Common Errors Discovered during Random On-Site Reviews

Amendments:

- The regulations require the IRB review and approve all proposed changes in a research study, prior to the initiation of such changes.
  A. Only Exception: When changes are made to eliminate apparent immediate hazards to the participant. The IRB will have to be notified as soon as possible following the change.
  B. All changes, no matter how small, require prior IRB review.
    i. Changes include, but are not limited to:
       1. New or revised recruitment materials
       2. Funding source changes
       3. Removing/adding a component of the study or questionnaires
       4. Consent language revisions
       5. Study status changes
       7. Change in study location
       8. Changes to improve the clarity of statements or to correct typographical errors
       9. Changes to the inclusion/exclusion criteria
- It is highly recommended to contact our office should you have questions regarding an Amendment submission.
- Exempt studies require the Exempt Amendment Form to be submitted
- Expedited and Full Board studies require the Amendment Form to be submitted.

Consent:

A. Upload your consent document in a Word document so the IRB can place a stamp in the footer of your consent document when the study is approved.
B. Approval Stamp:
   1. The IRB will place an approval stamp in the footer of your consent document(s). You must use this copy when consenting subjects.
   2. If the study involves an online survey, you will need to transfer over the approval stamp to your online version. The stamped consent can be found in document storage. It will be marked green and approved.
C. This applies to Exempt as well as Expedited and Full Board studies.

Please contact the Campus IRB Office at 573-882-9585 for assistance.

GROWING KNOWLEDGE

OHRP is pleased to invite you to the next presentation in our free Webinar Lecture Series designed to address critical issues of importance to everyone involved in the protection of human research subjects:

on

July 24, 2014 at 1pm CST

This session will address the HHS regulatory requirements that apply to reporting, and will discuss strategies for managing regulatory considerations, including:

- Regulatory background
- What needs to be reported?
- Time frames for reporting
- Common Areas of noncompliance reported to OHRP
- OHRP processing of reports
- Corrective Actions
- Institutional considerations
- Future of reporting

To log in and view the event live, go to: http://videocast.nih.gov/summary.asp?live=14345&bhcp=1
- You will be able to log in 5 to 10 minutes before the session begins.
- A “Click to Watch” tab will appear when the site is open for viewing.
- PowerPoint slides will be available at this website prior the event.
IRB Session: Case Report Forms and Source Documentation

Documentation and records for each subject and for the study over all are equally important.

Source documents are the original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects’ diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, microfiche, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories and at medical-technical departments involved in the clinical trial). ICH GCP 1.52

Case Report Forms (CRFs) are typically used for multicenter studies so the data can be collected and sent to the lead site or sponsor. These should not include the subject’s name or social security number. Some investigators use a data collection tool to enter the information they wish to collect and analyze instead of CRFs.

Designing your own Source Documents for research subjects:

The goal is to collect concise, complete, accurate, and consistent data that covers all data/information needed for the study. The goal should be for the fewest and simplest documents.

Source documents are most successful when they are in a format that is logical and chronological for a study visit. Unless there is a good reason, source documentation should not be repetitive or burdensome.

- Think about the information to be captured – inclusion/exclusion criteria, data points for each study visit, events, medication logs, etc.
- When applicable, pages should be numbered as “Page _ of _” in order to minimize the chance of losing pages or confusing the chronology.
- Make sure there are headers for “Subject ID” and time point e.g. date, period #, visit #, etc.
- It is a good idea to have a version number (in order to assure that the most recent version is being used) and, if applicable, a space for signature of the person completing the form etc.
- There should be signature/initials for everyone who makes entries.

You don’t have to design source documents for some data collection:

Lab reports, radiology reports, EKGs, films, etc. are considered source documents. Don’t recopy data unnecessarily (waste of time, potential transcription errors). Be sure to write interpretations or clinical significance on reports. All abnormal values MUST have notations of “NCS” (not clinically significant) or “CS” (clinically significant). All reports should be signed and dated by the PI or designated interpreter (whose signature and initials should be on the signature log mentioned above) if the document is to support FDA research.

Use the Sponsor’s actual diaries, questionnaires, or other forms filled out by the subject himself/herself as source documents.

Checklists are simple but can lead to mindless checking of boxes rather than true checking of whether you are actually in possession of a required document or whether a lab value truly fits criteria!! Filling in even obvious information, may discover missing items or items which turn out to disqualify the subject or which may require follow-up.

Complete Source Documents in a Timely Manner!

Filling out the source document:

All entries must be made in pen.
Prior to a subject’s participation in the trial, the written informed consent form should be signed and personally dated by the subject or by the subject’s legally acceptable representative
Do not use abbreviations unless they are considered universally standard.

There should be no blank pages. If a page does not apply (“N/A”) or if the required info is unknown (“UNK”) or was not obtained (“ND”), this is written across the entire page with explanations as necessary. Subject and time point identifiers must still be completed.

If you have received a waiver from the Sponsor, PI, etc. to enroll a subject that is outside of the criteria for Inclusion/Exclusion criterion or a particular study activity, be sure to get it in writing. (don’t forget to report it to the IRB)

Record all data, even if the results are unexpected or undesirable. Record the absence of expected events, complications, or other events specifically asked for in the CRFs.

Be sure to fill out all headers and footers (Subject ID, time point, etc.). Imagine what would happen if study files spilled out all over the floor...

The form or entry should be signed and dated according to the rules (SOPs) you’ve established for your study.

Completed source documents do not have to look beautiful but they MUST be readable!!! Use margins or other space for jotting down details, questions, explanatory notes, reminders to follow-up, etc. For example: when asking about medications, a subject may tell you something that might need follow-up re Medical Hx with possible implications for Inclusion/Exclusion Criteria. Jot this down somewhere on the form in order to document the info and to remind yourself to do some follow-up.

Be sure to note why a scheduled activity did not occur, why it was outside a time window, why/how an error occurred, etc. This will help to document protocol deviations.

It also will help in completion of CRFs and answering monitors’ questions.

Think about the form from this point of view: “If my study were to be reviewed, will I be able to understand why I gave a particular answer?” When using narrative notes, late entries must be written at the end of the text (not squeezed in between entries) and identified as a “Late Entry”. They identify the time/date of the event being clarified but are signed and dated with the date the late entry is actually written.

Making Corrections on source documents:

Errors must be crossed out with a single line and corrections initialed and dated with the date of correction
When in doubt, explain the why/how/details of an error.

For forms which have been completed by subjects themselves (such as a survey): If corrections/clarifications are necessary, subjects themselves should make the corrections and initial and date them. If the subject is not available, staff may correct the form but ONLY if there is strong documentation substantiating the correction and ONLY if the original entry remains visible. The new information must be signed and dated by the coordinator and MUST have a written explanation for the clarification AS WELL AS the source of the new information.

Source documents may be clarified by the study coordinator. If this is necessary, the original entry must remain readable. The new information must be signed and dated by the coordinator and MUST have an explanation for the clarification AS WELL AS the source of the new information.

For example: a narrative note describes an adverse event but an AE checklist suggests that no AE occurred; the AE checklist may be crossed out, initialed and dated and a note written which refers to the narrative note.

In general, source documents may not be recopied even for the sake of neatness or readability. If an entry is illegible, the person who made the entry may write a clarifying note (initialed and dated) in the margin, but the original entry MUST remain visible and unchanged. If a source document is badly disfigured (spills, tears, excessive cross-outs that hinder readability, etc.), it MIGHT be acceptable to recopy the document(s) (check with the Sponsor, your unit’s SOPs, etc.). In this case, the original MUST be kept, preferably attached to the copy but if necessary, with a note as to where the original may be found. The copy must be clearly identified as a copy and the person making the copy must sign and date the copy.

Source Documents must NOT be DISCARDED.

Please contact the Health Sciences IRB Office at 573-882-3181 for questions or assistance.