From: Woollen, Stan - OC on behalf of OC GCP Questions
Sent: Monday, September 16, 2002 6:04 PM
To: [purged]
Subject: RE: Question regarding informed consent documents on medical records

Dear Ms. [purged],
21 CFR 312.62(b) only requires clinical investigators to prepare and maintain case histories, the definition of which includes signed and dated consent forms. Although these are to be maintained by the clinical investigator, the precise location is not mandated. The best GCP guidance that FDA has on the topic of which records should be retained and where is the E6 ICH consolidated guide on Good Clinical Practice http://www.fda.gov/cder/guidance/959fnl.pdf . I would specifically refer you to section 8.3.12. I hope this information is helpful.
Stan W. Woollen
Associate Director for Bioresearch Monitoring
Office for Good Clinical Practice

-----Original Message-----
From: [purged]
Sent: Friday, September 13, 2002 3:48 PM
To: gcpquestions@oc.fda.gov
Subject: Question regarding informed consent documents on medical records

FDA:
I have a question regarding the practice of putting a copy of the informed consent document for a study participant on their hospital medical record. I have always understood (and taught my staff) to put a copy of the informed consent document on either their outpatient or inpatient record, depending on where they are treated. I can find no guidance that states that this is a requirement or a suggestion for good clinical practice. I know that for the new Medicare guidelines, documentation of research is required in the record.
Can someone please guide me on this topic? It is one of great concern at our center since staff have received conflicting information on this. Please let me know if it is required or suggested or if it is not something recommended by the FDA.
Thank you,
Susan Sambuco

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