From: Beers Block, Patricia on behalf of OC GCP Questions
Sent: Thursday, July 11, 2002 9:00 AM
To: [purged]
Subject: RE: Informed Consent Document Storage

Dear Ms. [purged],

Your email to the Office of Special Heath Issues was forwarded to our office for response. Thank you for your inquiry. First, let me direct you to our Office's internet web page as you may find some helpful information about good clinical practice. The address for our internet web page is:

http://www.fda.gov/oc/gcp/default.htm

The Office for Good Clinical Practice, created last year, serves as the Agency level office charged with addressing policies and emerging practice in the area of good clinical practice in human clinical trials. I hope you find the information on our web page helpful.

Your question about where to store records is a good one and one that perplexes many. Actually, our regulations (found in 21 CFR 50, 56, and 312) are pretty much silent on precisely WHERE records are to be stored. They require that an investigator shall prepare, maintain and retain records; and require the CI to permit access to all of the records in 21 CFR 312.62 for inspection. The relevant regulatory requirement for informed consent (21 CFR 312.62(b)) suggests the signed and dated consent forms would be part of the case history. As long as the investigator can fulfill these requirements for retention and access, the records can be kept just about anywhere, but are usually kept directly by the investigator or by the investigator's institution. The regulatory binder is usually retained at the site and in the case described in your question, would seem to meet both the regulatory requirement as well as be consistent with the ICH guidance.

You may find it useful to look at the ICH guidance entitled "E6: Good Clinical Practice, Consolidated Guidance" (see the OGCP web page under "Guidances"). In section 8 of this ICH guidance, there are helpful suggestions as to where records should reside. It suggests in 8.3.12 that during the trial the ICF be retained in the CI/Institution files. It is also important to note that the ICH guide allows certified copies to serve as source data, therefore retention of certified copies by the CI could meet the requirements of the regulations. This is a guidance and contains current information supported by FDA.

I hope this adequately addresses your questions. Should you have any additional questions, please feel free to write again.

Sincerely,

Pat Beers Block
Special Assistant to the Director
Office for Good Clinical Practice

Name: [purged]

E-Mail: [purged]

Comments: I work in cancer research as the Regulatory Coordinator at [purged]

I was asked to investigate the State and/or Federal

requirements/regulations for record keeping in regards to ICF's (Informed Consent Form).

One of our pharmaceutical sponsors has asked us to place the patient's ORIGINAL signed consent form in their regulatory binder that I keep in my office.

Could you by any chance answer the following questions for me and let me know how we should deal with this. I need to know the proper use, storage and access to:

(a)original confidential records (b)involving a clinical trial and (c)using an investigational agent?

I guess what I am asking is what sort of risks might there be if all original, signed consent forms are kept in the sponsor's regulatory binder? We now keep them all in the patient shadow charts. None of these are kept in a fire-proof cabinet or under lock and key. What would happen should we be audited? I have not been able to get any answers for these questions and need to know so we don't have any violations. Please respond to my e-mail address: debora.chudd@advocatehealth.com. Thanking you in advance for your help.--------[purged]

Documents checked:

INFORMATION SHEETS. Guidance for Institutional Review Boards and Clinical Investigators, 1998 Update. A Guide to Informed Consent

http://www.fda.gov/oc/ohrt/irbs/informedconsent.html

INFORMATION SHEETS. Guidance for Institutional Review Boards and Clinical Investigators, 1998 Update. FDA Operations

http://www.fda.gov/oc/ohrt/irbs/operations.html#inspections

INFORMATION SHEETS. Guidance for Institutional Review Boards and Clinical Investigators, 1998 Update. Appendix B, 21 CFR Part 50 - Protection of Human Subjects

http://www.fda.gov/oc/ohrt/irbs/appendixb.html

Guidance for Industry. E6 Good Clinical Practice: Consolidated Guidance
http://www.fda.gov/cder/guidance/959fnl.pdf