From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Wednesday, May 24, 2006 11:55 AM
To: [people]
Subject: RE: Access to Research Charts

Dear [people],

FDA's regulations do not explicitly address your question (below). FDA's regulations at 21 CFR 312.62 address recordkeeping and retention requirements for IND studies. I've included these regulations here.:

"Subpart D--Responsibilities of Sponsors and Investigators Sec. 312.62 Investigator recordkeeping and record retention.
(a) Disposition of drug. An investigator is required to maintain adequate records of the disposition of the drug, including dates, quantity, and use by subjects. If the investigation is terminated, suspended, discontinued, or completed, the investigator shall return the unused supplies of the drug to the sponsor, or otherwise provide for disposition of the unused supplies of the drug under 312.59.
(b) Case histories. An investigator is required to prepare and maintain adequate and accurate case histories that record all observations and other data pertinent to the investigation on each individual administered the investigational drug or employed as a control in the investigation. Case histories include the case report forms and supporting data including, for example, signed and dated consent forms and medical records including, for example, progress notes of the physician, the individual's hospital chart(s), and the nurses' notes. The case history for each individual shall document that informed consent was obtained prior to participation in the study.
(c) Record retention. An investigator shall retain records required to be maintained under this part for a period of 2 years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until 2 years after the investigation is discontinued and FDA is notified."

[I believe you are talking about drug studies; device regulations are similar at 21 CFR 812.140(d), although, interestingly, they do address custody of records in 21 CFR 812.145(c)- see below for the specific language of the regulations.]

I believe it is not uncommon, when an investigator leaves an institution, for that investigator to leave study records at that institution. When that is done, it would seem reasonable (I think) to assume the institution has the obligation to retain those records as required by 312.62(a) (above). Whether the institution is willing to provide access to those records to the researcher, is really up to institutional policy (and possibly State law). On one hand, one could argue that the researcher created the documents he is now trying to access and as such should be presented access to them. On the other hand, having "abandoned" the information should be be treated differently from other researchers who might want to access this information? (And, if so, how are other non-affiliated researchers treated at your institution when this question comes up and there is not a link between the researcher and data?) Finally, is there a concern that by providing access, the researcher could compromised the integrity of the original data by accessing it, thus compromising the institution's obligations to retain it? There are probably other questions I have not considered.

I would suggest that you consider taking the basic question to your IRB for discussion and decision. Whether you address this now in regard to this particular question or more generally, it does seem possible that this will come up again and it would be helpful for the institution to have a policy to cover it.

[I have included the relevant language from the device regulations: 21 CFR 812.140(d) and (e) here:
"(d) Retention period. An investigator or sponsor shall maintain the records required by this subpart during the investigation and for a period of 2 years after the latter of the following two dates: The date on which the investigation is terminated or completed, or the date that the records are no longer required for purposes of supporting a premarket approval application or a notice of completion of a product development protocol.
(e) Records custody. An investigator or sponsor may withdraw from the responsibility to maintain records for the period required in paragraph (d) of this section and transfer custody of the records to any other person who will accept responsibility for them under this part, including the requirements of 812.120. Notice of a transfer shall be given to FDA not later than 10 working days after transfer occurs."]

I hope this information is helpful to you.

Sincerely,

Bonnie

Bonnie M. Lee
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Office of Science and Chief Scientist Programs, 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(j)(1) 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.

-----Original Message-----
From: [people]
Sent: Thursday, May 18, 2006 12:16 PM
To: OC GCP Questions
Subject: Access to Research Charts

My question is related to access to research records after a PI leaves an institution.
The PI conducted clinical research at Institution A and completed several studies. The studies were terminated with Institution A's IRB. The PI now is affiliated with Institution B. The PI is still affiliated with Institution A but wants access to the research records to plan future research. The PI wants to review baseline lab values and pathology. The research records do not contain PHI (research records contain subject study ID numbers only.)
Should the PI have access to these research records?

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