



20 Ways to Improve Your IRB and Consent Content Audit

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For CALGB Participants Only



IRB

#20: Organize

- Keep IRB information for each protocol in a separate folder or separate by dividers.
- All IRB approvals for treatment and stand alone companions will need to be provided.
- Embedded companions are not applicable.

#19: Protocol Webpage and Audit Update List

- Print out individual protocol webpage for each study audited.
- Account for all updates, memos, broadcast SAEs, Action Letters, etc. listed on the protocol Web page.
- Print out most recent CALGB Audit Update List from CALGB Web site.

#18: Tag Initial or Original Approvals

- Verify full board (FB) approval performed before any patient was registered to study.

#17: Tag Annual Renewals or Continuing Reviews

- Verify annual renewals or continuing reviews are performed <365 days since initial approval or last renewal.
- Reviews provided for all open studies and all closed studies with patients that are still in follow-up status.

#16: Tag Update Approvals

- All updates that are bolded on the CALGB Audit Update List will be checked at audit time for IRB approval.
- Updates requiring IRB Approval *must* be approved within 90 days of distribution.

#15: Tag Action Letter Approvals

- All Action Letters distributed must be acknowledged within 90 days of distribution.

#14: Tag Broadcast Serious Adverse Event (SAE) Submissions

- All broadcast SAEs must be submitted within 90 days of distribution.

OR

- Provide institutional policy, procedure, or SOP for handling/processing broadcast SAEs (submission of SOPs to Central Office for approval must be done prior to audit).

#13: Submission of Local AEs

- The local IRB should be notified of local adverse events according to local institutional policy.
- Follow protocol guidelines in the designated section of the CALGB protocol titled *Adverse Event Reporting (AER)*.

#12: Internal Audit or Pre-Audit

- It is highly suggested that all studies on audit list be pre-audited prior to the official audit.
- Rule of thumb: Audit all open studies on a monthly basis, if possible, and note all missing items.
- Internal audits enable you to catch omissions and still make the 90 day time period.

#11: Designated IRB Person

- Assign one staff person familiar with the IRB files to sit with the auditor to aid in the review of the IRB portion of the audit.

#10: Stay Calm

- Keep a positive perspective.
- If error is found, communicate the corrective action plan your institution has implemented to avoid or prevent future errors.



Consent Content

#9: Duplicate CALGB Model Consent

- Maintain same format with the local institutional consent form that is used by the NCI approved CALGB model consent form.
- Add specific institutional information as required by the local IRB.

#8: Do NOT Omit Risk(s)

- The risk or side effect section of the local institutional consent form should match the CALGB model consent form with exact wording, if possible.
- One risk omitted results in a MAJOR deficiency.

#7: Complete All Blanks

- The patient consent forms must have all blanks (patient/participant initials and/or signature, IRB contact person and phone number, MD name and phone number, etc.) completed or filled in before the patient signs the consent form and before the patient is registered to the study.

#6: Original Consent

- Please provide the original consent form signed by the patient/participant.

#5: Consent Signed and Dated by Patient/Participant

- Patient/participant should date their own signature or initials.
- Research staff should *not* insert date the patient/participant signed the consent form.

#4: Alternatives or Other Options Section

- The options/alternatives or other choices of treatment or no treatment section of the local consent *must* be the same as the CALGB model consent form, unless the Central Office has approved different wording.

#3: NCI Required Elements

- Obtain the consent content checklist from the CALGB Web page under Resources titled *CALGB Audit Information*.
- Verify all elements are included in your local institutional consent form.

#2: IRB Approved Local Consent

- Provide most recently IRB approved local consent form that incorporates all consent form changes mandated by CALGB updates.
- Patient/participant consent form will be utilized to verify correct version was signed prior to registration.

#1: Suspension of Local Enrollment Due to New/Modified Risk Information

- CTEP issued a memo on 3/20/08 (OHRP & FDA included) re: instances where changes in risk info may result in suspension until IRB approval & modified consent obtained.
- CALGB Central Office will indicate on protocol update when local suspension of enrollment is required.

Resources

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