From: OC GCP Questions
To: [redacted]
Subject: RE: question regarding informed consent
Date: Thursday, July 16, 2015 7:07:00 AM

Good morning,

Please be aware that the clinical trial registration and submission of results to ClinicalTrials.gov is required under Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) for all "applicable clinical trials" regardless of whether the results of the trial will submitted to FDA. The determination of whether a trial is an "applicable clinical trial" must be made by the "responsible party" associated with that trial and familiar with all aspects of the clinical trial. The NIH website does contain the Elaboration of Definitions which can be referred to, as well as various FAQs. FDA cannot make that determination for any party.

The statement described in 21 CFR 50.25(c) is required to be included in the informed consent documents of "applicable clinical trials." I would refer you to FDA's guidance document that relates to this regulation (http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM291085.pdf).

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

From: [redacted]
Sent: Wednesday, July 15, 2015 2:15 PM
To: OC GCP Questions
Subject: question regarding informed consent

To whom it may concern,

We are a testing laboratory for [redacted] and we have a conundrum regarding our informed consent document. This is in regard to the inclusion of the statement regarding data to be placed on the website: www.clinicaltrials.gov. We have a sponsor that does not want to input the data to this website since they do not plan to submit the study as part of an IND to the FDA. Do we need to include the following required

statement?

"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."