From: OC GCP Questions
To: [redacted]
Cc: [redacted]
Subject: RE: ICF and required clinicaltrials.gov disclosure
Date: Wednesday, April 19, 2017 1:16:00 PM
Attachments: [redacted]

Good afternoon,

FDA has issued guidance related to the informed consent element at 21 CFR 50.25(c) which can be accessed at https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM291085.pdf . Questions 18 and 19 of the guidance document should address your question. The text is copied below.

18. If a clinical trial is not subject to the rule, do investigators have to inform trial participants about the availability of clinical trial information on www.ClinicalTrials.gov?
No, if the clinical trial is not subject to the rule (not an applicable clinical trial), then investigators/sponsors do not need to inform participants about the availability of information on the www.ClinicalTrials.gov website. The required statement should not be included in informed consent documents or processes for clinical trials that are not applicable clinical trials. However, if investigators/sponsors independently believe that reporting data on www.ClinicalTrials.gov may influence subjects' willingness to participate, nothing in this regulation prevents investigators/sponsors from voluntarily reporting trial data and informing trial participants in an appropriate manner.

19. Should investigators/sponsors include the statement in consent documents for a trial that is not an "applicable clinical trial?"
Because U.S. law only requires that applicable clinical trials be submitted to www.ClinicalTrials.gov, the new statement only applies to the legal requirements for applicable clinical trial informed consent documents. Again, the new rule does not prevent investigators from voluntarily reporting data from clinical trials that do not meet the definition of an applicable clinical trial to www.ClinicalTrials.gov and sharing that information with participants.

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

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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: Wednesday, April 19, 2017 12:49 PM
To: [redacted]; OC GCP Questions
Subject: ICF and required clinicaltrials.gov disclosure

Dear Experts,

My query pertains to required clinicaltrials.gov disclosure language in the ICF. The key phrase in the verbatim language is in yellow: **"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."**

Some of the regulatory sections that may affect this disclosure:

- FDAAA Section 801; 2007: http://clinicaltrials.gov/ct2/manage-recs/fdaaa
- FDAMA Section 113: 1997: http://www.gpo.gov/fdsys/pkg/PLAW-105publ115/pdf/PLAW-105publ115.pdf#page=16
- CMS: http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM8401.pdf
- NIH: http://grants.nih.gov/ClinicalTrials_fdaaa/steps.htm
- ICMJE: http://www.icmje.org/journals.html

There are various regulations, guidance's and recommendations (e.g. ICMJE) that require clinicaltrials.gov disclosure in the consent forms. While I note above, there are some laws, regulations, or guidance of other agencies than FDA that require some kind of listing on clinicaltrials.gov. In such cases, it's not completely inaccurate to say "as required by U.S. Law" because there is some legal or agency-driven reason the trial needs to be listed.

My question is specific to where if the sponsor is listing the trial on clinicaltrials.gov *voluntarily* (and there isn't an agency requirement), can we use the same verbatim as above? If allowed, this may help improve the outcome due to consistency in review process. If the above verbatim is not permitted, is there a suggested developed template of "alternative language" for situations where someone lists the trial on clinicaltrials.gov but there isn't a legal or regulatory reason to do so.

Your guidance will help our IRB to streamline the process when performing IRB reviews.

Regards

[redacted]

[redacted]