SITE PREPARATION FOR A SWOG AUDIT

NOTIFICATION OF AFFILIATES/COMPONENTS

Four weeks prior to the site visit, institutions will receive a list of the patient records, IRB records, consent forms and drug accountability records that are to be audited. Main Members, LAPS and NCORPs must notify their affiliates/components of the selected cases for their site with audit instructions, including the date, time, place and requirements of the audit. Each affiliate/ component should prepare for the audit in the same manner as the parent institution. Arrangements should be made for a representative from each affiliate or component site to be present at the audit or available by phone for questions.

IRB & INFORMED CONSENT

All IRB information pertinent to the protocols being audited should be reviewed prior to the audit to collect any missing information or submit any outstanding submissions to the IRB. The Regulatory files should be organized for easy access to the files pertaining to the audit. Colored tabs indicating the pertinent documentation (annual reviews, amendments, etc.) should be used for marking the files for the auditor's review.

Consent form documentation to be submitted to the SWOG Operations Office **prior** to the audit:

- Copies of the most current versions of consent forms for designated protocols on the case list.

IRB/Consent documentation to be available **during** the audit:

- Documentation pertaining to initial review, continuing reviews, protocol modifications (amendments, revisions, closure notices, etc.), internal Serious Adverse Events, and external Safety Reports. ***Documentation may be in the form of minutes of the IRB meeting or an IRB approval letter that is signed by the IRB chairman or designate. IRB Certification Forms are not considered acceptable documentation of IRB review.***
- If the CIRB is utilized, all documentation of CIRB approvals including approved consent boilerplate language must be obtained by the local site for the audit including notification from the CIRB that they are the IRB of record. Documentation of local approval or implementation of consent forms must also be available.
- If applicable, a copy of the IRB policy of an alternate method for handling submission/approval of external safety reports
- Copies of all versions of IRB approved consents or a detailed list of all versions for protocols to be reviewed.
- Specimen collection/banking consents and HIPAA authorizations, if separate from the treatment consents

DRUG ACCOUNTABILITY & PHARMACY REVIEW

The site should verify the following prior to the pharmacy audit:

- **Drug Accountability Record Forms (DARFs)**
  - DARFs are present for all investigational agents being audited as well as any current inventory. If any records for this audit cycle have been archived, these records should be retrieved prior to the audit.
- **Storage and Stability**
  - Ensure the balance on the DARF matches the physical inventory and account for any discrepancies.
  - Ensure all study drugs are stored in a secured and limited-access area at appropriate temperatures.
  - Review expiration dates of the drugs for confirmation of appropriate disposal, return of drug or transfer of drug for outdated and/or unused drug on closed or blinded studies.
- **Tracking and Disposition**
  - Shipping receipts, transfer forms, and drug return forms for each protocol must be on file.
  - If drugs may be destroyed on site per protocol, destruction records must also be on file.

Documentation to be submitted to the SWOG Operations Office **prior** to the audit:

- Drug accountability records (including DARFs, shipping receipts, drug return forms, and transfer forms) for all activity since the last audit date for select protocols including any satellite pharmacy records. Please see the case list for details. Records will be reviewed for compliance and compared to patient records prior to the audit.

Documentation to be available **during** the audit:

- Originals of the drug accountability records that were submitted to SWOG as well as for any current inventory.
- The auditors will conduct a pharmacy inspection for all on-site audits. The site should make arrangements with the pharmacy prior to the audit.

PATIENT CASE REVIEW

The following should be performed **prior** to the audit:

- Medical records and research charts should be obtained and kept in a secure location. If electronic medical records (EMRs) are used, computer access should be available to facilitate the retrieval of any information that is missing from the research chart.
- All supplemental data necessary for the audit (i.e. Radiology, Pathology, etc.) should be obtained from the various departments and kept in a secure location. If scans are available as electronic data (i.e. online, CD-Rom, etc.), arrangements should be made so that the auditor has easy access to the information.
- A review of all patient records being audited to verify that the following documents are available:
    - **Eligibility Criteria**
        - Documentation to support all eligibility criteria including operative and pathology reports, radiology reports, lab reports, medical history, doctor's notes, etc.
    - **Treatment**
        - Drug orders, prescriptions, chemo flowsheets, progress notes, intake calendars or other documentation of treatment administration;
        - Documentation to support and provide an explanation of modifications or delays in study treatment.
    - **Disease Outcome/Response Determination**
        - Documentation to support disease assessment/response evaluations as outlined in the protocol (physician notes, radiology reports, lab reports, etc.).
    - **Toxicity Assessment**
        - Documentation to support assessment of toxicities (grade, attribution, clinical significance).
        - Supporting laboratory reports;
        - Copies of CTEP-AERs forms for reportable SAEs.
    - **Data Quality**
        - All records including the subject's primary care chart and copies of medical records from outside sources that are considered relevant to the subject's study participation must be accessible for review during an audit. If records are missing, all attempts to secure the records must be documented;
        - Original records are preferred but shadow charts are acceptable if unable to obtain original records;
        - Copies of all case report forms with submission dates documented (RAVE forms do not need to be printed);
        - Documentation of specimen submission
    - **Consent Forms**
        - Original consent is in patient's record;
        - If applicable, documentation to verify patient was reconsented or informed of new information as instructed by the sponsor and/or local IRB.
- Tagging of all major study parameters in the source documents to facilitate the review of documents supporting eligibility requirements, treatment administration, toxicity evaluations, and disease assessment/tumor measurements

Examples of Color-Coding for Patient Charts

White	Operative and Pathology Reports: label tab with Op or Path and date
Purple	H&P, Weight, Performance Status: label tab with Pre-study or Cycle # and date
Orange	Treatment Records: label tab with Cycle # and date
Yellow	Toxicity Evaluations: label tab with date range
Red	Lab Tests: label tab with Pre-study or Cycle # and date
Green	Tumor Measurements/Disease Assessment: label tab with Pre-study or Cycle # and date
Blue	Specimen submission: label with pre-study or Cycle #

AUDIT ACCOMODATIONS

A quiet room for the audit team to work, wireless internet access and access to a copy machine should be provided. There are a lot of charts, binders, and other materials present during the audit and it is important that adequate space be available. See **Policy on Audit of EMRs** if auditors will be expected to review any electronic data. Please have a copy of the local **Site Authority Log** available for the audit team.

A regulatory representative and the persons who are most familiar with the patient charts should be available during the audit to assist with questions raised by the auditors. The Principal Investigator should also be available for the exit interview.