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SPMA.01: CTSU Auditing Procedures

Project Name: Cancer Trials Support Unit (CTSU)

Project Director: Steve Riordan

Effective Date: 12/15/2011

DOCUMENT CONTROL

Change Record:

EFFECTIVE DATE	AUTHOR	VERSION	CHANGE HISTORY LOG
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10/15/2007	Ruth Lambersky	02	No changes.
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12/25/2008	Ruth Lambersky	05	Removal of EPP from definitions list.
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CTSU PROCEDURE DOCUMENT

CTSU Procedure: SPMA.01
Title: CTSU Auditing Procedures

I. PURPOSE

The purpose of this procedure is to document the procedures for monitoring clinical trials for all Cancer Trials Support Unit (CTSU) enrollments, as well as facilitate coordination of CTSU-enrolled patient cases into the adult Cancer Center Research Base or Cooperative Group audit mechanism. The objectives are to ensure compliance with Federal regulatory requirements and National Cancer Institute (NCI)/ Cancer Therapy Evaluation Program (CTEP) Clinical Trials Monitoring Branch (CTMB) guidelines for the conduct of clinical trials and study data validity.

II. SCOPE

This procedure applies to all cancer protocols approved by NCI/CTEP that have patient enrollment on CTSU menu protocols that are not credited to the lead protocol group.

III. RESPONSIBILITY

- The CTSU staff and Cancer Center Research Base or Cooperative Group Audit Coordinator or designee, who perform clinical site auditing activities are responsible for complying with this procedure.
- The CTSU Audit Task Lead or designee, is responsible for overseeing this procedure.
- The CTSU Audit Task Lead or designee, is responsible for ensuring compliance with this procedure.
- The CTSU Project Director or designee, is responsible for ensuring compliance with this procedure.
- The CTSU Audit Task Leaders and/or the CTSU Project Director are under the oversight of the Clinical Trials Monitoring Branch (CTMB), which has the ultimate responsibility for auditing and ensuring compliance.

IV. REFERENCES

- Clinical Trials Monitoring Branch, CTEP, DCTD, NCI, Guidelines for Monitoring of Clinical Trials for Cancer Center Research Base or Cooperative Groups, CCOP Research Bases, and the Clinical Trials Support Unit (CTSU), version date October 2006, effective 01Jan2007, at http://ctep.cancer.gov/branches/ctmb/clinicalTrials/monitoring_coop_ccop_ctsu.htm.
- Pre-Audit Letter (Exhibit SPMA.01.11.e1)
- Non-Endorsed Cases (Exhibit SPMA.01.11.e2)
- Endorsed and Endorsement Plus+ Cases (Exhibit SPMA.01.11.e3)
- DCP Cases (Exhibit SPMA.01.11.e4)
- Preliminary Report of Audit Findings (Exhibit SPMA.01.11.e5)
- 21 CFR, Parts 50, 54, 56, 312 and 314. "FDA Regulations related to Good Clinical Practice and Clinical Trials."

- 45 CFR, part 46: Protection of Human Subjects

V. DEFINITIONS

See CTSU Glossary for the following definitions:

- Audit Information System (AIS)
- Aligned Site
- Audit Coordinator
- Cancer Center Research Base
- Clinical Trials Monitoring Branch (CTMB)
- Division of Cancer Prevention (DCP)
- Drug Accountability Record Forms (DARFs)
- Endorsed Study
- Endorsement Plus Study (E+)
- Institutional Review Board (IRB)
- Non-Endorsed Study

VI. BACKGROUND

The International Conference on Harmonization (ICH) and the Federal Regulations require a standardized practice on how functions are performed and documented in a clinical trials environment. The primary source of regulated procedures is provided via Standard Operating Procedure (SOP) generated in Westat's Clinical Trials Area (Westat's CTA), where development, oversight, maintenance, implementation and training of SOP processes are provided.

VII. PROCEDURE

1. The CTSU audit procedures are based on the CTMB/CTEP Guidelines (version date October 2006, effective 01Jan2007). This procedure will encompass all patient enrollments via the CTSU. The responsibility for assignment of the audit will be determined by the site's primary affiliation with a Cancer Center Research Base, Cooperative Group or CTSU.

   1.1 There are two distinct classes of institutions participating with the CTSU. The first are institutions that are members of an adult or pediatric Cooperative Group or Cancer Center Research Base, and the second is an NCI site participating as a CTSU managed site.

   1.2 This SOP will outline the audit procedures for both types of sites.

2. Audit Obligations for Patients Registered Through CTSU: For group-aligned sites, the audit of a patient registered through the CTSU is the responsibility of the group receiving credit for the enrollment. The CTSU Audit Coordinators work directly with the Cancer Center Research Base or Cooperative Group Audit Coordinators and Statistical Centers to manage the CTSU Audit Program. The CTSU obligations will vary based on the following scenarios:

CATEGORIES	**TASKS**	**RESPONSIBILITY**
NCI CTSU	Conduct the audit and all associated	▪ CTSU responsible for all

Managed Site Enrollment [applicable to MD115 only at this time]	tasks: ▪ Selection of sites ▪ Scheduling audit dates with site ▪ Scheduling auditors ▪ Selecting protocol cases ▪ Data Points ▪ Reporting requirements ▪ Providing follow up information	aspects of the audit.
CTSU Enrollment Credited to Group on Endorsed or Endorsement + Protocol	▪ Conduct audit of endorsed / endorsement + CTSU enrollment - **Group** ▪ Include CTSU cases in the regular Group audit	▪ Credited Group is responsible for all aspects of the audit. ▪ CTSU will provide a list of endorsed / endorsement + cases for the Group to use for case selection.
CTSU Enrollment Credited to Group on Non-Endorsed Protocol	▪ Conduct audit - **Group** ▪ Facilitate the selection of CTSU cases - **CTSU** ▪ Provide the Group with the necessary tools, i.e., CTSU site accrual reports and other audit tools – **CTSU** ▪ Provide additional audit staff if indicated - **CTSU**	▪ Credited Group will perform the audit and associated tasks. ▪ CTSU will assist as described.
DCP CTSU Enrollment Credited to Group on Non-Endorsed Protocol	▪ Conduct audit - **Group** ▪ Facilitate the selection of CTSU cases - **CTSU** ▪ Provide the Group with the necessary tools, i.e., CTSU site accrual reports and other audit tools – **CTSU** ▪ Provide additional audit staff if indicated - **CTSU**	▪ Credited Group will perform the audit and associated tasks. ▪ CTSU will assist as described.
Group to Group Enrollment	▪ Conduct the audit and perform all associated tasks	▪ As per current practice, the Group is responsible for all aspects of the audit.
Group to Intergroup	▪ Conduct the audit and perform all associated tasks	▪ As per current practice, the Group for which the site is a member is responsible for all aspects of the audit.

Copies of CTSU protocols, audit checklists, audit worksheets (Exhibit SPMA.02.11.e1), accrual listings and other relevant audit tools will be made available to the Cancer Center Research Base or Cooperative Group Auditors for CTSU cases. Cancer Center Research Base or Cooperative

Group Auditors may request all of the audit preparation material listed above or a selection as needed.

3. Timing of Audits: Based on CTMB guidelines, all new main member institutions will be audited within 18 months following entry of their first patient in NCI-sponsored treatment trials, regardless of the mechanism of enrollment. A new affiliate institution must be audited within 36 months of first accrual; the affiliate may be audited on site or off site at the main member, when the main member is audited.

   3.1 Following the initial audit, all institutions will be audited at least every 36 months and are at risk for audit during any one-year period. Institutions remain at risk for audit even if their membership in the Cancer Center Research Base or Cooperative Group is withdrawn or terminated, since they have made a commitment to long-term follow-up of patients on study, with provision of good quality data according to the study schedule.

   3.2 Selection of terminated institutions for audit is at the discretion of the CTSU in conjunction with CTMB, and will focus on institutions with high accrual, particularly to important or pivotal studies and/or a large number of patients in active follow-up.

   3.3 The CTSU managed site will be audited at least once every 36 months, but may be selected for audit at any time. Additionally, if the site accrues 10 or more patients within the first 36 month audit cycle, they will be at risk for audit prior to 36 months per the CTSU Audit Panel discretion.

4. Evaluation Components**:** The CTSU on-site audit consists of reviewing and evaluating three components independently with compliance to CTMB and NCI guidelines for the conduct of clinical trials. The three components are as follows:

   4.1 Institutional Review Board (IRB) documentation and informed consent content
   4.2 Accountability of investigational agents and pharmacy operations
   4.3 Individual patient case records

5. Site Selection: CTSU Audit Coordinators will use the Clinical Trials Monitoring Branch (CTMB) Audit Information System (AIS) to identify which institutions are due for audit and re-audit.

   5.1 For Group-affiliated sites: CTSU Audit Coordinators will communicate with the Cancer Center Research Base or Cooperative Group Audit Coordinators. The CTSU will assist the Groups in identifying the enrollment of CTSU cases at the sites by making CTSU accrual reports available. CTSU will provide a list of endorsed and endorsement + cases for the Group to use for case selection (Exhibit SPMA.01.11.e3). The CTSU will select and list the non-endorsed and DCP cases for the Group (Exhibit SPMA.01.11.e4).

   5.2 For the NCI CTSU managed site: The CTSU will coordinate the entire audit process. CTSU will schedule the audit date into the CTMB AIS at least 10 weeks prior to the audit. The CTSU will provide notice of CTSU's intent to audit the given site at least 8 weeks in advance of the audit date. The CTSU will provide the institution with a list of protocols and patient cases selected for audit review at least two but no more than four weeks prior to the audit.

   5.3 Selection of CTSU Patient Cases for Audit: CTSU Audit Coordinators will work with the Group for selection of CTSU cases and particular data items to be audited. The Groups will receive a Pre-Audit Letter (Exhibit SPMA.01.11.e1) approximately 8 weeks prior to the scheduled audit. Please note- not all audits scheduled will permit an 8 week notice. However, the Pre-Audit letter will be completed and submitted to the Groups for final record retention.

5.3.1 The CTSU Audit Coordinators receive daily CTMB AIS generated emails providing notification of scheduled Group audits.

5.3.2 A minimum number of cases equivalent to 10% of patients accrued since the last audit will be reviewed. The selection includes 10% of treatment cases and an additional 10% of cancer control / prevention cases.

5.3.3 The 10% of cases reviewed apply to each participating site being audited.

5.3.4 Case selection for all audits will follow the CTMB guidelines outlined below where appropriate:

- For each main member, affiliate, CCOP, and CCOP component, a minimum of 10% of enrollment for Group, Cancer Center Research Base and DCP protocols, 10% of endorsed and endorsement + cases, 10% of non-endorsed cases and 10% of cancer control / prevention cases credited to a Group / CCOP will be selected.
- For selection purposes, the 10% of chosen cases will always be rounded up. For example, if 12 patient cases are eligible for selection, at least two cases will be audited.

5.3.5 When selecting cases for audit, emphasis will be given to the following types of studies: IND, multi-modality, inter-group, designated prevention trials and potential licensing trials, a well as studies with high accrual.

5.3.6 Selected non-endorsed and DCP cases are those cases enrolled via the CTSU at least 90 days prior to the scheduled audit date.

5.3.7 If < 3 CTSU patients enrolled in non-endorsed or DCP cases are ***selected*** for audit at any one particular Cancer Center Research Base or Cooperative Group member site, the Cancer Center Research Base or Cooperative Group auditors will audit CTSU cases per the Cancer Center Research Base or Cooperative Group mechanism.

5.3.8 If ≥ 3 CTSU patients enrolled in non-endorsed or DCP cases are ***selected*** for audit at any one particular Cancer Center Research Base or Cooperative Group member site, CTSU auditors will augment the Cancer Center Research Base or Cooperative Group audit team for the CTSU cases if assistance is requested by the Group or Cancer Center Research Base. Audit dates will be coordinated with the Cancer Center Research Base or Cooperative Group Audit Coordinators. The Group may submit a request for assistance to their assigned CTSU Audit Coordinator via email.

5.3.9 One unannounced CTSU treatment and one DCP patient case may be selected for limited audit on the day of the audit consisting of, at a minimum, review of informed consent and eligibility. However, if the unannounced cases only receive a limited review, then these cases do not count towards the minimum of 10%.

5.3.10 If the Group or Cancer Center Research Base has a need for an additional CTSU Auditor to supply expertise in certain therapeutic area not addressed by the particular group, or if the Group feels there are other circumstances which would require additional audit support, the CTSU will be willing to consider supplementing the audit team on a case-by-case basis. The Group or Cancer

Center Research Base may submit a request for assistance to their assigned CTSU Audit Coordinator via email (treatment, DCP or combined requests for assistance will be provided when possible by the CTSU).

6. Selection of Material for Review: The CTSU Audit Coordinators will work with the Cancer Center Research Base or Cooperative Group Statistical Center sponsoring the study to provide copies of CTSU submitted data forms to verify against the primary medical records. The submitted forms should include all data regarding eligibility and crucial outcome endpoints.

   6.1 IRB approvals, annual re-approvals and all required amendment approvals for all audited studies are reviewed.
   6.2 A sample of at least 3 consent forms for at least three studies will be carefully reviewed for all elements required by Federal Regulations. Of the 3 consent forms reviewed, at least one must be from a CTSU study.
   6.3 NCI Drug Accountability Record Forms (DARFs) for NCI-supplied agents will be reviewed where applicable. DARFs also will be crosschecked with at least 1 patient case for each of these drugs. One of the patient case DARFs reviewed must be from a CTSU case.

7. Audit Preparation at the Institution: The institution is responsible for ensuring that all relevant materials are available for review at the time of the audit. If an affiliate institution is audited off site at the time of the main member institution's audit, the affiliate institution must provide either the original patient source documents or copies of the complete record.

   7.1 This includes:
   - the IRB approvals, re-approvals and amendment approvals;
   - annual reports submitted to the IRB;
   - copies of the external safety reports reviewed and submitted, and
   - the current version of the protocols, including any amendments and informed consents in use at the institution.

   7.2 Finally, all records regarding the disposition of investigational drugs, specifically copies of drug orders, return receipts, transfer forms, and the NCI DARFs, must be available. The pharmacy should be alerted that the auditors will conduct an on-site inspection of investigational agent storage and records.
   - If the physician's office, clinic or other institution receives a *multiple day supply* of CTEP-supplied investigational agents, satellite accountability records must be maintained for each satellite site and copies must be available for review by site auditors.

   7.3 The Principal Investigator, or his/her designee, and the research staff should be available throughout the audit to answer any questions and help the auditors locate necessary information in the source documents. The Principal Investigator must also participate in the Exit Interview.

8. On-Site Audit Procedures Overview: Auditors will review specific data related to research and regulatory requirements during the audit. Audit checklists will be utilized to ensure that all elements are reviewed. Any problems or discrepancies found are noted on the checklist, and the document must be signed by the auditors and retained by the responsible Group.

9. Review of Source Documents: Source documents should be used to independently verify study data. Source documents may include, but are not limited to, the following:
   - Inpatient and outpatient medical records
   - Progress notes
   - Diagnostic reports (x-rays, scans, ECGs, etc.)
   - Laboratory data
   - Admission forms
   - Study flow sheets signed/dated on a real time basis by the health care practitioner evaluating the patient and Protocol or Study Roadmaps that are also signed and dated
   - Enrollment tracking sheets
   - Subject diaries/calendars
   - NCI DARFS
   - Informed consents and IRB documents

10. Assessment of Audit Findings: Each of the three components (IRB/informed consent content, accountability of investigational agents and pharmacy operations, and individual patient case records) is assigned an assessment based on findings at the time of the audit as follows:

    Acceptable:
    - No deficiencies identified,
    - Few lesser deficiencies identified, or
    - Major deficiencies identified during audit that were addressed and/or corrected prior to the audit for which documentation exists and no further action is required by the Cancer Center Research Base or Cooperative Group, CCOP Research Base, the CTSU, the institution or the principal investigator.

    Acceptable Needs Follow-up:
    - Any major deficiency identified during the audit but not corrected and/or addressed prior to the audit, or
    - Multiple lesser deficiencies identified.

    Unacceptable:
    - Multiple major deficiencies identified,
    - A single major flagrant deficiency found, or
    - Excessive number of lesser deficiencies identified.

11. Exit Interview: At the conclusion of the visit, the audit team leader will conduct an exit interview with the responsible investigators and all other appropriate staff. During this exit interview, the preliminary findings and any recommendations from the audit team will be discussed. This interview provides opportunity for education, immediate dialogue, feedback, and clarification of preliminary audit findings. The audit team leader should document the discussion in detail. This will facilitate the submission of appropriate information for the AIS final audit report to CTMB. The Principal Investigator must participate in the exit interview process.

12. Reporting Requirements**:** For either a Group- or CTSU-led audit, the responsible party must submit a preliminary report (24 Hour Report) within one working day of completing the audit to the CTMB (Exhibit SPMA.01.11.e5).

12.1 If the audit is performed by a Cancer Center Research Base or Cooperative Group, the Group is responsible for submitting the preliminary audit report to the CTMB via fax within one working day of completing the audit.

12.2 If the audit is performed by a CTSU Audit Coordinator for the NCI CTSU managed site, the CTSU will submit the preliminary audit report to the CTMB via fax within one working day of completing the audit.

Any major deficiencies discovered during the audit must be described in the Preliminary Report. Any findings that are suggestive of intentional misrepresentation of data, and/or disregard for regulatory safeguards for any of the three components of the audit, must be reported to the ***CTMB immediately by telephone at (301) 496-0510***.

12.3 Utilizing the audit findings provided by the audit team, the Group or CTSU Audit Coordinator will enter the audit assessment information into the CTMB AIS within 70 working days of the audit date.

12.4 Once the Audit Report is finalized in AIS, the Audit Coordinator (Group or CTSU) will provide a copy of the audit report to the audit site.

12.5 If a CTSU case is audited by a non-lead Group, the Cancer Center Research Base or Cooperative Group sponsoring (lead) the protocol will be notified via email when the final audit report is available in AIS. The lead Group will be able to view the audit findings via the AIS.

13. Follow-up Requirements: For each component rated as Acceptable - Needs Follow-up or Unacceptable, the institution is required to submit a written response and/or corrective action plan to the audit coordinator within four weeks of the date the Final Report was mailed. A copy of the written response/corrective action plan, along with an assessment by the coordinating Cancer Center Research Base or Cooperative Group of the response/corrective action plan, must be submitted to the CTMB within 45 days of the date the final audit report was entered into the CTMB AIS.

13.1 A re-audit (either internal and/or on-site) is mandatory for any component rated as unacceptable within one year or when 3-5 patients have been enrolled at the site.

13.2 The CTSU reserves the right to conduct a re-audit of any of the CTSU patient cases, pharmacy and/or regulatory materials that are rated as unacceptable.

VIII. DOCUMENTATION REQUIREMENTS

The following documents are required as part of the audit trail process:

- Pre-Audit Letter to the Principal Investigator at the site announcing the date of the audit, a list of the patients and protocols to be reviewed and a description of all of the materials that must be available for review.
- Preliminary Audit Report of audit findings submitted to the CTMB via fax within one working day of completing the audit.
- Final Audit Report must be finalized in the CTMB AIS within 70 working days of the audit date.
- Post–Audit Letter describing the audit findings and requesting a written response/corrective action plan for all categories labeled Acceptable Needs Follow-Up or Unacceptable forwarded to the site with a copy of the Final Audit Report.
- Written Response/Corrective Action Plan submitted by the site to the Audit Coordinator within four weeks of the date the Final Audit Report was mailed and forwarded to the CTMB.

- When indicated, a Follow-Up Letter will be sent to the site (copy to CTMB) after review of items contained in the Written Response/Corrective Action Plan such as challenges to audit findings with supporting documentation provided or items that may require clarification or additional documentation.

IX. REVIEW AND REVISION

This procedure document will be reviewed and revised as necessary by the CTSU Project Director or designee a minimum of once per six months per contract specifications.

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Pre-Audit Letter

(***Insert date***)

(***Insert Group Contact Name / Address***)

Re: Cancer Trials Support Unit (CTSU) review of enrollment by (***List NCI Codes***) for (***insert Group Name***) audit

Dear (***insert Audit Coordinator's Name or Contact's Name***):

We have reviewed the Clinical Trials Monitoring Branch (CTMB) Audit Information System (AIS), for the (***insert NCI Codes***) scheduled for audit.

For case selection for all audits, CTMB (NCI) recommends a sampling stratification for 10% of Group cases, plus 10% of endorsed / endorsement plus + cases (where applicable), plus 10% of non-endorsed cases (where applicable) and 10% of cancer control (DCP) cases (where applicable). These guidelines were outlined in the CTMB Audit Guidelines (version October 2006) and have been incorporated in the CTSU Work Instruction Number SPMA-01.

Endorsed / Non-Endorsed Cases:

The CTSU Work Instruction SPMA-01 defines the case audit responsibility as follows:

> ***'For Group aligned site(s), the audit of a patient registered through CTSU will become the responsibility of the Group receiving the credit for the enrollment'.***

CTSU will identify all non-endorsed enrollments credited to your Group and select the specific cases for audit (attachment #1). For convenience, CTSU will also identify the endorsed / endorsement plus + enrollment credited to your Group (attachment #2). However, it will be the responsibility of the Group to select the endorsed / endorsement plus + cases for any given audit.

Cancer Control / Cancer Prevention (DCP) Cases:

With the addition of select DCP trials to the CTSU menu, the Pediatric and Adult Cooperative Group sites may enroll to trials to which they previously did not have access. There is no endorsement policy for DCP trials on the CTSU menu. At time of enrollment, the enrolling site selects one of their active affiliations for credit assignment. Per CTMB, 10% of the DCP cases must be selected for inclusion during audit. The CTSU has selected the cases (attachment #3) and provided for your review. The CTSU will accommodate ***all*** requests for assistance for DCP cases when at least 3 cases are select for audit at a specified site. The CTSU will also supply assistance when less than 3 cases are selected at a specified site provided CTSU auditors are available. Should you need assistance, please email your audit coordinator directly.

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The audit results of the CTSU cases will be reported directly to CTMB (NCI) via AIS on your Group audit report for the respective sites.

Please contact me at (***insert phone #)*** or (***insert email address***) if I can be of further assistance.

Thank you for your continued support and participation in the CTSU.

Sincerely,

(***Insert name / title***)

Cc: Ruth Lambersky, CCRP (CTSU)

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Non-Endorsed Cases (Attachment #1)

Non-Endorsed Cases (audit is responsibility of credited group for < 3 enrollments selected):

NCI Site Code:
Name of Institution:
Audit Date:
Audit Location:

Total Number of ECOG Non-Endorsed cases =
Protocol Number and number of cases:
*indicates IND

STUDY	INVESTIGATOR	PATIENT	TX_ARM	ENROLLMENT_DATE

Note: The CTSU has selected above noted Non Endorsed case(s) for inclusion in the upcoming ECOG audit at site (***insert site codes***). ***Should you need assistance with your non endorsed case auditing, please email your audit coordinator directly.***

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Endorsed and Endorsement Plus+ Cases (Attachment #2)

Endorsed & Endorsement Plus+ Cases (audit is responsibility of credited group) for (***insert NCI Site Code***):

NCI Site Code:
Name of Institution:
Audit Date:
Audit Location:

Total Number of ECOG Endorsed cases =
Total Number of ECOG Endorsement + cases =
Protocol Number C40101 (5 cases)
Protocol Number NCIC.BR.19 (1 case)

Protocol #	PID #	Treating MD	Treatment Arm	Registration Date
C40101				
C40101				
C40101				
C40101				
C40101				
NCIC.BR.19				

Note: ECOG will select from the above noted ECOG endorsed / endorsement plus + case(s) for inclusion at the upcoming ECOG audit at site (***insert NCI Code***). The minimum number of total cases selected for review should be equivalent to at least 10% of non-endorsed and 10% endorsed / endorsement plus+ cases. After selecting the case(s), please inform your CTSU Audit coordinator and they will contact the respective Cooperative Group for copies of the case report forms for the audit.

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DCP Cases (Attachment #3)

Cancer Control Cases selected for (***insert NCI Site Code***):

NCI Site Code:
Name of Institution:
Audit Date:
Audit Location:

Total Number of ECOG Cancer Control cases = 2

Protocol Number WFU-07-02-03 (1 case)
Protocol Number C170601 (1 case)

Protocol #	PID #	Treating MD	Treatment Arm	Registration Date
WFU-07-02-03				
C170601				

Note: The CTSU has selected above noted DCP case(s) for inclusion in the upcoming ECOG audit at site (***insert site codes***). ***The CTSU will accommodate all requests for assistance for DCP cases when at least 3 cases are select for audit at a specified site. The CTSU will also supply assistance when less than 3 cases are selected at a specified site provided CTSU auditors are available. Should you need assistance, please email your audit coordinator directly.***

PRELIMINARY REPORT OF AUDIT FINDINGS

Group: **NCI Code:** **Category:**

Institution:

Membership Type:
Main Member/
CCOP NCI Code:

Main Member/
CCOP Name:

Audit Date:

Date of Prior Audit:

Audit Type:

Components:

Audit Team Leader:

Telephone:

Name of NCI Representative Present:

MAJOR DEFICIENCIES WITH IRB OR INFORMED CONSENT CONTENT: NO / YES
If YES, briefly describe:

DRUG ACCOUNTABILITY/PHARMACY NON-COMPLIANCE: NO /YES
If YES, briefly describe:

PATIENT CASE REVIEW SUMMARY:

Category	No. of Patient Cases Reviewed	No. of MAJOR Deficiencies	Briefly describe MAJOR Deficiencies
Informed Consent			
Eligibility			
Treatment			
Disease Outcome /Response			
Adverse Event			
General Data Management Quality			

FAX THIS REPORT TO THE CLINICAL TRIALS MONITORING BRANCH, NCI
(301) 480-2642 WITHIN ONE WORKING DAY OF COMPLETION OF AUDIT.

Any data irregularities identified through quality control procedures or through the audit program that raise any suspicion of intentional misrepresentation of data must be immediately reported to CTMB, CTEP, NCI. The CTMB must be notified immediately by telephone [(301) 496-0510] of any findings suspicious and/or suggestive of intentional misrepresentation of data and/or disregard for regulatory safeguards for any of the three (regulatory, pharmacy and patient case) components of an audit. Similarly, any data irregularities identified through other quality control procedures suspicious and/ or suggestive of intentional misrepresentation of data must be immediately reported to CTMB. It is the responsibility of the Cooperative Group, CCOP Research Base or CTSU to immediately notify CTMB when they learn of any significant irregularities or allegations related to scientific misconduct by a staff member or institution participating in their research program. It should be emphasized the irregularity/misrepresentation does not need to be proven, a reasonable level of suspicion suffices for CTEP notification. It is also essential that involved individual(s) and/or institutions follow their own institutional misconduct procedures in these matters.