**From:** OC GCP Questions
**To:** [redacted]
**Subject:** RE: Phase I study, ClinicalTrials.gov ICF language
**Date:** Thursday, July 02, 2015 9:36:00 AM

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Good morning,

The statement described in 21 CFR 50.25(c) is only 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). Question 19. of this document states the following:

> " 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."

As the guidance document suggests, if your trial does not meet the definition of an "applicable clinical trial" but you voluntarily choose to register the trial with ClinicalTrials.gov the exact statement would not be required. However, it may be appropriate to inform the subjects that information about the trial may be available on ClinicalTrials.gov. If there is no clear expectation that the results of the trial would be included in the ClinicalTrials.gov databank or otherwise published, again there would be no requirement to include such a statement. Should expectations change during the course of the trial regarding publication of results, it may be appropriate to inform subjects of the availability of the trial results.

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 01, 2015 10:01 AM
**To:** OC GCP Questions
**Subject:** Phase I study, ClinicalTrials.gov ICF language

Hello,

If a sponsor of a Phase I study, operating under an IND, chooses to register their study with ClinicalTrials.gov, are they still required to include the ClinicalTrials.gov language in the informed consent form verbatim? What if they are unsure that they want to publish the results of the study?

I understand that a Phase I study does not fall under an applicable clinical trial.

Thank you,

[redacted]