



Central Office Update

Trini Ajazi, Group Administrator

CALGB Summer Group Meeting, June 24, 2010

For CALGB Participants Only

Central Office Staffing

- Andrea Eiring, Regulatory Affairs Manager
- Lynn Modla, Project Manager
- Michael Kelly, Acting Director of Protocol Operations

- Open Positions
 - Protocol Coordinators (3)
 - Project Manager
 - Medical Writer
 - Administrative Assistant (2)

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Funding Sheets

Study Funding Sheets have been completed and posted (or to be posted) on CALGB website.

- Funding Tab
 - Per-Case Payment Program
 - Study Funding Handouts
 - ✓ Specific Study Funding Handout
- Study Page
 - Per-Case Payments
 - ✓ Specific Study Funding Handout

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Change in CIRB Review Process of Adverse Event Reports for Phase 3 Clinical Trials

- CIRB memo dated April 1, 2010
- CIRB will no longer review adverse event reports related to phase 3 CTEP-sponsored multicenter trials
- CIRB will review DSMB reports at time of continuing review
- CIRB will review unanticipated problems reported by CTEP or Group

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Change in CIRB Review Process of Adverse Event Reports for Phase 3 Clinical Trials

- CALGB will continue to pass through IND Safety Updates received from CTEP for CTEO-held INDs, as required
- CALGB required to report unanticipated problems involving risks to subjects or others for CALGB-held INDs
- CALGB cover memo will specify if adverse event is unanticipated problem, changes risk/benefit ratio, requires changes to protocol/ICF

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Change in CIRB Review Process of Adverse Event Reports for Phase 3 Clinical Trials

- Encourage local IRBs to adopt a policy regarding review of external adverse event reports/IND safety updates
- Institutions implement tracking for review of IND safety reports by investigators to determine if IRB submission required
- No change in CALGB process for review and distribution of adverse events

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IRB Continuing Review

- CALGB provides DSMB Statements to institutions that indicate the decisions and recommended action by the DSMB.
- The CALGB does not release DSMB reports and minutes.
- In order to maintain the scientific integrity of the trials and in accordance with standard good practices for Data Monitoring Committees, our DSMB reports are confidential documents, not distributed beyond the DSMB members. Recommendations from the DSMB, not the reports, are forwarded to the Group Chair for action.
- Study summaries may be submitted to the IRB to satisfy requirements regarding cumulative toxicity

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Risks in Model Informed Consent Documents

- Per CTEP risks sections presented by both regimen and by investigational agent
- CALGB previously presented by regimen only

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Questions

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Resources

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