From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Wednesday, February 01, 2006 1:07 PM
To: [purged]
Subject: RE: question re: access to medical records by industry sponsor

Dear Ms. [purged]:

The question that you are asking--how much source documentation from a subject's medical history is needed to establish that an individual qualifies for a study--is very fundamental to the conduct of a clinical trial. Such documentation is important to assure that only qualified subjects are enrolled in the study, and that subjects are not put at risk because of some other underlying disease or condition that they may have. However, the question of "how much documentation is adequate" is not directly addressed by FDA's regulations.

The regulations pertaining to record keeping by the clinical investigator are found at 21 CFR 312.62(b). I have pasted the pertinent passage into this e-mail for your convenience:

"(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."

As you can see, the regulations are very general and while they state that the case histories must be "adequate and accurate", the regulations do not specify "how much" information about the subject's medical history is required. (As a rule, FDA's regulations are deliberately general, in order to afford investigators and institutions maximum flexibility in adopting practices they feel best suit their specific situations.)

The best guidance that FDA has on the topic of which records should be retained and where, is the ICH E6 "Good Clinical Practice: Consolidated Guidance." Again, the guidance is VERY general. While "source data" and "source documents" are both defined (Sections 1.51 and 1.52), Section 8.3.13 simply states that "source documents" should be maintained "to document the existence of the subject and substantiate integrity of trial data collected," and "to include original documents related to the trial, to medical treatment, and history of subject."

So, in answer to your first question, there is no specific regulatory citation that would require sites to obtain ALL records covering a subject's entire medical history.

In answer to your second question about "what is reasonable," again, that is a discretionary matter. Because FDA regulations do not specify exactly what or how much must be maintained, sponsors have the discretion to specify (in the study protocol) the level of documentation that the sponsor believes necessary to establish, during subsequent audits/inspections, that only qualified individuals are entered into a study.

In instances where the sponsor has not specified in the study protocol the amount of history to be collected, study sites would have the discretion to develop and follow their own standard operating procedures to ensure that sufficient source documentation is available to adequately and accurately document that the subjects enrolled in the study have the underlying medical condition/disease and meet/met all of the inclusion/exclusion criteria outlined in the approved study protocol.

By the way, FDA's regulations and the ICH guidance are both available on FDA's GCP website at http://www.fda.gov/oc/gcp.

I hope this is helpful.

Sincerely,

Carolyn Hommel
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Good Clinical Practice Program
Office of Science and Health Coordination
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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.

-----Original Message-----
From: [purged]
Sent: Tuesday, January 24, 2006 5:10 PM
To: gcpquestions@oc.fda.gov
Subject: GCP: question re: access to medical records by industry sponsor

Dear GCP.gov,

An industry sponsor is indicating to one of our
Principal Investigator's that it is "implied" in FDA
GCP, that to ensure inclusion/exclusion eligibility,
ALL Medical Histories (including ALL Primary care
physicians/Pediatric records "PCP's) must be made
available to their study monitors to determine
eligibility of subjects.

That means the PI going to each treating
physician/hospital in the history of a patient and
requesting access to those medical records and copies,
which are then made available to the sponsor's study
monitors.

If the industry sponsor Protocol fails to specify that
ALL prior medical histories from private
physicians/hospitals, etc must be obtained for the
study monitor, is that a reasonable expectation?

Is the sponsor correct that there is an "implied"
FDA/GCP duty to gain copies of ANY AND ALL prior PCP
records regardless of relevance to the study? If yes,
is there a specific FDA/CFR cite that specifies this?

Thank you,
[purged]