



## CALGB Central Office

*Marcia Kelly, Administrative Coordinator  
CALGB Central Office*

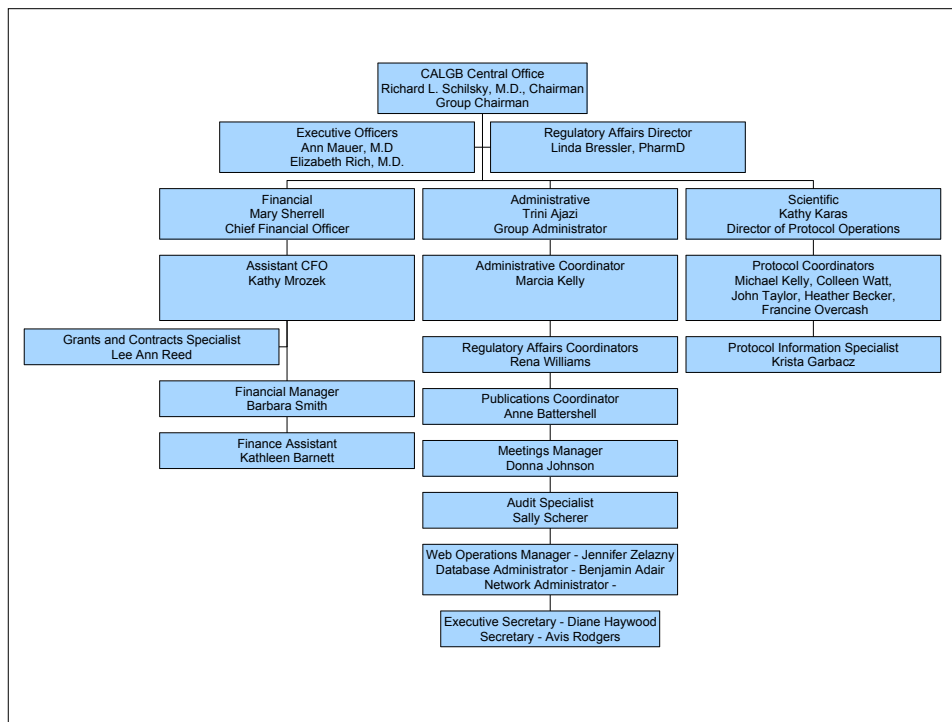
*CALGB Group Meeting, June 2005*

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## CALGB Central Office



230 W. Monroe Street  
Suite 2050  
Chicago, IL 60606  
773-702-9171



## Administrative

- Regulatory Affairs Director
  - Work with FDA to obtain CALGB-held Investigational New Drug (IND)
  - Coordinate distribution and use of INDs
  - Oversee adverse event reporting for CALGB-held INDs
  - Liaison to NCI Regulatory Affairs Branch, Drug Management and Authorization Section, Pharmaceutical Companies and the FDA

## Administrative

- Regulatory Affairs Coordinator
    - Coordinate special studies drug distribution
    - Maintain IRB approvals and other regulatory documents
    - Process membership applications and new investigator rosters
  - Audit Specialist
    - Enter audit reports and process related correspondence
    - Maintain roster and enter audit schedule in CTMB-AIS
    - Distribute adverse event reports internally
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## Administrative

- Publications Coordinator
    - Quarterly Newsletter - CALGaB
    - Group Meeting booklets and announcements
    - Maintain listing of CALGB Scientific Publications
      - Manuscripts
      - Abstracts
      - Presentations
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## Administrative

- Meetings Manager
    - Semi-annual Group meetings
    - Committee meetings
    - Ad hoc meetings
    - Continuing educational credits for meeting attendees
    - Travel policies
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## Administrative

- Web Operations Manager
    - CALGB Web Site
  - Database Administrator
    - Programming and Reports
  - Network Administrator
    - Central Office Network and User Support
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## Administrative

- Executive Secretary, Secretary
    - 400+ conference calls each year
    - Meeting materials
    - Incoming telephone calls
    - Correspondence
    - Copy, fax, mail
    - Roster updates
    - Other secretarial duties
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## Administrative

- Administrative Coordinator
    - Coordinate grant application processes
    - Oversee new membership processes
    - Human resource representative
    - Supervise the Central Office administrative staff
    - Manage Central Office
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## Administrative

- Group Administrator
    - Oversee administration of CALGB, including grant management; membership; regulatory affairs; disease, modality, working groups, and administrative committees; group meetings; group communications
    - Interact with NCI, PIO, CTEP, PMB, DCP, OHRP, and CTMB
    - Liaison between Central Office, Statistical Center, and Institutions
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## Scientific

- Executive Officers
    - Oversee protocol development process
    - Serve as resource to investigators
  - Director of Protocol Operations
    - Direct protocol operations including policies and procedures; development of protocol related infrastructure/information systems; scientific committee support; CTEP communications
    - Supervise protocol coordinators
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## Scientific

- Protocol Coordinators
    - Coordinate protocol development process
    - Primary liaison to assigned disease and modality committees
  - Protocol Information Specialist
    - Process protocol web postings
    - Maintain protocol database and files
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## Scientific

- The protocol development process represents a coordinated activity involving investigators (study chairs), statisticians, data coordinators, the scientific and modality committees, and the Central Office of the Group.
  - The entire process is coordinated by the responsible protocol editor in the Central Office and overseen by the responsible Executive Officer.
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## Scientific

- Protocol concepts are developed . . . and ultimately submitted to the Executive Committee for approval.
  - After approval, draft protocols are developed collaboratively by a study team including the study chair, statistician, protocol editor, data coordinator, committee chair, and the responsible Executive Officer.
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## Scientific

- Draft protocols are reviewed by representatives of the applicable modality committees, Oncology Nursing, Pharmacy, and CRA Committees and patient advocates.
  - Forms are developed with the Statistical Center and field tested in conjunction with draft protocol review.
  - Final draft is sent to NCI, CTEP, and CIRB for approval. Once obtained, the study is activated and announced through monthly protocol update listing via the web.
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## Scientific

- Amendments to protocols are processed in similar fashion and ultimately posted at the CALGB website.
  - Important notices (impending study suspensions, closures, unexpected toxicities, etc.) are distributed to member institutions via broadcast e-mail messages.
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## Financial

- Chief Financial Officer
    - Oversee all funding programs, contract negotiations, reimbursement programs, and financial systems
    - Manage development of CALGB budget proposals with the University of Chicago and granting agencies
    - Post-award management of the Group's funding including:
      - Subcontracts
      - Direct and indirect costs
      - Re-budgeting
      - Other compliance issues
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## Financial

- Assistant CFO
    - Prepare pre-award budgets and justifications for federal grant applications
    - Coordinate grant application review through University of Chicago
    - Liaison between granting agencies and member institutions
  - Grants and Contracts Specialist
    - Process subcontracts and assist in grant applications
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## Financial

- Financial Manager
    - Coordinate per-patient accrual reimbursement payments
    - Coordinate clinical research awards disbursement
  - Financial Assistant
    - Process travel reimbursement for CALGB-sponsored travelers
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# CALGB Directory

[http://calgb.org/Private/COOP\\_Groups/CALGB/CO/directory\\_info/roster.taf](http://calgb.org/Private/COOP_Groups/CALGB/CO/directory_info/roster.taf)

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