From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Monday, August 30, 2004 12:18 PM
To: [Redacted]
Subject: RE: Documentation of the ICF process
Dear [Redacted],

FDA regulations do not specify that the informed consent process (beyond the informed consent form) must be documented. However, documenting that process is a good idea, particularly if it may be questioned later. For example, if consent is obtained on the same day the person begins the investigational procedures, there should be a note in the case history/medical record that informed consent was obtained first. Your current practice for documentation sounds fine.

I wouldn't worry about the two patients you enrolled without documenting the process as the monitor asked, in nurses' notes. To be responsive to the monitor, that can be done for future patients. I hope this information is helpful to you.

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

> -----Original Message-----
> **From:** [Redacted]
> **Sent:** Wednesday, August 18, 2004 9:28 PM
> **To:** OC GCP Questions
> **Subject:** Documentation of the ICF process
>
> Informed consent
>
> A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subjects decision to participate. **Informed consent is documented by means of a written, signed, and dated informed consent form [ICH 1.28]**
>
> We follow strict IRB approved ICFs which contain all the elements of the consent process to enroll patients into our studies. Do I still need to record in the patients study file how the process was obtained as a nurses note or is the informed consent evidence that the process was strictly adhered to? We also document on our yearly progress reports how ICF was obtained and we have SPOs address how to obtain consent. Is this enough or do I still have to document the process again in the patients file?
>
> I started working at a new research site and the study monitor is asking that I record the process as a nurses note. If this is correct how do I correct the 2 patients I enrolled prior to this notice from the monitor?
>
> Thanks, [Redacted]