

FAQ

Human Research Protection Program Quality Improvement Program Review Process at Case

What are the bases on which the Office of Research Compliance conducts quality improvement 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, Case's Federalwide Assurance (FWA 00004428), and local policy.

Why are quality improvement reviews conducted?

Quality improvement reviews are conducted to ensure compliance with regulations and policy protecting human subjects in research.

What will the review process include?

The quality improvement review process includes an evaluation of investigators' implementation of their Case IRB approved protocols.

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

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.

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 IRB protocol and any changes; hardcopies of advertising used to recruit human subjects; any copies of communication between human subjects and the investigator; any letters of complaints; reports of all instances of adverse events; all information regarding subjects who prematurely discontinued participation in the study; list of all faculty, staff and students involved with the research; documentation that all persons involved with the protocol have received appropriate training with regard to the protection of human subjects; 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 information obtained from the review confidential, except that the Case IRB and the University Compliance Officer will be notified of any violations of regulations and policy. The Case IRB will also receive a copy of the QIP report.