

**Policy Memorandum No. 19**  
**Subject:** Quality Assurance Program  
**Departments Affected:** All

**Page 1 of 2 pages**  
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## **QUALITY ASSURANCE PROGRAM**

### **PURPOSE**

The SWOG Quality Assurance Program was developed to enhance the reliability and validity of clinical trials data from Group institutions through the use of routine monitoring procedures. Audits are designed to provide assurance that the data reported on the research records accurately reflect the data as reported in the primary patient record and to verify compliance with protocol and regulatory requirements and adherence to NCI and SWOG policies and procedures. The Program also surveys data management practices at each institution in order to provide educational support to the clinical trial sites regarding issues related to good clinical practice (GCP), data collection, and other aspects of quality assurance.

### **QUALITY ASSURANCE SITE VISITS**

Each SWOG institution will be audited at least once every three years but will remain at annual risk of an audit. Institutions will remain at risk for audit even if their membership in the Group is withdrawn or terminated since they have made a commitment to long-term follow-up of patients on study for as long as the patient remains alive.

To become full Group members, new probationary Member, LAPS and NCORP institutions must undergo a successful on-site Quality Assurance Audit within 6-18 months of registering their first patient. New component and affiliate institutions will be audited at the next scheduled audit of their parent institution. After a successful Quality Assurance Audit, the institution will be placed in the normal rotation to be audited again within three years.

The audit team will consist of a qualified nurse or CRA, and a Quality Assurance representative from the Group's Network Operations Center. All auditors are knowledgeable in GCP and the NCI guidelines and have completed the National Cancer Institute – Clinical Trials Monitoring Branch (NCI-CTMB) Auditor/Monitor Training as well as training in Human Subjects Protection and HIPAA.

Institutions will be contacted three to six months prior to the audit to schedule a mutually agreeable date for the Quality Assurance Audit. The NCI-CTMB will be notified at least 42 days in advance of all scheduled Quality Assurance Audits and may choose to attend an audit.

A list of the protocols and cases selected for the audit will be sent to the institution approximately four to six weeks prior to the audit to allow for preparation of records. A review of regulatory, pharmacy and patient cases will be conducted as outlined in the **SWOG Quality Assurance Guidelines**.

To facilitate preparation for the audit and assist the person at the institution responsible for collecting the requisite information, the document **Site Preparation for an Audit** has been developed. This document will be provided to the institution with the list of patient cases to be audited. It is highly recommended that staff designated to assist the team review the primary records prior to the audit to identify and flag the source of the data reported if maintained in paper charts. Many institutions now collect and store research data electronically; therefore, auditors can review data directly in the Electronic Medical Record (EMR) per the requirements outlined in the **QA Policy on Audit of EMRs**.

It is important that the staff who is most familiar with the data be present during the audit to assist the auditors in locating the documentation in the primary records. Staff from off-site locations must be available by telephone or email to answer questions. It is also recommended that the Principal Investigator and co-investigators be available during the audit for clarification of issues raised by the auditors.

### **ASSESSING AUDIT FINDINGS**

The audit consists of reviewing and evaluating three separate components: 1) compliance to IRB and consent form requirements, 2) the pharmacy and use of NCI DARFs, and 3) patient case review. During the audit, each of these components will independently be assigned an assessment of Acceptable, Acceptable Needs Follow-up, or Unacceptable, based on findings at the time of the audit.

- a. Acceptable: No deficiencies, few lesser deficiencies, or major deficiencies that were addressed and/or corrected prior to the audit. No follow-up is required.
- b. Acceptable, Needs Follow-Up: Multiple lesser deficiencies identified, or major deficiencies identified that were not corrected and/or addressed prior to the audit. Requires a written response and/or corrective action plan.
- c. Unacceptable: Multiple major deficiencies identified, a single flagrant deficiency identified, or excessive number of lesser deficiencies. Requires (as a minimum) a written response and/or corrective action plan and a reaudit of any component rated as unacceptable.

At the conclusion of the audit, the auditors will conduct an exit interview with the Principal Investigator and staff on the findings from the audit. This will provide an opportunity to clear up any questions which could have a direct influence on the final report submitted to the NCI. A preliminary report of any major findings must be submitted to the NCI-CTMB within one working day of the audit.

The auditors will then compile and analyze the data, and a final report will be prepared and submitted to the NCI within ten weeks of the audit, where a review of the audit findings and Group recommendation is made. If the NCI has any comments or questions, the Network Operations Center is notified.

A copy of the Quality Assurance Audit Report is sent to the Principal Investigator at the time it is submitted to the NCI. The Principal Investigator is responsible for notifying the IRB, co-investigators and affiliate/component investigators of the results of the audit. Results of all Quality Assurance Audits are reported to the SWOG Board of Governors.

Institutions found to be “unacceptable” or “acceptable but needs follow-up” on any component are required to submit a written response and/or corrective action plan to the SWOG Network Operations Center within 21 days of receipt of the final audit report. The corrective action plan along with an assessment of acceptability by the Quality Assurance Department must be forwarded to the NCI within 45 days of the date of the final audit report. Failure to meet the NCI deadline will result in suspension of registration privileges at the institution.

A reaudit of any component rated as unacceptable will be conducted within one year after the unacceptable audit. An unacceptable rating for the same audit component on two consecutive audits may result in probation. Accrual will be suspended pending submission of a site improvement plan that addresses key infrastructural issues contributing to poor performance. An unacceptable rating at the second reaudit may result in termination from SWOG. This action will be done in consultation with the Group Chair and NCI-CTMB.

If research misconduct is identified on an audit or reported by a Group member, the Group Chair, the Professional Review Committee and the NCI-CTMB will be notified immediately.