



Title:	Quality Assurance		
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Previous Version Dates:			

1 Purpose

The University of North Carolina at Chapel Hill (UNC-Chapel Hill) 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 Procedures

2.1 External Monitoring, Audit, and Inspection Reports

All reports from external monitors, auditors, or inspectors must be submitted by investigators. The Office of Clinical Trials Clinical Trials Quality Assurance (CTQA) Program is responsible for reviewing 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 researcher will be instructed to submit a “new safety information” report to the IRB. Such reports will be handled as described in Section (See SOPs 1401 & 1402).

2.2 Investigator Compliance Reviews

The OHRE Quality Assurance/Quality Improvement (QA/QI) Manager is responsible for conducting post-approval Directed (“for cause”) audits and periodic (not “for cause”) reviews of the consent process. Additionally, the IRB 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 IRB members and staff from within, or individuals from and outside of the organization. The Clinical Trials Quality Assurance (CTQA) Program conducts random (non-directed) post-approval reviews for a percentage of clinical research studies as well as “friendly” audits (at the request of the research team).

Compliance reviews are conducted to assess investigator compliance with federal, state, and local law, and the UNC-Chapel Hill policies, and to identify areas for improvement, and to provide recommendations based on existing policies and procedures. The results of directed compliance reviews will be reported to the OHRE Director, the IRB, and the investigator. Any non-compliance will be handled according to the procedures in SOP 1402.

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 Safety Committee Chair and/or Compliance Manager for immediate action. IRB Chairs have authority to temporarily suspend research in cases where subjects may be exposed to harm.

If issues are identified that indicate possible misconduct in research, the procedures in the *Policy and Procedures on Responding to Allegations of Research Misconduct* (<http://policies.unc.edu/files/2014/10/Research-Misconduct.pdf>) will be initiated.

Compliance reviews may include:

- a) Requesting progress reports from investigators;
- b) Examining investigator-held research records;
- c) Contacting research subjects;
- d) Observing research sites where research involving human research subjects and/or the informed consent process is being conducted;
- e) Reviewing advertisements and other recruiting materials;
- f) Reviewing projects to verify from sources other than the investigator that no unapproved changes have occurred since previous review;
- g) Assuring that the consent documents include the appropriate information and disclosures about conflicts of interest;
- h) Monitoring HIPAA authorizations;
- i) Conducting other monitoring or auditing activities as deemed appropriate by the HRPP or IRB.

2.3 IRB Compliance Reviews

The OHRE QA/QI Manager 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 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;
- j) Verifying IRB approvals for collaborating institutions or external performance sites;
- k) Reviewing the appropriate metrics (for example, time from submission to first review) to evaluate the quality, efficiency, and effectiveness of the IRB review process;
- l) Reviewing the workload of IRB staff to evaluate appropriate staffing level; and
- m) Other monitoring or auditing activities deemed appropriate.

The OHRE Director will review the results of IRB QA/QI reviews. If any deficiencies are noted in the review, a corrective action plan will be developed by the Director, QA/QI Manager, and as applicable, IRB Chairs and/or staff. The Director (or designee) will have responsibility for implementing the corrective action plan, and for evaluating the results.

2.4 HRPP Quality Assessment and Improvement

At least annually, the Director, in collaboration with members of the OHRE executive committee, 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, the QA/QI manager in collaboration with the Data Information Manager/Business Systems Analyst, collects, records, and provides a written report to the Director. At minimum, the report will 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 are reviewed by the OHRE Director in order to identify trends and to determine if systemic changes are required to prevent re-occurrence. If so, the Director and members of the OHRE executive committee will collaborate in the development of a corrective action plan, its implementation, and evaluation of its effectiveness.

The Data Information Manager/Business Systems Analyst is 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, assignment to the IRB, 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 Director as requested.