From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Tuesday, April 25, 2006 1:44 PM
To: [purged]
Subject: RE: A doubt regarding ICH- GCP

Dear [purged]:

Your e-mail to the GCP Questions e-mail account was forwarded to me for a response. It's usually best not to direct your questions to a specific person, as it may delay your getting a response if the individual you specify is traveling or otherwise unable to retrieve his/her e-mail.

Getting to your questions--you asked:

- We have one patient, enrolled into clinical study, that was hospitalized in another hospital due to femur fracture (SAE). During the hospitalization this patient was followed by orthopedist and our staff. This patient was discharged from hospital to be followed in outpatient clinic. Regarding the source documents for this hospitalization, we would like to know if we can ask to the hospital a copy of patient's file. We have had a information from our Ethic Comitte that the patient can solicite the file to the hospital and if he agrees to give us, he will need to write an autorization to us to collect information regarding clinical research.
For GCP is this procedure correct?

Answer: The procedure that you have identified would be in keeping with good clinical practice. Generally, before a hospital or physician may release a patient's medical records, the patient must first authorize such release. In the United States, the Health Insurance Portability and Accountability Act (HIPAA) was enacted to allow patients more control over who has access to their medical records and health information. HIPAA is enforced by the US Office for Civil Rights. You can obtain more information about HIPAA at the following website:
http://www.hhs.gov/ocr/hipaa/.

You also asked:

- Another doubt is regarding a biopsy result report. The study requires a graft biopsy from cadaveric donor after removal (from donor) and before the transplant surgery (in the back table). We would like to know which is correct: the biospy result report with the name of the donor or with the name of the patient that will receive the kidney?

Answer: The biopsy result report should contain the name of the donor. FDA's regulations pertaining to "Human Tissue Intended for Transplantation" are found at 21 CFR 1270. Section 21 CFR 1271, " Human Cells, Tissues, and Cellular and Tissue Based Products," may also be of interest. I have pasted two of the relevant sections from 21 CFR 1270 into this e-mail for your convenience, but I would encourage you to read FDA's regulations on transplantation in their entirety:

Section 1270.3 Definitions

"...(t) Relevant medical records means a collection of documents including a donor medical history interview, a physical assessment of the donor, laboratory test results, medical records, existing coroner and autopsy reports, or information obtained from any source or records which may pertain to donor suitability regarding high risk behaviors, clinical signs and symptoms for HIV and hepatitis, and treatments related to medical conditions suggestive of such risk. ..."

Sec. 1270.35 Specific records.

"Records shall be maintained that include, but are not limited to:
(a) Documentation of results and interpretation of all required infectious disease tests;
(b) Information on the identity and relevant medical records of the donor, as required by Sec. 1270.21(e) in English or, if in another language translated to English and accompanied by a statement of authenticity by the translator which specifically identifies the translated document;
(c) Documentation of the receipt and/or distribution of human tissue; and
(d) Documentation of the destruction or other disposition of human tissue."

Section 21 CFR 1271.290(e)

"(e) Tracking from donor to consignee or final disposition. As part of your tracking system, you must establish and maintain a method for documenting the disposition of each of your [Human Cells, Tissues, and Cellular and Tissue Based Products] (HCT/Ps), to enable tracking from the donor to the consignee or final disposition. The information you maintain must permit the prompt identification of the consignee of the HCT/P, if any."

As you can see, the records should document the results/interpretation of infectious disease tests performed on the tissue specimen, the identity of the donor, as well as information as to how the tissues were distributed. It should be possible to trace the human tissues through the entire distribution chain, so that if any problems are subsequently identified (e.g., HIV, hepatitis, other infectious disease), the tissues can be traced back to the donor. Donors may provide more than one type of tissue (kidneys, liver, corneas, skin) for transplant, and the tissue(s) could have been transplanted into more than one recipient. Because there may be confidentiality issues (donors and recipients both often request anonymity), the tissues may be coded for confidentiality. Information as to the registered establishment that processed the material, and any code(s) related to the donor should be included in the recipient's file in case it becomes necessary to trace the tissues back to the donor.

FDA has published various guidances that address donor screening, and processing and labeling of human cells, tissues, and related products. Here is a link to FDA's regulations and guidance about tissue-related topics: http://www.fda.gov/cber/tissue/docs.htm.

I hope this is helpful.

Sincerely,
Carolyn Hommel
Consumer Safety Officer
Good Clinical Practice Program
Office of Science and Health Coordination
Office of the Commissioner
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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.

From: [purged]
Sent: Wednesday, April 05, 2006 10:36 AM
To: OC GCP Questions
Subject: A doubt regarding ICH- GCP

Dear Bonnie M. Lee

My name is [purged] and I am pharmacist and study coordinator from kidney transplant site.
I would like to ask you some doubts:

- We have one patient, enrolled into clinical study, that was hospitalized in another hospital due to femur fracture (SAE). During the hospitalization this patient was followed by orthopedist and our staff. This patient was discharged from hospital to be followed in outpatient clinic. Regarding the source documents for this hospitalization, we would like to know if we can ask to the hospital a copy of patient's file. We have had a information from our Ethic Comitte that the patient can solicite the file to the hospital and if he agrees to give us, he will need to write an autorization to us to collect information regarding clinical research.
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Thank you in advance,
With kind regards,

[purged]