to conducting research according to good clinical practices/best practices and ensuring operational compliance with federal regulations, laws, and IRB determinations. The program is assessed annually with goals and outcomes defined from completed HRPP needs assessments. Mixed-methods approaches that follows principles of adult education forms the foundation of the

education and training programming. Metrics and tracking of outcomes are shared routinely with research/HRPP leadership and the IRB.

In addition, ORIC conducts activities designed to enhance and facilitate the communication between the HRPP and the Institution's research enterprise. This includes having ORIC staff membership on research committees throughout the Institution, conducting regular needs assessments as stated above, promoting regular office hours for consultation with ORIC staff, and communicating HRPP changes and improvement activities via global emails. The HRPP also performs outreach activities that seeks the understanding of human research by participants, prospective participants, or their communities. These outreach activities are evaluated on a periodic basis for improvement.