From: Donnelly, Janet
To: [redacted]
Subject: RE: REVISION OF PREVIOUS QUESTION re elements of consent
Date: Tuesday, February 04, 2014 12:05:00 PM

Hello [Redacted]-

Thanks for your question. I've copied below your previous question as well so I can make sure I respond appropriately.

You are correct that the eight basic elements of informed consent and the six additional elements (when appropriate) are the same between 21 CFR (FDA) and 45 CFR (HHS) regulations. You can access these elements at 21 CFR 50.25(a) and (b) at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=50.25) and 45 CFR 46.116(a) and (b) at http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.116.

As stated in the guidance document you reference below, in the Federal Register (FR) of January 4, 2011 (76 FR 256), FDA published a final regulation (21 CFR § 50.25(c)) amending the current informed consent regulations to require that informed consent documents and processes for applicable drug (including biological products) and device clinical trials include a specific statement that clinical trial information will be entered into a databank. The databank referred to in this final rule is the clinical trial registry databank maintained by the National Institutes of Health/National Library of Medicine (NIH/NLM) which was created by statute. The submission of clinical trial information to this data bank also is required by statute. The amendment to the informed consent regulations was required by the Food and Drug Administration Amendments Act of 2007 (FDAAA), Public Law 110-85 (September 27, 2007), and is designed to promote transparency of clinical research to participants and patients.

The need to include this new requirement for informed consent documents is dependent on whether the FDA-regulated drug, biologic or device study meets the definition of an "applicable clinical trial". You can refer to the guidance for an explanation of what an applicable clinical trial is. You can also see from the guidance that trial sponsors and investigators have the responsibility of determining whether or not a trial is an "applicable clinical trial".

This new regulatory requirement can be found in FDA's regulations at 21 CFR 50.25(c) at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=50.25.

FDA also has a web page where you can read more about ClinicalTrials.gov and FDA's Role – see http://www.fda.gov/scienceresearch/specialtopics/runningclinicaltrials/fdasroleclinicaltrials.govinformation/default.htm.

Essentially, the new FDA informed consent requirement found at 21 CFR 50.25(c) is required to be included in the ICF when the clinical trial meets the definition of an "applicable clinical trial". If the clinical trial is NOT determined to be an applicable clinical trial, then this regulatory requirement does not apply.

This new requirement is neither listed under the basic elements of informed consent at 21 CFR 50.25(a) nor the additional elements at 21 CFR 50.25(b). Rather, it has its own regulatory citation found at 21 CFR 50.25(c) and is required to be included in the ICF when the study in question is an "applicable clinical trial".

I hope this information is useful. If you need further information and/or have additional questions, please feel free to contact us at the official GCP mailbox, gcp.questions@fda.hhs.gov. You may also find it useful to access the set of redacted GCP e-mails found at http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriestoFDAonGoodClinicalPractice/default.htm since we find that many questions and concerns are repeated over time.

Best Regards,

Janet

Janet Donnelly, RAC, CIP
Policy Analyst, Office of Good Clinical Practice
Office of Special Medical Programs, Food and Drug Administration

From: [Redacted]
Sent: Monday, February 03, 2014 8:49 PM
To: Donnelly, Janet
Subject: REVISION OF PREVIOUS QUESTION re elements of consent

Dear Miss Donnelly,

I am so sorry to take your valuable time, but I think I have found the answer in my collection of documents, just reviewed. In Guidance for Sponsors, Investigators, and Institutional Review Boards, dated February, 2012, by the FDA. In the document, further titled Questions and Answers on Informed Consent Elements, it is apparently considering the clinical trials.gov a "requirement." (If I am right or wrong, let me know).

Sorry for the intrusion.

Warmest regards,

[Redacted]

Sent Monday, 8:13pm

Dear Miss Donnelly,

I hope this finds you well.

I am making a presentation in the near future to Research Specialists. I would like to clear up one small item. I have always learned and subsequently taught that Title 21 and Title 45 had similar eight required and six suggested elements (if appropriate).

I was recently admonished that they now contained 8 required and 7 (SEVEN) suggested elements, in that the ClinicalTrials.gov paragraph is now considered a suggested element if appropriate.

Is that so, or does the actual number of elements not matter? That is, is it now under (b) section of the required elements?

Thank you for you help.

Very respectfully,

[Redacted]