

**SWOG
QUALITY ASSURANCE AUDIT GUIDELINES**

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QUALITY ASSURANCE AUDIT GUIDELINES

Introduction

As a sponsor and funding agency for cancer clinical trials, FDA regulations require the NCI's Division of Cancer Treatment and Diagnosis (DCTD) to maintain a monitoring program. The Clinical Trials Monitoring Branch (CTMB) of the Cancer Therapy Evaluation Program (CTEP) in the DCTD, provides direct oversight of each Network Group's monitoring program which includes auditing as one component. Auditing is conducted by the Quality Assurance Department and is administered through the Operations Office in San Antonio.

Purpose

The purpose of an audit is to document the accuracy of data submitted to SWOG and to verify investigator compliance with protocol and regulatory requirements. In addition, the monitoring program provides an opportunity for the audit team to share with the institution staff, information concerning data quality, data management, and other aspects of quality assurance. The major objective of the audit program is to verify study data that could affect the interpretation of primary study endpoints. This is done through independent verification of study data with source documents. The NCI CTMB Guidelines for auditing of clinical trials for the Network Groups and NCORP Research Bases form the basis of the SWOG audit program.

Quality Assurance Site Visits

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 Institutions will remain at risk for audit even if their membership in the Group is withdrawn or terminated since they have made a commitment to long-term follow-up of patients on study for as long as the patient remains alive.

- 1) To become full Group members, new probationary Member, LAPS and NCORP institutions must undergo a successful Quality Assurance audit within 18 months of registering their first patient. After a successful audit, the institution will be placed in the normal rotation to be audited again within 3 years. New affiliates and NCORP components will be audited at the next scheduled audit of their parent institution.
- 2) All Members, LAPS and NCORPs will be audited on-site. Affiliates registering less than thirty patients in a three-year period may be audited at the same time as their Member institution. Affiliates registering greater than thirty patients in a three-year period will be audited separately on-site.
- 3) Affiliate sites will have an on-site pharmacy audit conducted at least once every other audit cycle if time and budget constraints allow. The case review and regulatory components of the audit will be conducted on-site at the time of the pharmacy audit in most cases.
- 4) In most instances, the on-site audit will take one full day; however, if accrual is exceptionally large 2 - 4 days may be required. The audit team will consist of at least one RN or CRA auditor and a Quality Assurance representative from the Operations Office.
- 5) Institutions will be contacted to schedule a date for the Quality Assurance audit approximately 3 - 6 months prior to the audit. The NCI will be notified in advance of all scheduled audits at least six weeks in advance. The NCI may choose to attend an audit or send a representative from Theradex.
- 6) A list of the cases selected for the audit will be sent to the institution 4 – 6 weeks prior to the audit to allow for preparation of records.
- 7) A number of patients equal to 10% of treatment and cancer control accrual since the last audit with a minimum of three will be randomly selected for each institution. 10% of SWOG and 10% of CTSU accrual will be selected. While most cases will be selected from accruals since the last audit, all patients accrued will be at risk for selection. A minimum of one unannounced case will also be selected for review at each on-site audit. Institutions that must travel to an off-site location for their audit will be exempted from this requirement.
- 8) The institution is required to produce the following original data or legible copies (see **Appendix A** for policy on review of electronic medical records) for the audit:

- a) Original signed and dated consent forms for each patient case.
- b) Research charts
- c) Complete medical records including clinic (outpatient) and hospital charts, if applicable.
- d) Operative, pathology, radiotherapy reports, etc., if applicable.

Note: Data from Rave does not need to be printed for the auditors.

NOTE: Failure to provide the above documentation during an audit may result in an unacceptable audit.

- 9) To facilitate this review, **Site Preparation for an Audit (Appendix B)** has been developed to assist the person responsible for collecting documentation for the audit. It is important that the person who is most familiar with the charts be present during the audit to assist the auditors in locating the documentation in the primary records. It is highly recommended that the person designated to assist the team review the primary records prior to the audit to identify and flag the source of the data reported.
- 10) 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 provides an opportunity for the audit team to answer questions and clear up any issues which could have a direct influence on the final report submitted to the NCI.
- 11) Auditors will complete protocol and patient specific narratives of deficiencies using the Audit Review Forms. The QA Representative will prepare a final report by entering audit findings into the CTMB-AIS database.
- 12) Audit Assessment: The audit consists of reviewing and evaluating three separate components: 1.) compliance to IRB and consent form content 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.
- 13) The final audit report must be submitted to the NCI within ten weeks of the audit. If the NCI has any comments or questions, the SWOG QA is notified. A copy of the audit report is sent to the Principal Investigator, the Group Chair and the SWOG Statistical Center to inform the statisticians, data coordinators and study coordinators of any significant discrepancies involving eligibility, treatment, toxicity or response assessments. The Principal Investigator is responsible for notifying the IRB, co-investigators and affiliate investigators of the results of the audit. The Principal Investigator may challenge or respond to the findings in writing to the Group Chairman. Results of all Quality Assurance Audits are reported to the SWOG Board of Governors.
- 14) Institutions found to be "unacceptable" or "acceptable but requires follow-up" on any component are required to submit a corrective and preventive action plan to the SWOG Operations Office within 21 days of receipt of the final audit report. Failure to submit a a corrective action plan within the required timeframe will result in suspension of registration privileges.
- 15) A reaudit of any component rated as unacceptable will be conducted within one year after the unacceptable audit. For budgetary reasons, reaudits of IRB, consent form content and drug accountability are conducted off-site at the Operations Office when possible. An unacceptable rating for the same audit component on two consecutive audits will 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.

- 16) If systematic or intentional misrepresentation of data is identified on an audit, the Group Chair and the NCI-CTMB will be notified immediately and an immediate repeat audit will be scheduled by the Quality Assurance Department with the NCI and/or the FDA.

CONDUCT OF A QUALITY ASSURANCE AUDIT

The purpose of the audit is to assure the accuracy of the data submitted to the SWOG Data Operations Office and to verify compliance with protocol and regulatory requirements. The audit team will verify that all research was conducted in compliance with FDA regulations and NCI and SWOG Guidelines. The audit is conducted in three parts:

REGULATORY REQUIREMENTS

IRB Approvals

IRB documentation will be verified for all the protocols selected for the case review as well as 1 - 2 additional protocols active for follow-up only. Documentation will be reviewed to ensure IRB approval and timely implementation of protocols and protocol updates. IRB compliance will be assessed using the IRB Review Form **(see Appendix C)**.

Consent Form Content

Consent forms will be compared to the model consent and must contain applicable elements as outlined in Title 45, Code of Federal Regulations, Part 46, Protection of Human Subjects, and be updated with new information as required by protocol modifications. Special attention will be given to verify the wording of specimen banking questions, if applicable. To facilitate consent form content review, copies of selected consent forms must be sent to the Operations Office for review prior to the audit. Consent forms are assessed per the Consent Form Content Review Form **(see Appendix D)**.

INVESTIGATIONAL DRUG ACCOUNTABILITY

Federal regulations require that adequate records be maintained to show disposition of investigational drugs. Institutions must use the NCI Drug Accountability Record Form (DARF) or NCI Oral DARF to account for all drugs that are supplied by the NCI (including commercially available drugs). Investigational agents that are not supplied by the NCI should also be logged onto the NCI DARF unless the protocol specifies otherwise. Auditors are required to inspect the drug accountability records and tour the area where the investigational drugs are stored, if applicable.

To facilitate this drug audit, copies of drug accountability records for the selected protocols must be sent to the Operations Office for review prior to the audit. This review verifies that the DARFs are maintained according to NCI requirements, that expired or unused drugs are disposed of or returned to the NCI, and drug from closed studies are transferred to another active study or returned to the NCI. If any drugs have been dispensed to a satellite location, these records will also be reviewed. The dates and dosages documented in the medical record will then be compared to the drug logs for the patients selected for the drug audit.

During the on-site audit, a tour of the storage facilities will be conducted to ensure that drugs are stored in a separate, secure, limited-access area; and the drugs are stored at the correct temperature and identified by protocol number. The physical inventory will be verified by comparing the quantity and lot against the drug logs for accuracy and to ensure disposition of expired or unused drug. Refer to <http://ctep.info.nih.gov/requisition/> for additional guidance on policies of the NCI/Pharmaceutical Management Branch. Drug accountability is assessed per the Drug Accountability and Pharmacy Review Form **(see Appendix E)**.

PATIENT CASE REVIEW

The patient case review will entail examination of the following criteria for each patient:

Eligibility

Verify all eligibility criteria, stratification factors and required prestudy parameters to confirm patient met all eligibility criteria as specified by the protocol.

Treatment Compliance with Protocol

Establish in the primary record the patient's actual height and weight and body surface area. Verify doses, dates of treatment, and sequence and route of administration were according to protocol requirements.

Disease Outcome/Response Determination

Verify that disease outcome was evaluated according to protocol. Responses (PR, CR) should be verified through review of x-rays, scans, pathology reports, lab reports, and records of physical examinations.

Toxicity Assessment

Verify that toxicity was assessed according to protocol by use of required baseline and follow-up studies. Verify that toxicities were properly graded and accurately reported and any Serious Adverse Events were reported within the required timeframes. Timeliness of reporting SAEs is also monitored centrally at the Operations Office.

Data Quality

Source documents will be compared to the reported data in Medidata Rave to determine thoroughness and accuracy in the reporting of study parameters to the Data Operations Office. Good documentation practices must be followed. Data must be submitted in Rave in a timely manner. Specimens must also be collected and submitted to the appropriate repository within required timeframes.

Consent Form

Consent Forms must be the current IRB-approved version at the time of patient registration, be dated and signed prior to registration and treatment, and contain all required signatures. Any significant new findings that may relate to the subject's willingness to continue participation must be provided to the subject in accordance with 45 CFR 46.116(b)(5). The patient's intent for use of specimens must be reported correctly.

Patient Case Review will be assessed using the Case Review Form (**see Appendix F**) and deficiencies will be graded per the following guidelines.

- **MAJOR DEFICIENCY:** variance from protocol-specified procedures that makes the resulting data questionable.
- **MINOR DEFICIENCIES:** deviations that do not affect the outcome or interpretation of the study and are not described above as major deviations. An unacceptable frequency of minor deviations may be treated as a major deviation.

Examples of deviations include:

ELIGIBILITY

- Patient did not meet eligibility criteria as specified by protocol
- Unable to confirm eligibility due to missing documentation.

TREATMENT

- Incorrect agent/treatment/intervention used.
- Additional agent/treatment/intervention used which is not permitted by protocol.
- Greater than +/- 5% dose deviations (> 10% deviation is a major deficiency).

- Treatment not administered correctly, incorrectly calculated, or not adequately documented.
- Unjustified dose modifications or failure to modify doses according to protocol.
- Unjustified delays in treatment.
- Timing and sequencing of treatment not per protocol.

DISEASE OUTCOME/RESPONSE ASSESSMENT

- Inaccurate documentation of initial sites of involvement.
- Tumor measurements/evaluation of status of disease not performed according to protocol.
- Failure to detect cancer (as in prevention study) or failure to identify cancer progression.
- Claimed response (PR, CR) cannot be verified.
- Failure to detect cancer (prevention study) or failure to identify cancer progression.

TOXICITY

- Failure to obtain required baseline and follow-up studies to effectively assess toxicity.
- Grades, types, or dates/duration of serious toxicities inaccurately recorded.
- Toxicities cannot be substantiated.
- Recurrent under or over-reporting of toxicities.
- Failure to report a Serious Adverse Event within the required timeframe.

GENERAL DATA QUALITY

- Recurrent missing documentation (i.e. missing charts, insufficient source documentation).
- Protocol-specified laboratory tests not reported or documented.
- Protocol-specified diagnostic studies including baseline assessments not done
- Frequent data inaccuracies or errors in submitted data.
- Protocol-specified research/imaging studies not done or submitted appropriately.
- Frequent data inaccuracies (use of white out in the primary record, corrections not made appropriately)..
- Delinquent data and specimen submission (> 3 months for baseline forms and pathology materials, > than 6 months for on treatment and follow-up data are major deficiencies).

INFORMED CONSENT

- Consent form missing.
- Consent form not signed and dated by patient.
- Consent form signed after patient was registered.
- Consent form not the current IRB-approved version at the time of registration.
- Consent form does not include updates required by protocol modifications.
- Patients not reconsented and/or informed of new findings
- Specimen banking questions missing, different from model or patient responses reported incorrectly.

ADDITIONAL RESOURCES

The following documents are available to provide additional guidance for the audit process:

- Regulatory Guidance
- Patient Chart Review Guidance
- Policy on auditing on Electronic Medical Records
- Best Practices for SWOG studies
- Preparation for an FDA Inspection: Trial Master File

Appendix A

REVIEW OF ELECTRONIC MEDICAL RECORDS

SWOG recognizes that many institutions now collect and store research data electronically. Electronic data used to support NCTN studies must adhere to the same guidelines as a paper system and adhere to 21 CFR Part 11:

- When original observations are entered directly into a computerized system, the electronic record is the source document.
- Data entry should be designed so that individuals need to enter digitized or electronic signatures to ensure the data is attributable.
- Any change to a record should not obscure the original information. The record should clearly indicate that a change was made and clearly provide a means to locate and read the prior information.
- Changes to data that are stored electronically require an audit trail including who made the changes, when, and why they were made. Audit trails must be available for review during the audit, if requested.
- Data should be retrievable in such a fashion that all information regarding each individual subject in a study is attributable to that subject.
- Electronic records related to SWOG-credited studies must be available for inspection by the FDA, NCI, or SWOG.
- Electronic data must meet the same applicable regulatory requirements for record keeping and record retention in clinical trials as paper systems.

SWOG will review EMRs during audits with the following restrictions and guidelines:

- 1) Original consent forms must be preserved and provided for auditors to review.
- 2) A computer(s) with EMR access must be available for each auditor in or near the conference room where the audit is taking place. EMR data from remote locations such as affiliates or NCORP components may also be reviewed if made available at the main member location during the audit.
- 3) Access to the EMR for each auditor must be arranged prior to the audit. It is important that access and any password requirements are verified prior to the audit date to ensure a smooth and efficient audit process. Failure to provide timely access to the auditors will require that audit documents be printed for review.
- 4) Complete the attached EMR Source Document Locator Form and return to the auditor prior to the audit.
- 5) A CRA or other knowledgeable person must be available to guide the auditors in navigating the EMR the first morning of the audit.
- 6) It is important that a paper/shadow chart of documents that often are not part of the EMR be made available for auditor review. Some examples of such data include:
 - Original signed consent forms
 - Signed eligibility checklists, registration worksheets, etc.
 - Documentation of drug compliance such as nursing notes, patient diaries or calendars
 - Documentation of specimen submission (Specimen Tracking printouts, lab notes, etc.)
 - Documentation of calculations (BSA, calculated creatinine clearance, etc.)
 - Adverse event logs signed by the investigator
 - Documentation of tumor measurements/grids that are signed by radiologists or investigators
 - Documentation of communications (with SWOG, patient, etc.)
- 7) Regulatory documents may also be reviewed electronically provided files are labeled and a knowledgeable person is available to assist during the review.

EMR Source Documentation Locator Form

Instructions: Please indicate below where the documents are located within the eMR, and any specific instructions to navigate to the source data. If any of the data is located in a paper or shadow chart, indicate this also.

EMR System:

Are any documents located in a paper chart? Yes No If yes, which documents: _____

Document	How labeled in EMR	Tab	Additional instructions
History & Physical Exams			
Prior Cancer Treatment			
Performance Status			
Height & Weight			
Vital Signs (flowsheets)			
CRA / Nurses Notes			
Pathology reports			
Operative Reports			
Radiation summary note(s)			
Radiation Treatment			
Cardiac tests EKG, MUGA, ECHO			
Disease Assessment/Scans/ Measurements/Response			
Laboratory Flowsheets			
Systemic Treatment Volume / dose / administration times			
Oral Drug Compliance			
Adverse Events Grade / attributions / immune relationship			
Specimen Collection & Shipment			
Scanned copies of records from outside facilities			

Appendix B

SITE PREPARATION FOR A SWOG AUDIT

AUDIT NOTIFICATION

Four to six weeks prior to the site visit, a list of the patient records, IRB records, consent forms and drug accountability records that are to be audited will be sent by email. Main Members, LAPS and NCORPs must notify their affiliates/ components of their selected cases 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 site to be present or available by phone during the audit for questions.

REGULATORY DOCUMENTS

All IRB information pertinent to the protocols being audited should be reviewed prior to the audit to collect any missing information. The Regulatory files should be organized for easy access. Colored tabs indicating the pertinent documentation (annual reviews, protocol updates, etc.) are recommended for flagging 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.
- If using the CIRB, copy of the current approved boilerplate language (Study-Specific Worksheet About Local Context).

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

- Local IRB: Documentation pertaining to initial review, continuing reviews, protocol updates, internal SAEs, 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.**
- CIRB: A copy of the initial and subsequent revisions, if applicable, of the **CIRB Approval of the Study-Specific Worksheet About Local Context** giving approval to conduct the study as well as documentation of local implementation date for protocol updates and informed consent versions. CIRB protocol approval documents are available on the CTSU website and do not need to be printed for the auditors.
- 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/locally implemented consent forms or a detailed list of all versions for protocols that will be reviewed during the audit.
- Specimen collection/banking consents and HIPAA authorizations, if separate from the treatment consents.

Additional documents:

A copy of the local **Site Authority Log** must be available for the audit team. A **Trial Master File** should be available for potential FDA registration studies (**S1400/LUNGMAP, S1404, S1418, S1605 and S1806**). The CTSU **Delegation of Task Log** will also be verified for applicable studies.

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 must be retrieved prior to the audit.
- **Storage and Stability**
 - The balance on the DARF matches the physical inventory and account for any discrepancies.
 - All study drugs are stored in a secured, limited-access area that is monitored for temperature.
 - 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.
 - Procedures are in place to verify an investigator has an active investigator registration with CTEP prior to ordering investigational agents

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 treatment administration data 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 must be obtained and kept in a secure location. If electronic medical records (EMRs) are used, computer access must be available to facilitate the retrieval of any information that is missing from the research chart.
- 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 (i.e., signed AE logs with grade and attribution).
 - 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;
 - Supporting research documents (i.e., questionnaires, specimen submission);
 - Original records are preferred but shadow charts are acceptable if unable to obtain original records;
 - **Consent Forms**
 - Signed consent forms;
 - If applicable, documentation to verify patient was reconsented or notified 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 and wireless internet access 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.

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.

Appendix D

Institution: _____

Audit Date: _____

SWOG CONSENT FORM CONTENT REVIEW

Consent Form Deficiency	Protocol No.				
	Version				
	Approval Date				
Involves research; purpose; duration of participation; description of procedures; identification of experimental procedures					
Description of risks or discomforts					
Description of benefits to subject or others					
Disclosure of alternative procedures or treatments					
Description of the extent of confidentiality of records					
Explanation regarding compensation and/or whether treatment available if injury occurs					
Contact for research questions, information regarding subjects' rights, and contact for research-related injury					
Participation is voluntary; refusal to participate involves no penalty; subject may discontinue participation at any time					
Unforeseeable risks to subject, embryo, or fetus					
Circumstances in which subject's participation may be terminated by investigator without subject's consent					
Additional costs to subject which may result from participation in research					
Statement that new findings which may relate to subject's willingness to continue participation will be provided to subject					
Disclosure of approximate number of participants					
Specimen banking questions correctly stated					
Overall assessment					

Deficiency details:

Protocol # _____ :

Protocol # _____ :

Protocol # _____ :

Protocol # _____ :

Comments: _____

Reviewer Signature: _____

Appendix E

Institution: _____

Audit Date: _____

SWOG DRUG ACCOUNTABILITY and PHARMACY REVIEW

Protocol #:						
Corresponding Case#:						
NCI Drug Accountability Forms						
Completely & correctly filled out						
Satellite records accounted for						
Patient treatment records cross-checked						
Tracking and Disposition						
Drug shipping receipts kept						
Return & transfer forms kept						
Drugs returned/transferred in timely manner						
Expired drugs returned or destroyed						

Storage Conditions

- Identified by protocol number _____
- Secure/limited access area _____
- Temperature monitoring _____

Destruction Policy _____

Policy for verifying prescribing physician is a CTEP registered investigator _____

Number of NCI DARFs compared to inventory _____ **Number of patients cross-checked** _____

Physical Inventory			
Protocol #	Drug/Dose/Lot #	DARF Balance/Date	Actual Balance/Expir.

Protocol # _____ :

Protocol # _____ :

Protocol # _____ :

Comments: _____

Over for additional comments

Appendix F

Institution: _____

Audit Date: _____

SWOG PATIENT CASE REVIEW FORM

Case #:	Protocol #:	Disease Site:
SWOG Patient #:	Registration Date:	Investigator:

ELIGIBILITY	OK	Major	Lesser	NA
Patient meets all eligibility criteria as specified by protocol.				
Documentation missing; unable to confirm eligibility.				
Eligibility affirmation signed by investigator				

TREATMENT:

Incorrect agent/treatment used.				
Additional agent/treatment used which is not permitted by protocol.				
Incorrect dose deviations (> +/- 10% is a major).				
Unjustified dose modifications or failure to modify doses according to protocol.				
Treatment doses incorrectly administered, calculated, or documented.				
Unjustified delays in treatment.				

DISEASE OUTCOME/RESPONSE DETERMINATION

Inaccurate documentation of initial sites of involvement.				
Tumor measurements/evaluation of status of disease not performed per protocol.				
Protocol-directed response criteria not followed.				
Claimed response (CR, PR) cannot be verified.				
Failure to detect cancer (prevention study) or failure to identify cancer progression.				

TOXICITY

Grades/types or dates/duration of serious toxicities inaccurately recorded.				
Toxicities cannot be substantiated.				
Follow-up studies necessary to assess toxicities not performed.				
Failure to report a Serious Adverse Event (SAE).				
Recurrent under or over-reporting of toxicities.				

DATA QUALITY Last contact reported: _____ Off treatment: _____

Recurrent missing documentation (i.e. data, specimens).				
Protocol-specified laboratory tests/diagnostic studies not documented.				
Protocol-specified research studies not done or submitted appropriately.				
Use of white out or failure to follow good documentation practices.				
Frequent data inaccuracies.				
Errors in submitted data				
Delinquent data or specimen submission.				
Other (specify)				

CONSENT FORM Version _____ Date Signed: _____ OK Major Lesser NA

Consent form missing.				
Consent form not signed and dated by patient.				
Consent form signed after patient registered and/or started on treatment.				
Consent form does not contain all required signatures.				
Consent form signed by patient was not the current IRB-approved version.				
Consent form does not include updates or information required by protocol modifications.				
Specimen banking questions missing, different from model, or reported incorrectly.				
HIPAA authorization not signed				

Comments:

Auditor Signature: _____