From: OC GCP Questions
To: [redacted]
Subject: RE: Question related to a "delayed posting"
Date: Thursday, May 11, 2017 8:31:00 AM
Attachments: [redacted]

Dear [redacted],

If the study you are describing is determined by the responsible party to be an applicable clinical trial, the statement required under 21 CFR 50.25(c) must be included even if the responsible party for the applicable clinical trial is not yet required to submit clinical trial information to ClinicalTrials.gov. Also, under the statutory provisions, responsible parties of applicable device clinical trials are required to submit the clinical trial information although the information is not posted on the public website until after FDA approval and clinical trial participants should be informed of this possibility. Please note that 21 CFR 50.25(c) states "This will notify the clinical trial subject that clinical trial information has been or will be submitted for inclusion in the clinical trial registry databank under paragraph (j) of section 402 of the Public Health Service Act." (emphasis added)

In addition, the requirements for informed consent at 21 CFR 50.25(a)(7) include an explanation of whom to contact for answers to pertinent questions about the research. Should a subject not be able to find information related to the trial in question, the informed consent document should have contact information for the subject to obtain information related to the trial.

FDA's official guidance on 21 CFR 50.25(c) can be found at http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM291085.pdf .

I hope this information is helpful to you. If you need further assistance, please feel free to contact the GCP mailbox at gcp.questions@fda.hhs.gov .

Best regards,

Sheila

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This communication does not constitute a written advisory opinion under Title 21 CFR 10.85, but rather is an informal communication under Title 21 CFR 10.85(k), which represents the best judgment 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.

From: [redacted]
Sent: Wednesday, May 10, 2017 1:28 PM
To: OC GCP Questions
Subject: Question related to a "delayed posting"

If the sponsor has received a delayed posting, is the clinical trials language still required in the consent document? I've found the delayed posting for the study I'm working on (I work for an IRB) really difficult (pretty much impossible unless you have the NCT#) to find when searched. Doesn't seem to make much sense to put the "A description of this clinical trial..." the study is listed if they won't be able to find it.

[redacted]