



## Physician/PI Perspective

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For CALGB Participants Only

## 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.

## 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

## 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.
- Perform periodic mock-audits of your institution and affiliates. Don't assume that everything is fine--- assure yourself!
- Be certain that IRB and Pharmacy policies conform to CALGB standards; negotiate compliance, if necessary!

## 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.

## 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."

## 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.

## Hierarchy of Audit Problems

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

