

CALGB DATA AUDIT

Policies and Procedures

Susan Tuttle, R.N.

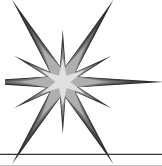
Audit Committee Vice-Chair

CALGB Audit Preparation Workshop, November 2008

Copyright 2004 by Randy Glasbergen. www.glasbergen.com

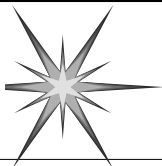
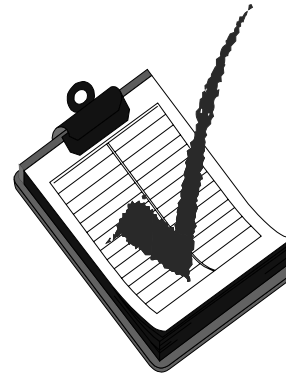


**“I’ve developed a stress management program based
on the Shut Up And Stop Whining Principle.”**



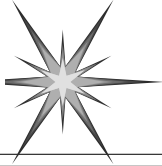
Regulatory Compliance

- 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



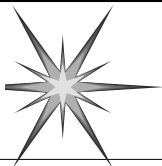
Regulatory Compliance

- Broadcast SAEs submitted to IRB within 90 days of distribution **UNLESS** institution has policy/SOPs for handling differently than within 90 days
- Action Letters acknowledged by IRB within 90 days of distribution
- Audit update and broadcast SAE list on web (resources → audit)



Regulatory Compliance

- Participant notification accomplished as indicated
- IRB informed of local AEs and appropriate reporting of serious Adverse Events reported to NCI via AdEERS

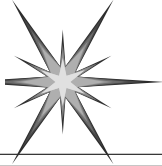


Regulatory Compliance

Additional Reviews

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

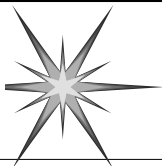




Regulatory Compliance

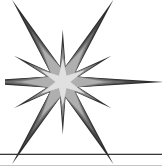
- Suspension of local enrollment due to new or modified risk information (i.e., 40302)
- The Central Office will indicate on update cover page when local suspension of enrollment is required.

CTEP issued memo on 3/20/08 (OHRP and FDA were included in memo) regarding instances where changes in risk may result in suspension until IRB approval and revised consent obtained.



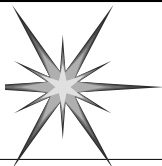
Consent Content

- Provide most recently IRB approved consent form for consent content review
- All required content present (refer to NCI required consent elements checklist) – best to duplicate CALGB model consent



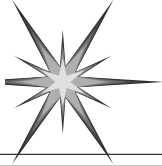
Consent Content

- ↗ One risk omitted → **MAJOR**
- ↗ Options/alternatives or other choices of treatment or no treatment section of local consent form must be the same as the CALGB model consent **UNLESS** the Central Office has approved different wording → **MAJOR**



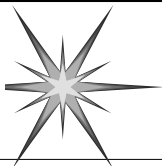
Informed Consent

- ↗ Original, signed, witnessed, and dated on or before date of registration
- ↗ Patient should date own signature
- ↗ Patient should have signed the correct updated consent form



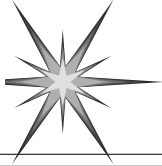
Informed Consent

- Evidence of understanding -interpreter if not mentally competent or non-English speaking
- All blanks completed (i.e., contact numbers, MD names, etc.) when patient signs the consent
- Tissue/blood submission patient option matches PCO report on tumor/tissue/blood receipt



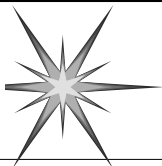
Eligibility

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



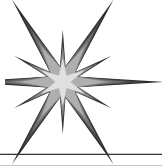
Eligibility

- ↗ Pt declared ineligible if specific requirements not present
- ↗ Accurate height and weight (ideal vs. real as specified per protocol) and BSA noted in patient chart



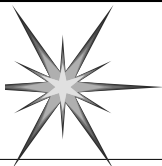
Treatment

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



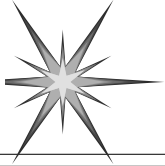
Treatment

- ↗ 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.)



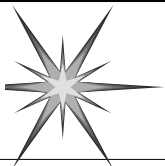
Toxicity

- ↗ 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)



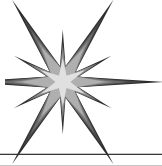
Response

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



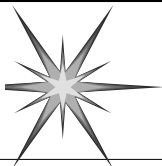
Follow-Up

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



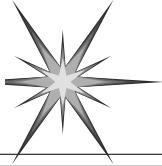
Follow-Up

- Follow-up forms & reports are current
- Progression or other endpoint event not reported within 6 months is considered a **MAJOR** deviation



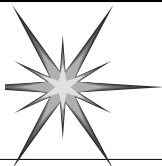
Records and Data Quality

- 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



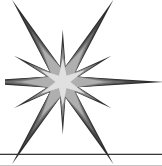
Records and Data Quality

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



LabTrak

- To be replaced with Specimen Tracking System
- Verify sample submissions on all registered patients
- If checked periodically, then no surprises day of audit
- No path submission → **MAJOR** deviation



CTSU Audits

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

Copyright 2001 by Randy Glasbergen. www.glasbergen.com



“It’s a special hearing aid. It filters out criticism and amplifies compliments.”