INTERNAL QA PROGRAM

It is suggested that each site develop its own Quality Assurance program for continued monitoring of all clinical trials, both treatment and cancer control, to ensure proper conduct of all aspects of the research program, including regulatory, drug accountability and patient case review. There are six components of a QA Program that are considered to be the core structure of a successful program:

- Eligibility Quality Control
- Data Quality Control
- Patient Case Internal Audit
- Pharmacy/Drug Accountability QC
- Regulatory QC
- Education/Corrective Actions

1. Eligibility Quality Control

A double-check system should be in place to ensure that any eligibility errors are caught *before* the patient is enrolled in the study. A second review should be performed on *every* patient by a second research nurse or CRA to confirm eligibility and to verify all source documentation is available to verify eligibility *prior* to enrollment in the trial.

2. Data Quality Control

- All forms that are submitted to any research base should be *prospectively* reviewed for completeness of data. This prospective review detects and corrects data problems before the forms are submitted to the research bases.
- In the first six months of employment for any new research staff, all of the data submitted by this employee should be closely scrutinized for integrity and completeness and verified against source documentation.
- "*As needed"* reviews should be conducted when problems are identified. These reviews should continue until the precipitating factor is resolved.
- Expectation Reports and Query Reports from research bases should be reviewed by the Program Coordinator and delinquent or incorrect data should be submitted or amended within two weeks by the research nurse/CRA.

3. Patient Case Internal Audit

Select patients' charts should be reviewed for completeness, protocol adherence, and data quality on a routine basis. A review of a minimum of 10% of charts is recommended. A suggested time for the review is at the end of the protocol treatment unless the treatment plan is greater than 6 months, in which case an audit within 6-9 months of registration is suggested.

Using the Quality Assurance Guidelines and checklists provided by the research base, evaluate each chart for the following:

- Informed consent
- Eligibility
- Drug Dosing
- Toxicity assessment/reporting of SAEs
- Lab tests/procedures
- Follow up visits
- Evaluation of endpoint status
- Good documentation practices
- Accurate completion of Case Report Forms
- Timeliness of data submission

4. Pharmacy / Drug Accountability QC

Review of drug accountability records and routine verification of inventory should be done at each pharmacy storing or dispensing investigational agents. The frequency of reviews and inventory checks is dependent on the volume of investigational agents in use. A monthly schedule is recommended at the beginning with the frequency decreased to quarterly review once a level of confidence is established. Determine that records are organized and maintained appropriately, and that policies and procedures are in place for oversight of drug receipt and dispensing.

New staff or anyone needing additional training that have *any* interaction with investigational agents are required to complete certification in the "*Investigational Agent Handling Video*". This video provides guidance on the proper handling of investigational drugs and is required training for new staff involved in ordering, accounting for, and disposing of investigational drugs. Control pharmacies are responsible for monitoring any satellite pharmacies under their jurisdiction.

5. Regulatory Quality Control

It is recommended that institutions designate one person whose primary responsibility includes IRB submissions and internal regulatory tracking.

Internal checks should verify that the following are in place:

- IRB documents are neatly organized in binders in chronological order and filed separately by protocol. Documentation to confirm IRB review, approval and/or acknowledgement of all IRB submissions should be on file.
- A system to systematically check the SWOG/CTSU websites for the status of protocol updates.
- A system such as a data base or spreadsheet for tracking all amendments, revisions, informed consent changes, annual renewals, and serious adverse events that require IRB review.
- A system to ensure the use of the most current version of the consent form when consenting new patients.
- A system to ensure that patients currently on study are informed of important new findings (e.g. risks) in a timely manner.
- A system to determine if annual review is being conducted for all protocols with patients on active follow up. A "List of Patients in Follow-up" at the local site as well as the "List of Protocols with No Required Follow-up" available on the CRA Workbench are useful tools.

6. Education/Corrective Actions

Findings from the review should be used to identify areas that require the implementation of corrective action plans or additional training. The following will help in developing in-house training plans:

- All findings and quality assurance reports should be discussed with staff and investigators.
- A method of tracking areas of deficiency in order to identify trends that need to be addressed with research staff.
- Policies and procedures should be developed and updated as needed to ensure the internal Quality Assurance program is followed.
- Staff education should be on an ongoing basis. Areas noted to be deficient during either the internal audits or research base audits should be incorporated into the education process as needed. Annual review of ethical and regulatory issues should be held. It is suggested that tracking of all educational events, topics, and attendance should be recorded and kept on file at the institution.