From: Beers Block, Patricia on behalf of OC GCP Questions
Sent: Tuesday, May 13, 2003 9:21 AM
To: [purged]
Subject: RE: HIPA and the release of participant information to the
participant prior to the close of a blinded clinical trial

Dear Ms. [purged],

I apologize for the delay in our reply to your inquiry. By way of a little background, the Office of Civil Rights (OCR) within the Department of Health and Human Services has been designated the official arbiter for all HIPAA related issues and questions. We consult with OCR on all HIPAA issues. In this instance, we determined your question has been addressed in one of the Department's guidances on HIPAA.

As the Department of Health and Human Services has stated in guidance, available at www.hhs.gov/ocr/hipaa:

"With few exceptions, the Privacy Rule gives patients the right to inspect and obtain a copy of health information about themselves that is maintained by a covered entity or its business associate in a designated record set. See 45 C.F.R. 164.521(a)(1). A designated record set is basically a group of records which a covered entity uses to make decisions about individuals, and includes a health care provider's medical records and billing records, and a health plan's enrollment, payment, claims adjudication, and case or medical management record systems. See 45 C.F.R. 164.501. While it may be unlikely that a researcher would be maintaining a designated record set, any research records or results that are actually maintained by the covered entity as part of a designated record set would be accessible to research participants unless one of the Privacy Rule's permitted exceptions applies.

One of the permitted exceptions applies to protected health information created or obtained by a covered health care provider/researcher for a clinical trial. The Privacy Rule permits the individual's access rights in these cases to be suspended while the clinical trial is in progress, provided the research participant agreed to this denial of access when consenting to participate in the clinical trial. In addition, the health care provider/researcher must inform the research participant that the right to access protected health information will be reinstated at the conclusion of the clinical trial."

The Privacy Rule states the participant must be notified "during the consent process" about the denial of access to their medical records until the research is complete. The Rule doesn't specifically state that this notification be contained within the research consent document. Therefore, it could be contained either in the research consent document or in the HIPAA Authorization.

Finally, with limited exceptions, covered entities must act on a request for access to protected health information in a designated record set no less than 30 days after receipt of the request. See 45 C.F.R. 164.524(b)(2).

If you have additional questions about HIPAA, you may want to visit OCR's website at the following url:
http://www.hhs.gov/ocr/hipaa/. Guidances will be posted to this website as they become available. You may also want to submit questions directly to OCR. Instructions on how to submit questions to OCR can be found at this website.

I hope this information helps.

Most sincerely,

Patricia M. Beers Block
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Good Clinical Practice Program (HF-34)
Office of Science and Health Coordination
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301-827-3340

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 judgement of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind nor otherwise obligate or commit the agency to the views expressed.

-----Original Message-----
From:[purged]
Sent: Thursday, May 08, 2003 3:54 PM
To: gcpquestions@oc.hhs.gov; Carolyn.Hummel@oc.hhs.gov
Subject: HIPA and the release of participant information to the
participant prior to the close of a blinded clinical trial

One of our clinical trial study participants was curious about his records when talking with a counselor, initially asking for a full copy of the record, but then seemed less interested as the conversation progressed (He declined at the end of the visit to have a copy of the record).

However, what should we tell participants who ask for their records in the new age of HIPA? According to HIPA regulations, we are required to give the participant a copy of his research record if requested. However, we can withhold the copy for a specific time period if we believe it might compromise the study findings or the intervention.

Can we construct a plan for when we could send a copy (i.e. immediately or soon after, when the participant ends the study, when unblinding occurs, etc)?

Per HIPA 10/22 section 164.524 Access of individuals to protected health information: can only be denied "provided that the individual has agreed to the denial of access when consenting to participate in the research that includes treatment, and the covered health care provider has informed the individual that the right of access will be reinstated upon completion of the research."

Our participants didn't agree to this clause because their consent forms predate all HIPA. Hence –strict rule suggests we should provide the information within 30 days of their request. But -is there a strict rule or what guidance can we provide to sites about providing participants access to their own charts in a blinded study?