



## CALGB Audit Program Management

Trini Ajazi  
Group Administrator  
June 2007 Group Meeting

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## Audit Program Personnel

- Data Audit Committee
    - Chair, Ray Weiss, David Hurd (effective 7/1/07)
    - Vice-chair, Susan Tuttle
    - Auditors
  - Central Office
    - Audit Coordinator (AC), Sally Scherer
    - Audit Program Consultant (APC), Barbara Barrett
    - Group Administrator, Trini Ajazi
    - Financial Assistant, Kathy Barnett
    - Meetings Manager, Donna Johnson
  - Statistical Center
    - Staff Statistician, Jeff Johnson
    - Audit Chart Coordinator, Iola Baker
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## Pre-audit Logistics

- Audit coordinator schedules audit at least 3 months in advance
    - Institutional personnel
    - Audit team leader
    - Audit teams
    - Important to respond to request for participation promptly
  - Statistician prepares patient case list including CTSU cases (consult CTSU Audit Coordinator)
    - Unannounced patients may be selected for day of audit (not disclosed to site)
    - Minimum 10% of CALGB cases and minimum 10% of CTSU endorsed and non-endorsed cases
  - AC sends notification to institutional PI (copy lead CRA) with patient selection
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## Pre-audit Logistics continued

- AC sends memo of instructions to auditors via e-mail
    - Auditors book travel with Colpitts at least 1 month prior to the audit
    - Colpitts will book both air, hotel and car (see audit travel instructions)
    - Meetings Manager primary Central Office contact for travel logistics
    - Auditors receive audit worksheets, audit segment and case review assignments, reports from specimen repositories and QARC
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## Post-audit Logistics

- Audit Team Leader (ATL) sends preliminary report to Central Office within 24 hours of audit
  - Auditors give audit findings information to team leader for draft report
  - ATL drafts audit report and sends to AC
  - AC and APC review draft audit report
    - Follow-up with auditors and site personnel if questions
    - Assigns specific deficiencies per CTMB guidelines
    - AC enters audit report into CTMB-AIS (online system)
  - DAC Chair and Group Administrator review/approve audit reports
  - AC sends audit report to institutional PI with request for response and corrective action plan as applicable
  - Institutional response reviewed by Central Office staff and submitted to CTMB
  - Audit results reported to Institutional Performance Evaluation Committee by DAC Chair
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## CTMB Guidelines Revised

- CALGB Audit Policies and Procedures in revision based on CTMB guidelines
  - Points of emphasis
    - Minimum 10% patient cases selected the norm
    - Off-site reaudits and off-site audit of affiliates at main member
    - External safety reports/adverse event IRB review policies accepted but must be approved by CALGB Central Office; CALGB required to review minimum 10% of external adverse events; deficiencies major per CTMB
    - Pharmacy deficiencies clarified - drug return required within 90 days of study closure
    - Failure to submit corrective action plan within 45 days of audit report distribution could result in suspension of registration privileges for institution. If affiliate does not provide response, *both* main, at-large or CCOP member *and* the affiliate suspended.
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## CTMB Guidelines Revised

- Points of emphasis continued
    - Reaudits must be conducted within 12 months
    - CALGB required to place institutions on probation if two consecutive unacceptable audits in same category and possible termination if third unacceptable reaudit - CALGB institutional probation policy compliant
    - Data irregularities that raise suspicion of intentional misrepresentation of data, identified through quality control procedures or audit program must be immediately reported to CTMB
      - Notify CALGB Central Office
      - Central Office notifies CTMB
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## Challenges and Plans

- Augment auditor pool with ad hoc auditors
  - Evaluate audit staffing at Central Office
  - Enhance training for auditors
  - Enhance training for institutional personnel
    - Regulatory knowledge and compliance
    - Audit preparation
  - Implement audit policies and procedures changes
  - Improve CALGB institutional performance and audit ratings
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## Summary

- New DAC Chair - David Hurd, M.D.
  - New Audit Program Consultant - Barbara Barrett
  - Audit Scheduling - Sally Scherer
  - Ad hoc physician auditors recruited
  - Audit Policies in revision to comply with CTMB Guidelines revised October 2006
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## Resources and Contacts

Sally Scherer [sscherer@uchicago.edu](mailto:sscherer@uchicago.edu)  
Audit Coordinator 773-702-9973

CALGB web site:  
[http://www.calgb.org/Private/COOP\\_Groups/CALGB/resources/audit/audit\\_resources.php](http://www.calgb.org/Private/COOP_Groups/CALGB/resources/audit/audit_resources.php)  
CTMB: <http://ctep.cancer.gov/monitoring/guidelines.html>

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