



Physician/PI Perspective

Alan Lyss, M.D.

Missouri Baptist Medical Center

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Investigator's Role in CALGB Research

"[An investigator is] ... a physician who assumes full responsibility for the treatment and evaluation of patients on research protocols, as well as the integrity of the research data. The investigator assures CTEP that the clinical trial will be conducted according to ethically and scientifically sound principles."*

**integrity: 1. Unimpaired condition; soundness. 2. Adherence to a code; 3. State of completeness.*

Obligations of Investigators

- Submit FDA 1572, attesting to qualifications to perform cooperative group research.
- Affirm that a properly constituted IRB will review and approve all studies, initially and annually.
- Assure secure storage and maintain accurate accountability records for investigational agents.
- Prepare and maintain accurate case histories, recording all pertinent observations.
- Furnish reports to CTEP, CALGB, and CTSU.
- Report promptly SAEs.
- Assure that institutional guidelines regarding privacy for participants in clinical research trials are obeyed.

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Responsibilities of Affiliate Investigators

- Demonstrate competence in the treatment of cancer patients, as defined by the research base.
- Accrue a minimum number of patients, as set by the research base.
- Participate in group meetings/educational sessions.
- Complete a probation period, demonstrating:
 - » ability to enter patients & comply with guidelines.
 - » provide adequate data to the research base.
 - » adhere to CALGB regulatory stds/procedures.
 - » have an appropriate OHRP assurance for human subjects' protection.
 - » adhere to institutional HIPAA guidelines regarding research

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Investigator's Role for CALGB Audits

Prior to Audit

- Treat each patient as if he/she will be audited.
- Make the treatment program, dose modifications, and schedule of tests an obvious portion of the patient's chart.
- Provide complete documentation of clinical care and the rationale for protocol deviations.
- Demand compulsivity from other medical personnel.
- Consider interim, periodic mock-audits of potential problem areas.
- Be certain that IRB and Pharmacy policies conform to CALGB standards; negotiate compliance, if necessary!

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Investigator's Role for CALGB Audits

Preparation for Audit

- Recognize stress level and "clear the decks."
- Be available for last-minute data resolution.
- Provide "goldenrod" sheet to all personnel involved with the audit, especially affiliates.
- Impress ancillary departments with the importance of cooperation and support.
- Be available for introductions and exit interview.

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Investigator's Role for CALGB Audits

An Actual E-mail to Colleagues (July 2005)

"As you know, the Research Office staff is preparing for a CALGB audit this month. This audit is particularly large and rigorous. For that reason, it would be helpful if July was actually a SLOW MONTH for accruals.

If you have patients with **stage IV disease**, whose participation in a clinical trial would allow them **access to a potentially important new drug**, please call the Research Office staff for a consent form--- those patients should not be denied access, regardless of the audit. On the other hand, July is probably **NOT** a month in which we wish to enroll patients on trials of **adjuvant therapy** for early cancers.

Thanks for your cooperation during this unique and stressful time. Business-as-usual will resume in August."

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Investigator's Role for CALGB Audits

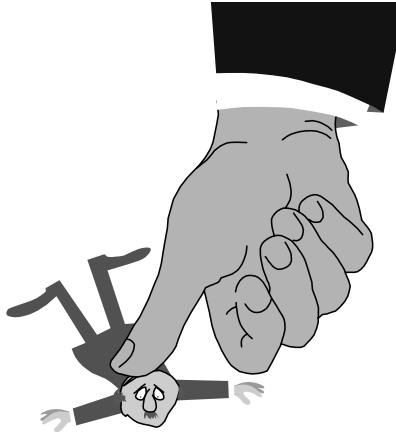
Aftermath of the Audit

- Share results with other investigators and departments that are involved in CALGB research.
- Re-examine strengths and weaknesses in the structure of the research office/program.
- Address clinical and organizational issues in a written response to the audit findings, including findings that may have been erroneous or require clarification.
- Use the critique of the extramural reviewers to help improve the research/overall cancer program.

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Hierarchy of Audit Problems

- I-words
 - » Informed consent
 - » Ineligibility
 - » IRB
 - » IND
- D-words
 - » Drugs
 - » Documentation
 - » Diagnostic studies
- F-words
 - » Follow-up
 - » Forms
 - » pro Forma



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