From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Wednesday, August 21, 2002 10:46 AM
To: [purged]
Subject: RE: Consent Form

Dear [purged],

The answer to your question depends whether information in the informed consent form would change. I am assuming that the informed consent was for participation in a research study--not for the screening itself. If an extended period of time has elapsed between the subject signing a consent form, then it is appropriate for the investigator to re-review the information contained in it with the subject. If the protocol requires a re-screening process if >30 days have elapsed, and the screening process was a part of the consent document, the fact that the patient may now need to be rescreened (depending upon what this entails) may be information that could affect the subject's willingness to participate in the trial. In that case an updated consent form may need to be signed.

I hope this is helpful to you. If I have misunderstood you question, please feel free to get back to me.

Bonnie

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-----Original Message-----
From: [purged]
Sent: Friday, August 09, 2002 8:15 AM
To: gcpquestions@oc.fda.gov
Subject: Consent Form

please advise if the agency has a regulatory document (biologics or drug trials) available for the following scenario:

- informed consent was obtained prior to screening; however, >30 days had passed and the patient had to be re-screened. Should the investigator asked the study subject/patient to sign another consent. Or, should the investigator re-review the informed consent and document this discussion in the study subjects/patients chart.

Your assistance is appreciated.

[purged]