



Central Office Update

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CALGB Group Meeting, November 13, 2008

For CALGB Participants Only

Staffing Update

- New Protocol Coordinator: Michele Seiler
– Lymphoma, Transplant and Imaging

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Slide 2

IRB Review of Protocol and Consent Changes

- OHRP Memorandum, September 29, 2008
 - Temporary suspension of new patient enrollment when description of risks revised
 - Expedited IRB review of changes to descriptions of risks
 - Changes other than risk description requiring temporary suspensions
 - Proposed changes that do not require temporary suspension
 - Communication of new risk information to patients already enrolled

Temporary Suspension Required

- New patient enrollment must be suspended locally when new or modified risk information requires changes to description of reasonably foreseeable risks or discomforts in the informed consent form.
- Patients consented but not enrolled as of notice date can be registered.
- IRB Approval of revised informed consent form required prior to local reactivation of study to patient accrual.

Expedited IRB Approval

- IRB may use expedited review for minor changes in previously approved research per 45 CFR 46.110.
- CTEP may indicate in Action Letters
 - New or modified risk considered minor and eligible for expedited review
 - New or modified risk considered significant and impacts overall risk-benefit relationship
- CALGB will indicate in cover memo of update if expedited approval allowed or if full board IRB approval required
- If expedited allowed, local IRB makes final decision to expedite

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Slide 5

Temporary Suspension Required

- Changes to other required elements of informed consent, examples below
 - additional description of research procedure
 - amendment to description of benefits
 - additional alternative course of treatment
- CALGB will indicate in cover memo of update if expedited approval allowed or if full board IRB approval required
- If expedited allowed, local IRB makes final decision to expedite

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Slide 6

Temporary Suspension Not Required

- Clarification of existing risk
 - Example: change “nausea” to “nausea and stomach upset”
- Additional specifics regarding risks that are already described in the approved ICF
- Slight changes regarding probability of adverse event occurrence that is lower or slightly higher than previous (e.g., 10% to 12%)
- Changes regarding level of severity of specific adverse event that is **lower** than level indicated in current ICF

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Slide 7

Patients Already Enrolled

- Inform patients of significant new information
- No requirement per 45 CFR for IRB review and approval of communication to already enrolled patients regarding new risk information
- When new risks are significant, institutions advised to promptly notify patients and provide IRBs with copies of patient notification statements
 - Follow local IRB requirements
- CALGB update cover memo will indicate when CALGB requires patient notification

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Slide 8