

QUALITY ASSURANCE / IMPROVEMENT PROGRAM

1. PURPOSE

- a) The QA/QI Program identifies and corrects deficiencies on an ongoing basis, which is the foundation for providing ongoing training and education to VA research staff regarding ethical principles and proper conduct of research.

2. PROCEDURES

- a) Using the audit tools provided by the Research Compliance Office, Investigators and/or study staff are encouraged to self-audit their study performance prior to a VA Compliance audit or monitor visit. VA Research Compliance Office audit tools are available at <http://atlares.org/forms/vamc.cfm>
- b) Each active VA protocol will be reviewed at least annually.
- c) Annual informed consent audits will take place at the time of Continuing Review. The Compliance Office will notify the PI via email approximately 2-4 weeks prior to the study's expiration date. The PI and study staff will have 10 business days to respond with required documents for the consent audits. For the triennial regulatory audits, these will also occur at the time of Continuing Review, in conjunction with the consent audit. The Compliance Office will notify the PI via email approximately 2-4 weeks in advance to schedule a time to review the study binder and other documentation, with a response requested from the PI within 10 business days.
- d) The PI and Research Coordinator will make regulatory binder and necessary study files accessible to the Research Compliance Office for review.
- e) All study documents must be available to the RCO to review upon the scheduled audit. Items reviewed will include but are not limited to:
 - I. Regulatory Study Binder
 - II. Approved Protocol
 - III. Original and revised Informed Consent Forms and HIPAAs (or documentation of appropriate waivers)
 - IV. IRB Submission and R&D Committee Forms
 - V. IRB and R&D Committee approval letters
 - VI. Enrollment log
 - VII. Recruitment methods
 - VIII. Modifications (amendments)
 - IX. SAE Reports
 - X. Continuing Review (renewals)
 - XI. Case Report Forms/ Data Collection Forms
 - XII. Source Documents
 - XIII. Study staff log and training records
 - XIV. Documentation verification of the informed consent discussion and research encounters
 - XV. Sponsor Correspondence (if applicable)
 - XVI. Data Security and Data Use Requirements
 - XVII. Privacy and Confidentiality Requirements

- f) If any compliance issues are found during the audit, Compliance Office staff will meet with the study coordinator (and PI if necessary) to discuss discrepancies, findings, and to make study performance improvement recommendations
- g) The PI or designee will be responsible for clarifying any pending issues and for locating any missing documents in the study binder
- h) Once the assessment is completed, a written summary will be sent to the PI and Research Coordinator
- i) If the study involves drugs, the Research Pharmacist will complete the Investigational Drug section and notify the RCO of any discrepancies
- j) If a non-compliance issue is discovered during the visit, the RCO will follow MCM 151-7