



Central Office Update

Trini Ajazi
CALGB Group Meeting, Chicago

CRA Committee Meeting, June 25, 2009

For CALGB Participants Only

Presentation Objectives

- Update CRAs on Central Office (CO) Staffing Changes.
- Discuss affiliate management and preview Central Office presentation to PIs on affiliate management.

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Central Office Staffing Updates

- Protocol Coordinator: Julia Melnick
- Administrative Assistant: Yvana Mols

Membership Policies – Affiliate Management

- Main/at-large member responsibilities:
Communications
 - Ensure that all institutional participants and disciplines have access to CALGB electronic distribution of information. Ensure that communication network established for affiliates.
 - Maintain network rosters. All participants must have an e-mail address. Roster update forms come from lead CRAs, not affiliate CRAs

Membership Policies – Affiliate Management

- Main/at-large responsibilities: Management of affiliate data
 - Conduct quality control of data submitted by affiliates.
 - May maintain copies of affiliate research files. Ensure availability for audit.
 - Ensure that affiliates submit data on a timely basis. Main/at-large member responsible even if affiliate becomes inactive. If affiliate changes networks, new main/at-large is responsible for previous registrations.

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Membership Policies – Affiliate Management

- Main/at-large responsibilities: Monitoring Study Conduct
 - Confirm patient eligibility before patient is entered on study.
 - Establish mechanism for prospective review of patient while on study to ensure study parameters and protocol guidelines for dosage modifications applied correctly.
 - Responsible for collection and preparation of patient records for audit.

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Membership Policies – Affiliate Management

- Main/at-large responsibilities
 - Investigational Drug Handling: Ensure compliance with all federal regulations regarding investigational drugs and compliance with protocol specific requirements.
 - Human Subject Protection: Ensure compliance with all regulations regarding human subject protection. Main/at-large must know which protocols have been reviewed by affiliate IRB and open at affiliate sites.
 - Training: Serve as resource for affiliates and provide training to further understanding of clinical research and expand and encourage participation in studies.

Membership Policies – Affiliate Management

For additional details see Section 2.3:
Responsibilities of main or at-large
member, CALGB Policies and Procedures.

Suggestions for Ensuring Affiliate Success

- Deliver training programs and educational opportunities
- Conduct internal audits
- Centralize processing of regulatory documents
- Have regular meetings and conference calls with affiliates. Communication is key.
- Host network meeting or retreat for affiliates
- Official signed agreements with expectations and deliverables

Funding

- Per-case funding is provided to affiliates.
- Tutorial on looking up payment information is available on the CALGB website under the Funding tab.
http://www.calgb.org/Private/COOP_Groups/CALGB/funding/funding.php

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Feedback

- Challenges for main/at-large members?
- Challenges for affiliates?

