Questions from "What ICH E6(R2) Really Means for Research Sites!"

Document Retention

- FDA regulations differ from ICH. FDA is 2 years after market approval, where ICH states 15 years. Which should we be following? The confusion comes in as FDA has regulations, where ICH is just "guidance."
- How do sites manage all these boxes in storage for 25+ years. This is a huge cost (space and time to manage).
- If a Sponsor gives written permission to destroy study records, how and where would the Sponsor's written permission be saved/stored?
- If sponsor is bought out can the new company come and ask for data from a previously closed study?
- Is the length of time to retain the CRF's the same for device studies as for clinical drug trials? After the study?
- In regards to the subject's right to privacy, what are your recommendations for deidentifying subject documents such as medical records and other source documents which contain subject name, date of birth or initials. One of our recent CTAs specifically states that records will be retained for a period of 2 years following study closure. If the sponsor approves the destruction of the records in writing after the 2 year period are we in compliance? I'm referring to deidentifying the documents before they become part of the subject source
- Is the investigator or the site responsible for record storage at the end of a trial? CFR's say investigator-but if the PI leaves the site who is responsible going forward?
- Record storage duration is highly variable; what do you recommend as the longest duration?
- Our hospital purges Radiology Images after 10 years, do you recommend getting copies of the images on CD for each subject and kept in the record (or is the written report enough)?
- What should you do if the sponsor is out of business. and you think that records should be able to be destroyed/discarded. "My question was misread regarding record destruction - AND you think it is relevant to destroy. Not just IF the sponsor is out of business. I cannot locate anyone to confirm to discard the files. No luck with CROs, either."
- After we close out a study, we went the paper CRFs, paper reg documents and disks to an off-site storage facility. We used to include paper records, but what do we do now that everything is electronic?

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Allowing Access to Complete Records

- How do you handle the audit request from the sponsor to look in the EMR if the University will not allow direct access?
- Back to the question about complete medical records - when you are talking about complete medical records, do you mean any visit the patient makes that would be in the electronic medical record at the institution such as PCP, rehab, etc? Or just standard of care visits mixed in with research visits that are related to the actual clinical trial?
- Can a site print out labs from a visit and sign them to consider them "certified"? Does the site have to print the entire progress notes etc from the visit and include them in the subject binder?
- Can you give examples of different electronic source systems?
- Do you automatically create a subject file with the patient's entire medical record, or only when sponsors request to review all of their med record? And also, is that since the beginning of their medical record or just since signing consent?
- Why would it be an issue to scan in and save the regulatory binder. The FDA has guidance documents that states that sites can do this as long as the site has a validation process and audit controls on the documents they scan in.
- eSource contains names, which allow identification, while a sponsor should not have names or control the eSource? then the CD of source should not be made/controlled by a sponsor, correct?
- Do you have examples of guidelines or procedures of what should be written and contained for data collection that would satisfy an audit- for example audit trails, signatures, data collection?
- Since our sponsor can't have access to our EMR- we print out the labs, notes, etc and place them in our research chart. We verify that they are certified copies- this info gets stored with the CRF's at the end of the study. Is this acceptable?

Consent

- Are PIs allowed to make any notes on the Informed consents or nothing can be written directly on the consent by anyone?
- If a question/statement on the consent is not applicable for a particular patient would it be better to leave that black or note that it is not applicable? blank*
- If you don't have a patient sign/date at the bottom of each page of the consent form, how do you "prove" the pages were reviewed with the patient?
- Regarding writing on the signed consent form, is it ok to capture subject data on consent document. Subject data should be captured on source records / worksheets. Please provide additional clarification.

- What is your recommendation on having participant initials on EACH PAGE of the informed consent document? We have an IRB that does not recommend this (because they state it increases chance of deviation and compliance audit findings) - This differs from our current practice. Does that include your institution records or ALL patient medical records - PCP, Specialists, etc

Miscellaneous

- For many patients who receiving many medications at the same time say for examples ESRD patients, how frequently should be concomitant medications list to be updated?
- Usually, patient demographics used in study CRF is added from the information available on patient medical record. This is usually updated by clinic staff, should there be reference provided of the person who added patient demographic information on Medical record on the study CRF?
- What is the responsibility and required training of Project Managers in the context of ICH E6 R2? Some PMs are promoted from CRC positions but some come from the Managerial pool. Therefore they may or not have first hands clinical research experience.
- Is there specific E6 R2 training that physicians can take to comply with Sponsor requirements?
- Is there a direct ICH guidance that requires the sponsor to provide a copy of the eData to the site? Please provide that guidance
- Our eMR does not print out date and time when I print from the EMR to place in the source - are initials and date acceptable?
- Is buring a CD equal to transferring data to a thumb drive? We are keeping an electronic Regulatory Binder. Why is there an issue with my site keeping my own eRegulatory binder? PHI is limited and sponsor and CRO all sign confidentiality agreements. I am trying to cut down on paper. We allow for wet signatures. Many institutions are using this method.
- Sometimes some of the data the sponsor wants collected is not collected per SOC. Is is okay to make source docs for these data points while using the EMR as a source for the rest of other data points that's collected for SOC?
- Also, what do you think about a paper shadow file? Our PI does not allow that because medical records can be updated." "A follow-up to my last question. If the subject's source medical records exist in electronic form on a hospital's database, are we responsbile for printing off a paper copy and saving it with the paper CRFs/CRF data disk?"
- You mentioned an example of vital signs being taken by the dialysis RN and using that data to complete the CRF's. I missed you saying what documentation is needed other than the dialysis RN's records?