From: Woollen, Stan - OC
Sent: Monday, March 31, 2003 2:27 PM
To: [Redacted]
Subject: RE: Found it
[Redacted],
Sorry I didn't get back to you earlier. I recently did a little research on the topic and was surprised to learn that there is a rather extended discussion of this topic in the comments section of the preamble to our FR notice issued Nov. 5, 1996 (FR 57278 Vol. 61. No 215). I've included the text below and underlined the portion I believe is most relevant. I believe you will find it quite interesting

Stan W. Woollen
Associate Director for Bioresearch Monitoring
Good Clinical Practice Programs
OSHC, Office of the Commissioner

1. One comment suggested that the agency should require not only the date, but also the time, that the consent form was signed in order to be able to verify that consent was obtained prior to a subject's entry into a study. This comment expressed concern by the potential 24-hour window created by requiring the date and not the time for research subjects who sign the consent form on the day that they begin their participation in the study. The comment suggested that this 24-hour window should be closed to ensure that investigators fulfill their responsibilities and to enable the agency to verify that consent is obtained prior to entry into the study. The comment provided the following three additional reasons for requiring the time of day that the consent form is signed: (1) The role of informed consent in clinical investigations is to help ensure voluntary decisionmaking about enrollment in a study, (2) documentation of the timing of the signature helps to provide evidence of when consent was obtained in relation to when the investigational intervention commenced, and (3) the interest of historians and scholars in knowing whether the research was conducted in accordance with societal standards related to the conduct of research.

The agency has considered this comment and whether the regulation should be modified to permit verification that consent was obtained prior to a subject's entry into a study when both consent is obtained and participation in a study occur on the same day. The agency agrees that when, for example, the consent form is signed on the same day that the subject begins participation in the study, it may not be able to verify from a dated consent form that consent was obtained prior to an individual's participation in the research; therefore, other documentation may be needed. However, the agency does not think that it is appropriate to require the time of signature to be included on every consent form in order to permit this verification.

FDA notes that adding the time of day to the consent form may not provide the additional assurance suggested by the comment. The investigational new drug application and investigational device exemption regulations (parts 312 and 812 (21 CFR parts 312 and 812)) do not require the time of day to be recorded in the individual's case history for each research intervention. 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 Secs. 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.

The agency notes that 21 CFR 56.109(c) provides for an exception from the requirement for written documentation of informed consent and that part 50 (21 CFR part 50) provides for certain limited exceptions to the requirement for obtaining informed consent. This rule does not change those regulatory provisions.

-----Original Message-----
From: [Redacted]
Sent: Monday, March 31, 2003 1:41 PM
To: Stan Wollen
Subject: Found it

Hi Stan- I found the reg reference for ICF execution prior to study procedures (312.62(b)). I knew I had read it (oh so many times) but couldn't find it when asked by a client. I'm sorry to have hit you with this one.
Best regards,
[Redacted]