Preparing Your Audit Response: Corrective Action Plans (CAP)

Barbara Barrett, Audit Program Manager

Alliance Chicago Office

Alliance Summer 2012 Group Meeting

Audit Exit Interview

- Take notes throughout audit and at Exit Interview
- Make sure to understand the comments from the Exit Interview, don’t be afraid to ask questions

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

Preparing the Audit Report

- Team Leader creates a draft audit report and resolves any outstanding issues with the site.
- A second review is conducted to check for accuracy and for consistency between sites.

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

The Final Report

The final version is submitted in the CTMB via the AIS (Audit Information System) electronic database.

The final audit report is sent via electronic mail and/or Fed Ex to the Principal Investigator and Lead CRA

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

Audit Report Distribution

It is the Main Member's responsibility to review the audit report with affiliate(s)/components.

Communication between main member and affiliate is key.

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

Understanding the Audit Report

Reminder of three audit components:

- IRB/ Consent Content
- Pharmacy
- Patient Case Review

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

Understanding the Audit Report

Category ratings:

- *OK* (no deficiency is warranted)
- *Lesser Deviation* (minor deficiency)
- *Major Deviation* (significant error or omission)

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

Understanding the Audit Report

Overall Category Assessment:

Acceptable – No follow-up is needed

Acceptable Needs Follow-up – corrective action plan required within 15 business days

Unacceptable – As above and re-audit scheduled within 12 months required

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

Clinical Trials Monitoring Branch - Final Report

Run By : SCHERERS

Date: 1/26/2007

Audit Date : 12/01/2006 **Group :** CALGB **Audit Category :** Treatment **Audit Type :** Routine audit
Institution Code : CK000 **Name :**
Main Member / CCOP Code : *CO000* ***Name :***
Audit Location :
Revision Number: 0 **Revision Date:** 0 1-DEC-06

Date of Prior Audit : **Number of Cases Audited :**10 **Average Annual Accrual :**10 **Principal Investigator :** Tom Jones, MD

Audit Outcome Summary

Component	Assessment	Followup Required (Y/N)	Followup Due	Reaudit Required (Y/N)	Reaudit Time (in months)
IRB and Informed Consent Content Review	Acceptable needs follow-up	Yes	02/23/2007	No	
Accountability of Investigational Agents and Pharmacy Operations Review	Acceptable needs follow-up	Yes	02/27/2007	No	
Patient Case Review	Unacceptable	Yes	02/23/2007	Y	18 Months

Reaudit Timeline History

Component	Readuit Time	Readuit CTMB Comments
IRB Reaudit Time Line History		
Pharmacy Reaudit Time Line History		
Patient Case Reaudit Time Line History	18 months	

Institution Staff	Title	Affiliation

Audit Team	Title	Affiliation
Weiss, Raymond B. (MD)	Team Leader	Georgetown University Medical Center

Co-site Visitor	Title	Affiliation

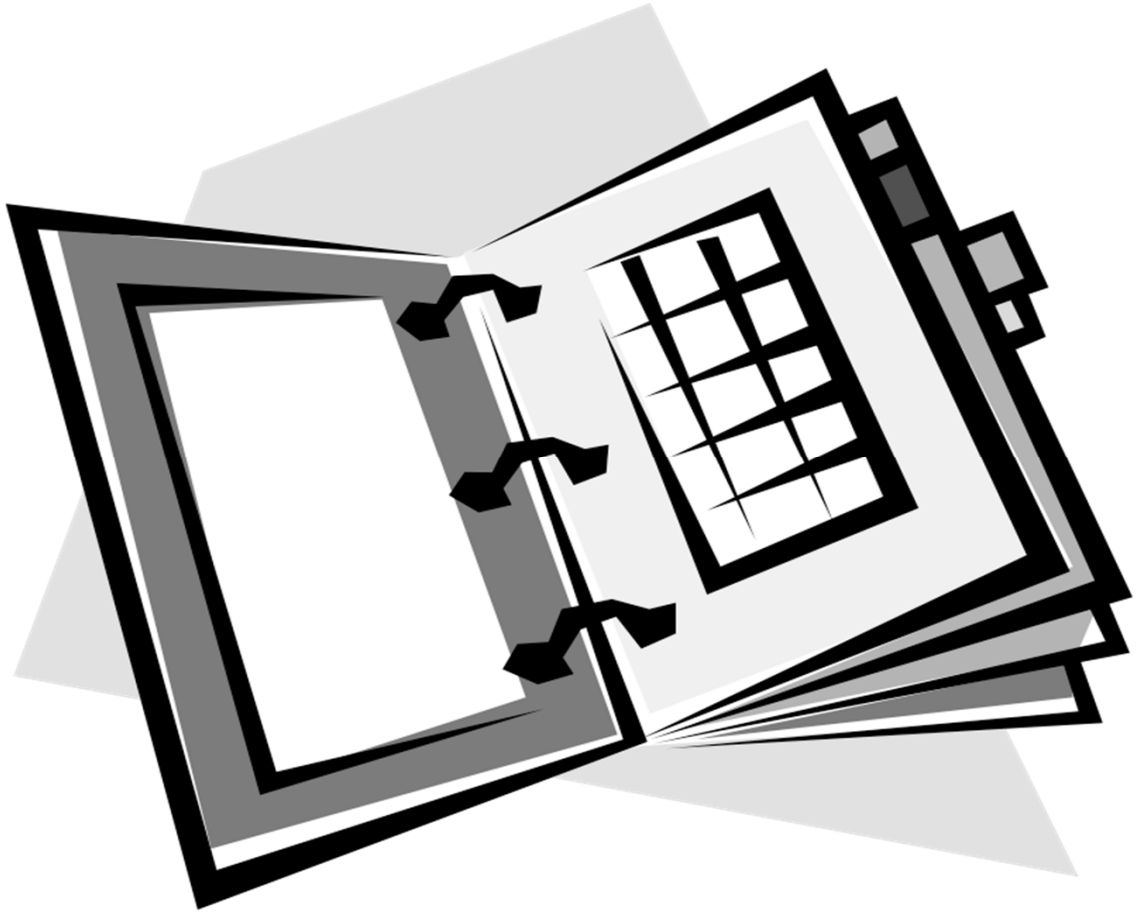
If you received an IRB Unacceptable rating…

- Alliance policy - An Unacceptable rating in any section of the audit is evaluated on a case-by-case basis and may warrant immediate suspension of registration privileges.

- This suspension will be lifted when a response is submitted and found to be Acceptable.

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

Sample Audit Reports



ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

Audit Report Cover Letter

- Summarizes the three ratings:

The IRB/Consent Content review was rated ***Acceptable Needs Follow-up****. The deficiency includes……. Pharmacy review was rated* ***Acceptable****. The Patient Case review was rated* ***Unacceptable****. The deficiencies include. …….*

- Provide a date the CAP is due:

A written corrective plan addressing the deficiencies in these areas must be submitted by ***Tuesday, July 19, 2012.***

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

Clinical Trials Monitoring Branch - Final Report

Run By : SCHERERS

Date: 01/27/2007

Audit Date : 12/01/2006 **Group :** CALGB **Audit Category :** Treatment **Audit Type :** Routine audit

Institution Code : **Name :**

Main Member / CCOP Code : ***Name :***

Audit Location :

Revision Number: 2 **Revision Date:** 2-JAN-07

Protocol #	Patient #	Informed Consent	Eligibility	Treatment	Toxicity	Disease Outcome	Data Quality
CALGB-XXXX	XXXXX	OK	OK	OK	OK	OK	Major

Total # of Major deficiencies : 2 **Total # of Lesser deficiencies :** 0 **Total # of deficiencies Not Reviewed :** 0

Total # of Patient cases : 1 **Total # of Patient cases :** 1

Patient Case Review Assessment

Patient Case Review Assessment : Acceptable needs follow-up

Follow-up required for Informed Consent : No

Follow-up required for Eligibility : No

Follow-up required for Treatment : No

Follow-up required for Disease Outcome/Response : No

Follow-up required for Toxicity : No

Follow-up required for General Data Quality : Yes COMMENTS : The required submission of the pathology and operative reports to the Data Operations Center should now be done.

Re-audit required : No

Audit Procedures : The audit was conducted at the practice offices of the and followed normal CALGB procedures.

General Comments : There were 2 major deficiencies in the IRB review process that were corrected just prior to the audit. However, the site should note that annual renewals of this one study must continue as long as CALGB is collecting data for this one patient.

One major deficiency in the Patient Case review was corrected in preparation for the audit. Another one (the deficiency in submitting the pathology and operative reports) must now be corrected. A written response regarding the above deficiencies must be submitted by----

Exit Interview Comments : An exit interview was held with , and the deficiencies were discussed.

Submission of CAPs

CAPS should include:

- measures for prevention of deficiencies in the future, e.g. revision of your P&Ps, additional training, discussion with IRB regarding procedures and timelines, re-education of staff involved.
- Confirmation of correction for specific deficiencies, e.g., submission of outstanding data.

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

Submission of CAPs

- Author(s) of CAP should be identified.
- CAP MUST be submitted on letterhead and signed by the PI plus any other author.
- Attach any needed support documentation.
- No need to attach copy of your audit report.
- Submit CAPs via email or fax, following up with originals.

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

CAP Review

- The audit program manager (APM) reviews the corrective action plan to determine if the response is Acceptable. If the CAP is not Acceptable, clarification of additional information will be requested. (*happy to review drafts!)*
- The APM will submit the CAP to CTMB.
- If the CTMB requires additional information, they will contact the group. We do not receive notification of acceptance of CAPs from CTMB.

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

Writing a Satisfactory CAP

- Address each issue listed in report as needing follow-up.
- Address 3 questions:
  - Why did this deficiency occur? (i.e, what was the problem?)
  - Has the specific problem been corrected *(i.e. has the outstanding data in question been submitted? Has the patient been re-consented with the updated consent form?)*
  - What plan has been implemented to ensure this type of deficiency will not occur in the future?

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

Samples of Acceptable/Unacceptable Corrective Action Plans

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

IRB Deficiency

Major Deficiency	Partially Acceptable CAP
Update #6 posted on 02/15/11 has not been approved by the IRB. Three IND reports posted on 03/15/11 have not been submitted to the IRB.	As updates and safety reports are identified, they will be entered on the Outlook calendar to submit and track.

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

IRB Consent Content Deficiency

Major Deficiency	Partially Acceptable CAP
The local ICF does not include sample submission question #1 from page 2 of the model consent. This study is still open to new enrollment.	A revision has been submitted to the IRB that includes all model consent questions. The site will now use the consent content checklist and review local consents compared to model consents.

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

Pharmacy Deficiency

[*Audience Response*]

Major Deficiency	Acceptable or Unacceptable Plan?
Patient returned drug was logged back onto the DARF for this open labeled study.	**Two new sections have been added to our Pharmacy policy (see attached). One is "Patient Return of Unused Study Medication" and the other is to include the CTMB Guidelines section 5.3. Pharmacy staff have been re-educated.**

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

Treatment Deficiency

[*Audience Response*]

Major Deficiency	Acceptable or Unacceptable Plan?
Dose modification error for Cycle 4. A 25% dose was warranted and the patient received a 40% dose reduction. This is greater than 10% margin of error.	"In reviewing these, I believe she did a very good job overall, but there were some confusing items which were misinterpreted. I believe that with her experience now, the next case would be much better."

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

Data Quality Deficiency

[*Audience Response*]

Major Deficiency	Acceptable or Unacceptable Plan?
Per the Pathology Coordinating Office, the study required blood samples and blocks were not submitted.	"This was an isolated event and we do not feel it will occur again."

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

Data Quality Deficiency

[*Audience Response*]

Major Deficiency	Acceptable or Unacceptable Plan?
Data forms for treatment, AE and disease response have not been submitted since cycle #7 (11/19/10). Patient had progressive disease on 11/26/2011.	All forms have been submitted. The cancer center has hired an additional experienced CRA. Next monthly staff meeting will cover data submission schedules. A quarterly review of data will be performed by the office manager."

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

Two Consecutive Unacceptable Ratings?
(In the same component)

CTMB section 6.3.2: **Probation of Participating Institutions**

- The institution will be placed on probation.
- The Group may assign a mentor.
- A “site improvement plan” must be developed to “address key infrastructural issues contributing to poor performance” (ALL this in addition to the corrective plan.)

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

Example: Site Improvement Plan for IRB

- The local IRB policies were revised in response to the audit findings.
- The main member network will cover the costs of the site's CRA to attend the audit prep workshop at the next Alliance group meeting.
- The Lead CRA will perform two IRB audits of the affiliate over the next year.

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

Audit Program Managers:

- Tammy Neseth
  - neseth.tammy@mayo.edu
  - Phone: (507) 266-4051
  - Fax: (507) 284-2643

- Jean Wittlief
  - e.wittlief@duke.edu
  - Phone: 919-602-8735
  - Fax: 919-266-5195

- Barbara Barrett
  - bbarrett@uchicago.edu
  - Phone: (312) 206-8216
  - Fax: (312) 345-0117

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

Additional Contact Information

- Crystal Newkirk, Audit Coordinator
  - cnewkirk@uchicago.edu
  - Phone: (773) 702-9973
  - Fax: (312) 345-0117

- Dawn Deno, Audit Coordinator
  - Deno.dawn@mayo.edu
  - Phone: 507-284-8755
  - Fax: Fax: (507) 284-2643

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

Thank you!

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

2012 Summer Group Meeting

June 28 – 30 / Chicago, IL