CASE WESTERN RESERVE UNIVERSITY

FAQ
Human Research Protection Program (HRPP)
Quality Improvement Program (QIP)
Review Process at CWRU

What are the bases on which the Office of Research Compliance conducts QIP reviews of human subject research projects?

The University is responsible for conducting quality improvement reviews of human subject research protocols based on regulation and policy found in Title 45 Code of Federal Regulations Part 46, CWRU's Federalwide Assurance (FWA 00004428), CWRU's AAHRPP Accreditation, and local policy. Both CWRU IRB approved studies and studies with sponsor funding going directly to CWRU, regardless of IRB of record, may be selected for CWRU QIP reviews.

Why are quality improvement reviews conducted?

QIP reviews are conducted to ensure compliance with regulations and policy protecting human subjects in research. Studies are selected at random to ensure a wide variety of protocol types, recruitment populations, and risk levels.

What will the review process include?

The quality improvement review process is an overall evaluation of the investigators' implementation of their IRB approved protocols. Depending on the nature of the protocol, QIP reviews will be performed in person at the study team's office(s) or remotely by Zoom.

Who should I contact with specific questions about the review process of human subject protocols at CWRU?

Contact Kimberly Volarcik, HRPP Quality Improvement Program Director, Office of Research Compliance, by phone at (216) 368-0134 or by e-mail at kav6@case.edu, or Jennifer Frame, Manager of Regulatory Compliance Monitoring, Office of Research Compliance, by email at jmf41@case.edu

What documents should I make available to the QIP reviewer?

The QIP reviewer will request to evaluate all executed informed consent documents; the research data; data collection instruments; the current and modified IRB protocol; advertising used to recruit participants; participant communication; letters of complaints; reports of all instances of adverse events; information regarding participant withdrawals; list of all study team members; study team member training, credentialing, and certification; and any other information, data, or records requested by the reviewer relating directly to the investigator's interaction or intervention with human subjects.

Is the quality improvement review process confidential?

Yes, the reviewer is bound by policy to keep any review information confidential, except that the CWRU IRB and the University Compliance Officer will be notified of any violations of regulations and policy. The CWRU IRB will also receive a copy of the QIP report.