

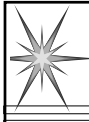


CALGB Data Audit: Relevant Elements from Policies and Procedures

Susan Tuttle, R.N.
Vice Chair, Audit Committee

CALGB Audit Preparation Workshop, June 2007

For CALGB Participants Only

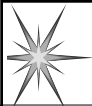


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"I've developed a stress management program based on the Shut Up And Stop Whining Principle."

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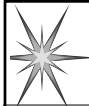


REGULATORY COMPLIANCE

- IRB review/approval required before entry
- Annual review at least every 12 months or <365 days
- All updates reviewed as required within 90 days of implementation/distribution




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REGULATORY COMPLIANCE

- Broadcast SAEs acknowledged by IRB within 90 days of distribution
- Action Letters acknowledged by IRB within 90 days of distribution
- Audit update and broadcast SAE list on web (resources → audit)

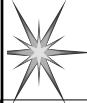
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 **REGULATORY COMPLIANCE**

- Participant notification accomplished as indicated
- IRB informed of local AERs (C-804, Medwatch Addendum)




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 **REGULATORY COMPLIANCE**

Additional Reviews

- Companion studies
- Closed studies with patients still being followed – Expedited versus Full Board

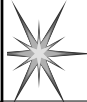


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 **INFORMED CONSENT**

- All required content present (refer to NCI required consent elements checklist)
- One risk omitted → MAJOR
- Original, signed, witnessed, and dated on or before date of registration

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 **INFORMED CONSENT**

- Evidence of understanding - interpreter if not mentally competent or non-English speaking
- All blanks completed (e.g., contact numbers, MD names, etc.) when patient signs the consent

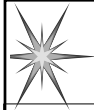
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ELIGIBILITY

- Source documents for each eligibility criterion support the data submitted (including hx of prior Rx or disease; documentation of appropriate PS)
- Pre-Rx diagnostics accurate and obtained within required time frames; concurrence with path diagnosis if required

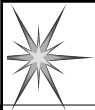
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ELIGIBILITY

- Pt declared ineligible if requirements not present
- Accurate ht/wt (ideal vs. real as specified per protocol) and BSA

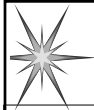
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TREATMENT

- BSA accurate; recalculated each cycle if specified/instructed in protocol
- Rx doses and dates accurate and in concordance with protocol; no prohibited medications/Rxs
- Documentation of Rx administration, including oral agents and protocol-specific supportive Rxs

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TREATMENT

- Dose reductions, escalations or delays justified by the protocol and documented in MD/RN notes and flowsheets
- Interim pt monitoring conducted according to protocol (labs, restaging diagnostics, etc.)

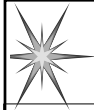
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TOXICITY

- All toxicities recorded in chart reported on data forms; accurately graded
- Adverse event procedures followed as required (accurate, complete data provided to study officials; timeliness of reporting)
- Patient death within 30 days of Rx reported appropriately (even if *after* Rx completed)

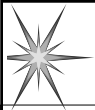
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RESPONSE

- Measurements are verifiable and obtained at appropriate time points
- Same method of measurement at each interval
- Response/progression reported is accurate
- All *sites* of disease followed and recorded as required

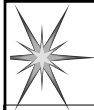
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FOLLOW-UP

- Pts off-Rx but not off-study are followed at intervals required by protocol
- Required follow-up exams and diagnostics completed (e.g., annual mammograms, gyn exams, etc.) and reported as required

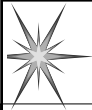
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FOLLOW-UP

- Follow-up forms and reports are current (progression or other endpoint event not reported within 6 months is considered a Major deviation)

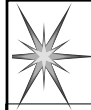
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RECORDS AND DATA QUALITY

- Hospital/clinic charts in concordance with submitted data
- Treatment started within required time frame after entry (CALGB requires Rx to start within 7 days of registration unless stated otherwise)
- Flow sheets, if required, complete and accurate reflection of records

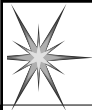
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RECORDS AND DATA QUALITY

- Forms submitted within required time frames
- Records are legible and reasonably well-organized
- Required submissions complete (e.g., slides, blocks, RT materials, serum samples) and utilized LabTrak

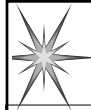
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LabTrak

- Verify sample submissions on all registered patients
- If checked periodically, then no surprises day of audit
- No path submission → MAJOR deviation

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CTSU Audits

- Done by CALGB if registration credit given to CALGB
- Performed on all 3 areas –
IRB/Consent Content
Pharmacy
Patient Case Review

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