From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Monday, April 26, 2004 11:46 AM
To: [Redacted]
Cc: CDER DRUGINFO
Subject: Verification of Informed Consent/Case Histories

Dear [Redacted], The requirements in the informed consent verification rule, published in 1996, are still current. FDA regulations state what case histories must include. See 21 CFR 312.62(b). This section of the regulations states, in part, that case histories need to include "...signed and dated consent forms...." and "The case history for each individual shall document that informed consent was obtained prior to participation in the study." FDA's informed consent regulations require the consent form to be signed and dated by the subject or the subject's legally authorized representative at the time of consent. See 21 CFR 50.27. One reason for adding the dating requirement in 1996 was to ensure that consent was obtained prior to participation in the study. The date, however, would not provide this assurance if the subject's participation began on the same day the subject signed the consent form. Thus, in that situation, we indicated that there would need to be documentation beyond the date that would indicate consent was obtained prior to study participation. That documentation could be a time of signature added to the consent and a time of initiation of study participation elsewhere in the case history; it could be a notation in the case history that consent was obtained at a certain time and study participation began at a certain later time; or some other documentation. As I indicated, the time is only important if both the consent and participation in the research begin on the same date. If they are on different dates, then the case history would (by that fact) hopefully document that consent was obtained prior to participation in the study by the different dates.

I hope that this information is helpful to you. If you want to look at the regulations, I encourage you to access them from our website at: http://www.fda.gov/oc/gcp/regulations.html.

Sincerely,

Bonnie
Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Good Clinical Practice Program, FDA

-----Original Message-----
From: CDER DRUGINFO
Sent: Thursday, April 22, 2004 1:04 AM
To: OC GCP Questions
Subject: FW: DrugInfo Comment Form FDA/CDER Site

-----Original Message-----
From: [Redacted]
Sent: Wednesday, April 21, 2004 6:42 PM
To: druginfo@cder.fda.gov
Subject: DrugInfo Comment Form FDA/CDER Site

Name: [Redacted]

E-Mail: [Redacted]

Comments: To whom it may concern:

Regarding:
Federal REgister November 5, 1996 (volume 61, Number 215) Part VIII for 21 CFR Parts 50, 312, and 812 Protection of Human Subjects; Informed Consent Verification; Final Rule

Is this document still current or has it been replaced with something newer. I'm specifically interested in the clarification of waht adequate case histories include. Is it still required that there be documentation in the case history that consent was obtained prior to pariticipation in a study? Can the consent stand alone with just signature and date? What if the time is added to the consent, is a notation in the case history still required?

Thank you for time.
Regards,
[Redacted]