From: Hommel, Carolyn - OC
Sent: Wednesday, May 21, 2003 9:53 AM
To: [Redacted]
Cc: Chin, Tom M
Subject: Time Stamps on Consent Forms

Follow Up Flag: Follow up
Due By: Wednesday, May 21, 2003 5:00 PM
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Dear Ms. [Redacted],

Your question about time stamps for documentation of informed consent was forwarded to me for a response.

As you pointed out, 50.27(a) requires that informed consent be "documented by the use of a written consent form approved by the IRB and signed and dated by the subject or the subject's legally authorized representative at the time of consent." The regulations do not require that the consent form be time stamped.

There is a thorough discussion about this issue in Comment #1, in preamble to the final regulations, "Protection of Human Subjects; Informed Consent Verification," published in the November 5, 1996, Federal Register (FR), page 57278.

The agency noted:

> In practice, the time of day is generally not recorded in case histories, except when time sensitive procedures are carried out. Therefore, recording the time of day on the consent form may not establish that the form was signed before participation in the study. Rather than requiring the time of day to accomplish the agency's verification goal, the agency has modified [Sections} 312.62(b) and 812.140(a)(3)(i) to allow flexibility in approaches to providing verification.
>
> These sections now state, "The case history for each individual shall document that informed consent was obtained prior to participation in the study." This case history documentation may be contained in the case report form; in the individual's medical record, e.g., in progress notes of the physician, on the individual's hospital chart, in the nurse's notes; on the consent form; in a combination of these documents; or elsewhere in the individual's case history. The documentation may consist of, e.g., a chronological record of the sequence of events that establishes that informed consent was obtained prior to a procedure required by the clinical investigation, or the time that consent was obtained and the time of the first study-related procedure performed on the individual.

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 was performed.

5Nov96FR.pdf

I have attached a copy of the FR notice for your information.

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
U.S. Food and Drug Administration (HF-34)
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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, May 16, 2003 8:42 AM
To: TChin@ora.fda.gov
Subject: Question regarding Informed Consents

Dear Mr Chin,
We have a query reading 21 CFR Part 50.27
http://www.access.gpo.gov/nara/cfr/waisidx_02/21cfr50_02.html

it states in (a)
Except as provided in Sec. 56.109(c), informed consent shall be documented by the use of a written consent form approved by the IRB and signed and dated by the subject or the subject's legally authorized representative at the time of consent.

Our company is divided in their opinion whether it would be required to add a box on the Informed Consent Form where the actual TIME of the signature is recorded (as well as the date). In my view recording of the time of consent is required as the subject may start the study on the same day as the consent is signed and it should be clear that the consent was signed before any study related activities were performed, lets say when the first laboratory blood sample was taken.

Could you give me your view and clarification on this please.

Many thanks
Kind regards

[Redacted]