



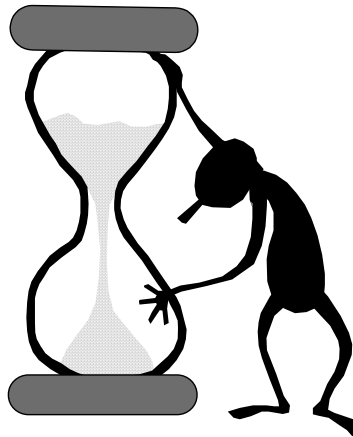
Audit Preparation Timeline

Barbara Barrett, M.S., C.C.R.P.
Ellis Fischel Cancer Center
University of Missouri – Columbia

CALGB CRA Orientation, November 2006

Audit Preparation Timeline

- CALGB Audit Preparation Workshop

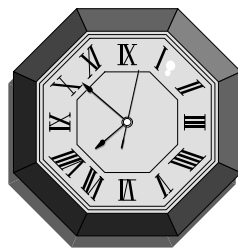


Audit Preparation Timeline

- ***When*** do I start preparing?
 - ***How*** do I prepare?
 - ***Who*** should I contact?
 - ***What*** arrangements need to be made?
 - ***Who*** attends the audit from our institution?
-

When do I prepare?

- **Start NOW!**





Start Audit Preparation Now!

- *Review* the Audit Guidelines from the CALGB Policy and Procedures Manual
 - *Review* a copy of your institution's last audit report
 - *Think* "AUDIT" with each IRB file and patient documentation
 - *Audit* your pharmacy on a regular basis
-

Start Audit Preparation Now

- *Do* a mock audit of your institution and affiliate institutions at least twice a year (quality assurance)
 - *Submit* materials to the Statistical Center, Data Operations as required per protocol
 - *Monitor* submission of required slides, blocks, and x-rays
-

When do I prepare?

- Start NOW!
 - **Audit Date(s) Identified**
-

Audit Date(s) Identified

- *Obtain* the “Golden Rod PI Letter” and read carefully
 - *Start* a correspondence folder
 - *Notify* and *schedule* date with PI, Co-PIs, all CRAs, pharmacists, IRB MR staff
 - Ditto above for your affiliates
 - *Reserve* adequate space for the audit date(s)
-

Audit Date(s) Identified

- *Reserve* adequate space for audit preparation
 - *Order* supplies needed to tag charts (i.e., several colors of post-its)
 - *Reserve* x-ray view box
 - *Arrange* access to food for audit day(s)
-

When do I prepare?

- Start NOW!
 - Audit Date(s) Identified
 - **1 Month Before Audit**
-

1 Month Before Audit

- *Compile* list of patients to be audited in organized fashion (i.e., expired, off tx, active tx)
 - *Make* POA with Medical Records department
 - *Make* POA with Radiology
 - *Make* at least 2 copies of each protocol to be audited (IRB and chart audit)
-

1 Month Before Audit

- *Tag* protocols for chart audit
 - *Begin* IRB review and tagging of each protocol to be audited
 - *Anticipate* “problem cases”
 - *Block* time on schedule of PI for touching base and exit interview
-

1 Month Before Audit

- *Tag* medical records.
 - If a form mistake is discovered, the form can be amended, but needs to be held until after the audit to be submitted.
-

When do I prepare?

- Start NOW!
 - Audit Date(s) Identified
 - 1 Month Before Audit
 - **2 Weeks Before Audit**
-

2 Weeks Before Audit

- *Continue* contact with affiliate institutions to monitor their progress
 - *Touch base* with pharmacist
 - *Be aware* of any new correspondence from Dr. Weiss
-

2 Weeks Before Audit

- *Review* any audit special studies reports to check for accuracy
 - *Expect* arrival of data packets for the auditors
 - *Forward* any affiliate packets to the affiliates, if the audit is taking place there
 - ***DO NOT OPEN Marked Envelopes!!!!***
-

When do I prepare?

- Start NOW!
 - Audit Date(s) Identified
 - 1 Month Before Audit
 - 2 Weeks Before Audit
 - **1-2 Days Before Audit**
-

1-2 Days Before Audit

- *Gather* supplies needed for auditors (i.e., calendars, calculators, BSA calculators, pencils, post-its, etc)
 - *Obtain* the last of medical records to be tagged
 - *Remind* pharmacist of need for at least 1/2 hour of time availability
-

1-2 Days Before Audit

- *Call* the specified audit team leader to verify time of arrival and provide directions
 - *Organize* charts for audit by protocol in audit room
 - *Organize* x-ray jackets for audit by protocol in audit room
 - *Organize* IRB reports by protocol
-

When do I prepare?

- Start NOW!
 - Audit Date(s) Identified
 - 1 Month Before Audit
 - 2 Weeks Before Audit
 - 1-2 Days Before Audit
 - **The Audit Day(s)**
-

The Audit Day(s)

- *Plan* to arrive early
stay late
 - *Plan* for a CRA to be
present at ALL times
 - *Take* 3 deep breaths
and *SMILE* - you've
done the best you can
do!
-



The Audit Day(s)

- *Let* the Audit Team Leader set the agenda for the day(s), advise of special times needed for pharmacy, etc.
 - *Have* a phone and fax available
 - *Take* notes throughout the day
 - *Take* notes at the Exit Interview
 - *Arrange* for return to airport, if necessary
-

When do I prepare?

- Start NOW!
 - Audit Date(s) Identified
 - 1 Month Before Audit
 - 2 Weeks Before Audit
 - 1-2 Days Before Audit
 - The Audit Day(s)
 - **After the Audit**
-

After the Audit

- *Submit* corrected data sheets to CALGB Statistical Center, Data Operations, if appropriate
 - *Read* carefully the Audit Report when it arrives
 - *Write* response to Audit Report
-

Audit Preparation

- Please remember the mission of CALGB. You are an important team member in the climb toward our goals. View the audit as the learning experience that it is.