From: Toth-Allen, Jean
Sent: Wednesday, August 23, 2006 12:49 PM
To: [purged]
Subject: RE: source documentation

Dear Mr. [purged]:

Thank you for your follow-up inquiry.

FDA regulations regarding the conduct of clinical trials (Title 21, Code of Federal Regulations - 21 CFR - Parts 312 and 812) do not define source documents or even use this terminology. The ICH guidance regarding the conduct of clinical trials, which FDA has endorsed and which is available at http://www.fda.gov/cder/guidance/959fnl.pdf, does define these documents. While that guidance document states it refers specifically to pharmaceutical studies, FDA believes the general areas discussed are applicable to all clinical trials. The definition given in this guidance is that source documents are "Original documents, data, and records (e.g., hospital records, clinical and office charts, diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate and complete, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories, and at medico-technical departments involved in the clinical trial.)"

As you correctly note, if information is copied into sponsor templates/booklets from another document that is the "original source," those templates/booklets would not be considered the source document. However, use of such templates/booklets does allow the sponsor to collect study information in a consistent way and there is nothing in regulation that would preclude such a practice. If FDA were to inspect a study that employed such templates/booklets and information contained therein was clearly copied from other documents or records, our investigators would indeed consider reviewing some or all of the actual source documents. When you speak of "auditor," however, I am assuming you mean the sponsor's study monitor or an actual study auditor employed or contracted by the sponsor and not FDA investigators, since your concern appears mainly to be with regard to access to proprietary information from a study conducted by a different sponsor, which would not be a concern with an FDA investigator. I would agree, monitors/auditors for the sponsor would want to verify the accuracy of study information with the actual source documents and so this becomes an issue if that source document is actually part of a different study which was conducted by a different sponsor. However, these issues arise

as a result of clinical investigators enrolling the same subjects into multiple clinical trials. I believe my original answer addresses the concerns that such a practice raises and this appears to be the real source of the problem, not the fact that the sponsor has chosen to collect study data consistently by the use of templates/booklets.

I am sorry if my discussion both above and below does not assist you in deciding how to deal with an existing condition. Hopefully it will at least provide information to be considered when future clinical trials are planned.

If you need further information and/or have additional questions, please submit them once again to the official GCP mailbox, gcpquestions@oc.fda.gov, in lieu of responding to my personal e-mail address.
Sincerely yours,
Jean Toth-Allen, Ph.D.
Good Clinical Practices Program
OSHC, Office of the Commissioner, US FDA
This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

From: [purged]
Sent: Monday, August 21, 2006 1:31 PM
To: OC GCP Questions
Subject: RE: source documentation

To Whom It May Concern:

I am clarifying my question as it appears I did not explain it clearly (by the below response):

Is using Sponsor provided source document templates/booklets the best case scenario?

For example: sites are using only these templates to record source, however, some of this information is taken from previous studies, subject verbal history (this would be appropriate to record), primary care information and other

sources. So, technically it is not "original". It could also lead the auditor, if he or she requests actual "original" source, to have to review another sponsor's study information, as this is where it was originally documented.

For some source like prior lab reports, the site is copying the report and placing it in the source. We have recommended they black out the previous studys' information (ie: study number, sponsor etc.).

I would love to hear your thoughts on this, if you were to come across this while auditing.

Thank you very much.

[purged]

From: Toth-Allen, Jean [mailto:jean.toth-allen@fda.hhs.gov]
Sent: Wednesday, August 16, 2006 3:02 PM
To: [purged]
Subject: RE: source documentation

Dear Mr. [purged]:

Thank you for your inquiry regarding source data from previous studies.

FDA regulations do not address such issues as you describe in your scenario. There would appear to be possible legal issues, however. Information accrued in clinical trials is usually proprietary. Therefore, the sponsors of the earlier trials may take issue with a different firm receiving any materials originating in their studies. In addition, this means that the clinical investigator in question is using the same individuals in more than one clinical study. Depending upon the nature and timing of the previous study or studies, this might not be advisable. Since, as stated previously, much clinical trial information is proprietary, it might be difficult to impossible to ascertain whether individuals who were subjects in previous clinical trials are appropriate for the new study.

Hope this information is useful.
If you need further information and/or have additional questions, please submit them once again to the official GCP mailbox, gcpquestions@oc.fda.gov, in lieu of responding to my personal e-mail address.
Sincerely yours,

Jean Toth-Allen, Ph.D.
Good Clinical Practices Program
OSHC, Office of the Commissioner, US FDA
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From: [purged]
Sent: Monday, August 14, 2006 1:17 PM
To: OC GCP Questions
Subject: source documentation
To Whom It May Concern:

With regards to source documentation for a particular study - what is the best way to handle using "source" obtained from a previous clinical trial with another sponsor?

For example: a site is using our provided source template booklets and completing them by filling in the forms based on subject interviews/history taking and also referring to data/labs/history obtained from previous studies by other sponsors. This often times means making a copy of a lab obtained for that other trial and filing it in the source for our trial. They are not removing study information such as pt #, study # etc. from this information prior to filing it in our study related source.

Can you give me a best case scenario or best way to handle this, recommendations for future etc.?

Thank you very much for your help.

[purged]