

2 Quality Assurance

University of Virginia performs Quality Assurance and Improvement activities for the purposes of monitoring the safety of ongoing studies and measuring and improving human research protection effectiveness, quality, and compliance with organizational policies and procedures and applicable federal, state, and local laws.

2.1 External Monitoring, Audit, and Inspection Reports

All reports from external monitors, auditors, or inspectors must be submitted by investigators to the IRB for review. The IRB Chair or designee will review such reports in order to monitor for issues that could impact the rights or welfare of human subjects and for issues indicative of possible serious or continuing non-compliance. If such issues are identified, the report will be forwarded to the convened IRB to determine what additional actions are necessary.

2.2 Investigator Compliance Reviews

The HRPP Post Approval Monitoring and Education (PAM&ED) program is responsible for conducting post-approval directed (“for cause”) audits and periodic (not “for cause”) compliance reviews of investigator research plans. Additionally, the PAM office may appoint a subcommittee for the purpose of conducting a for-cause or not for-cause compliance review of one or more research plans under its jurisdiction. The subcommittee may be composed of PAM&ED and IRB staff, IRB members from within, or individuals from and outside of the organization.

Compliance reviews are conducted to assess investigator compliance with federal, state, and local law, and University of Virginia policies, and to identify areas for improvement, and to provide recommendations based on existing policies and procedures. The results of compliance reviews will be reported to the IRB Directors, the IRB, and the investigator. Any non-compliance will be handled according to the procedures in Section 16.

If it is identified that subjects in a research project have been exposed to unexpected serious harm, the reviewer will promptly report such findings to the Institutional Official and the IRB Director/Chair for immediate action.

If issues are identified that indicate possible misconduct in research, the procedures in the University of Virginia Policy on Research Misconduct will be initiated.

PAM compliance reviews may include:

- a) Examining investigator-held research records;
- b) Confirming adherence to data and safety monitoring plans;
- c) Reviewing advertisements and other recruiting materials;
- d) Verifying that the researchers have not deviated from the approved, research protocol;

- e) Confirming that documents being used by the research team align with the most recently approved IRB protocol;
- f) Verifying accurate completion of consent documents and matching subject enrollment numbers with completed consents;
- g) Determine that the investigator has followed the subject selection criteria. Under special circumstances, observing research sites where research involving human research subjects and/or the informed consent process is being conducted;
- h) Monitoring and responding to the research subject hotline;
- i) Conducting other monitoring or auditing activities as deemed appropriate by the IRB;
- j) Formulating education programs for researchers as needed through the Ed program.

2.3 IRB Compliance Reviews

The HRPP program, with, or without, the assistance of an outside organization, will periodically review the activities of the IRB to assess compliance with regulatory requirements and to identify areas for improvement; this will include a review of IRB records at least annually.

Review activities by the IRB may include:

- a) Review of the IRB minutes to determine that adequate documentation of the meeting discussion has occurred. This review will include assessing the documentation surrounding the discussion for protections of vulnerable populations as well as risk/benefit ratio and consent issues that are included in the criteria for approval;
- b) Review of the IRB minutes to assure that quorum was met and maintained;
- c) Review of IRB documentation, including IRB minutes, to assess whether privacy provisions, according to HIPAA, have been adequately reviewed, discussed and documented;
- d) Evaluating the continuing review discussions to assure they are substantive and meaningful and that no lapse has occurred since the previous IRB review;
- e) Reviewing IRB files to assure retention of appropriate documentation and consistent organization of the IRB file according to current policies and procedures;
- f) Reviewing the IRB database to assure all required fields are completed accurately;
- k) Verifying IRB approvals for collaborating institutions or external performance sites;
- l) Reviewing the appropriate metrics (for example, time from submission to first review) to evaluate the quality, efficiency, and effectiveness of the IRB review process;
- m) Reviewing the workload of IRB staff to evaluate appropriate staffing level; and
- n) Other monitoring or auditing activities deemed appropriate.

Review activities of IRB files by PAM include:

- a) Periodic reviews of IRB files to assure retention of appropriate documentation and consistent organization of the IRB file according to current policies and procedures.

The IRB Directors and IRB Chairs will review the results of IRB compliance reviews with the Institutional Official. If any deficiencies are noted in the review, a corrective action plan will be developed by the Director and Chair and approved by the Institutional Official. The Director will have responsibility for implementing the corrective action plan, the results of which will be evaluated by the Institutional Official.

2.4 HRPP Quality Assessment and Improvement

Annually, a meeting is held by the HRPP Quality Assessment and Improvement Committee (QuAiC) comprised of the HRPP Director IRB Directors and Chairs, IO, PAM Compliance Monitors, and IRB Education Coordinator in which a quality improvement plan is put into place, to be carried out by an individual or committee named by the Institutional Official that assesses compliance and achieving targeted levels of quality, efficiency, and effectiveness of the HRPP (e.g., continuous investigator training; use of IRB-approved consent forms, turn-around time of exemption determinations, etc.). The plan will, at a minimum contain:

- The goals of the quality assessment/improvement plan with respect to measuring effectiveness, identifying opportunities for improvement and achieving and maintaining targeted levels of quality, efficiency, effectiveness and compliance are stated
- At least one objective to achieve or maintain compliance is defined
- At least one measure of compliance is defined
- The methods to assess compliance and make improvements are described
- At least one objective of quality, efficiency, or effectiveness is defined
- At least one measure of quality, efficiency, or effectiveness is defined
- The methods to assess quality, efficiency, or effectiveness and make improvements are described

Results of the plan report is reviewed by the QuAiC HRPP in order to identify trends and to determine if systemic changes are required to prevent re-occurrence. If so, the QuAiC will collaborate in the development of a corrective action plan, its implementation, and evaluation of its effectiveness.

The IRB Directors are responsible for tracking internal metrics that are informative in considering IRB and Investigator efficiency such as the amount of time from receipt of a submission through pre-review, and final approval and the amount of time it takes investigators to develop and submit responses to pre-review and IRB requirements. Metrics reports will be provided to the IO and IRB Chairs once a year.

Annually, QuAiC, in collaboration with other relevant parties, will define Quality Improvement goals for the year. The targeted issues, goals, and means to measure progress are documented in a written QA/QI plan. In order to evaluate whether the defined goals are being achieved, PAM HRPP Compliance Coordinators collect, record, and provide a written report to the IO for tracking purposes. At the end of each year, QuAiC evaluates whether the respective goals were achieved and adjusts the affected processes to correct any deficiencies.