From: [redacted]
[redacted]
Subject: RE: IRB's responsibility for disclosure of 21 CFR 50.25(c) for applicable clinical trials
Date: Wednesday, March 18, 2015 2:45:00 PM

Good afternoon [redacted],

Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) places the responsibility for determining whether a trial meets the definition on the "responsible party." The guidance notes that the sponsor and the investigator is responsible for making this determination as they could be the "responsible party," as defined under the statute. An IRB is required to ensure that the elements of consent are included in the informed consent for a clinical trial, including the statement required under 21 CFR 50.25(c) for applicable clinical trials.

FDA's Compliance Program Guidance Manual for inspection of IRBs instructs FDA field investigators to determine if the statement required under 21 CFR 50.25(c) is included in the informed consent document for applicable clinical trials. While the IRB is not required to make the determination whether the trial is an applicable clinical trial, should an informed consent document not include the required statement or the IRB questions whether the trial meets the definition of an applicable clinical trial, it may be appropriate to discuss this with the "responsible party" for the trial and document any discussions related to the issue.

Topics related to the requirements under Title VIII of FDAAA are discussed in the NIH Notice of Proposed Rulemaking which is currently open for public comment until March 23, 2015. You may wish to review the NPRM and provide comment on the proposed rule.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Patrick J. McNeilly, Ph.D., C.I.P.
Office of Good Clinical Practice
Food and Drug Administration

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 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: Monday, March 16, 2015 5:26 PM
To: OC GCP Questions
Subject: IRB's responsibility for disclosure of 21 CFR 50.25(c) for applicable clinical trials

I have a question about the IRB's responsibility for disclosure of 21 CFR 50.25(c) for applicable clinical trials.

A sponsor does not register a study because the sponsor believes that the research is not an applicable clinical trial, as defined in 42 U.S.C. 282(j)(1)(A). Based on the sponsor's decision, the IRB approves a consent document that does not include this disclosure. If in fact the research is an applicable clinical trial, the guidance (below) says that the sponsor and investigator are responsible.

Are the sponsor and investigator solely responsible?

That is, does the IRB bear any responsibility, assuming the IRB acted in good faith?

[redacted]

SUBCHAPTER A--GENERAL

PART 50 -- PROTECTION OF HUMAN SUBJECTS

Subpart B--Informed Consent of Human Subjects

Sec. 50.25 Elements of informed consent.

…

(c) When seeking informed consent for applicable clinical trials, as defined in 42 U.S.C. 282(j)(1)(A), the following statement shall be provided to each clinical trial subject in informed consent documents and processes. 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. The statement is: "A description of this clinical trial will be available on*http://www.ClinicalTrials.gov*, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."

http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM291085.pdf

16. What if non-compliant informed consent documents (documents without the new statement as required) are submitted to and approved by the IRB?

The investigator and sponsor are responsible for determining whether a trial is an applicable clinical trial and to include the required statement in the informed consent document, as appropriate, for approval by the IRB. If an error is made, the IRB should be notified as soon as possible and a revised consent form that includes the required statement should be provided to the IRB for review and approval.

[redacted]