From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Friday, April 18, 2003 3:41 PM
To: [Redacted]
Subject: RE: Informed Consent Procedure

Dear Ms. [Redacted],

In your e-mail, you asked whether a site must document in the subject's medical records that a copy of the informed consent document was provided to the subject.

The answer is no. Although 21 CFR 50.27(a) requires that a copy of the informed consent document be given to study subjects, FDA regulations do not specifically require that the subject's case history be annotated to show that this was done.

The case history is required to document, however, "that informed consent was obtained prior to participation in the study." [See 21 CFR 312.62(b).] Case histories, of course, include many documents: "...case report forms and supporting data, including, for example, signed and dated consent forms, any medical records, for example, progress notes of the physician, the individual's hospital chart(s), and nurses' notes." In other words, by reviewing the various documents that comprise the case history for each subject, one should be able to determine that consent was obtained from the subject before any study-related procedure is performed.

I hope this is helpful.

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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: [Redacted]
Sent: Friday, April 18, 2003 12:18 PM
To: gcpquestions@oc.fda.gov
Subject: Informed Consent Procedure

Hello,
Would you please tell me if it is required that upon obtaining informed consent and giving the subject a copy of the consent, one must also document in the medical record that the copy was given?

If that is the case, please let me know where in the CFR that is stated.
Thanks!
[Redacted]