From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Wednesday, May 24, 2006 4:45 PM
To: [purged]
Subject: RE: Question

Dear Ms. [purged]:

There isn't any specific regulatory citation in 21 CFR 312 related to signing and dating documents, except for 21 CFR 312.62(b): "An investigator is required to prepare and maintain ADEQUATE AND ACCURATE case histories that record all observations and other data pertinent to the investigation on each individual administered the investigational drug or employed as a control in the investigation. Case histories include the case report forms and supporting data including, for example, SIGNED AND DATED CONSENT FORMS AND MEDICAL RECORDS including, for example, progress notes of the physician, the individual's hospital chart(s), and the nurses' notes. The case history for each individual shall document that informed consent was obtained prior to participation in the study." [Emphasis added.]

In general, the date should reflect when an individual actually signs a document. Documents should not be "pre-dated" or "post-dated," and it's poor practice to do so. Simply put, "pre-dated" or "post-dated" records are not accurate. If pre-dating and/or post-dating is done routinely, it could be considered repeated and deliberate non-compliance.

I hope this clears up your confusion.

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 judgement 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: [purged]
Sent: Monday, May 22, 2006 9:11 AM
To: OC GCP Questions
Subject: Question

What is the best regulation to site to an auditee
regarding Pre-dating and Post dating?

Do You Yahoo!?
Tired of spam? Yahoo! Mail has the best spam protection around
http://mail.yahoo.com