**From:** OC GCP Questions
**To:** [redacted]
**Subject:** RE: 510(k) approved products - need for clinicaltrials.gov statement in consent form
**Date:** Friday, September 05, 2014 11:51:00 AM

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Good afternoon,

Informed consent documents for trials which meet the definition of an "applicable clinical trial" are required to include the statement at 21 CFR 50.25(c). Title VIII of FDAAA defines an "applicable device clinical trial" as:

(1) a prospective clinical study of health outcomes comparing an intervention with a device subject to section 510(k), 515, or 520(m) of the FD&C Act against a control in human subjects (other than a small clinical trial to determine the feasibility of a device, or a clinical trial to test prototype devices where the primary outcome measure relates to feasibility and not to health outcomes); or

(2) a pediatric postmarket surveillance as required under section 522 of the FD&C Act.

The National Institutes of Health document Elaboration of Definitions of Responsible Party and Applicable Clinical Trial provides further discussion on this definition and indicates that "In the view of the agency, a device … is subject to section 510(k), 515, or 520(m) of the FDC Act if any of the following is required before it may be legally marketed: (1) a finding of substantial equivalence under section 510(k) permitting the device to be marketed …" Therefore, a trial involving a device which is required to be cleared under 510(k) in order to be marketed and which otherwise meets the above definition would be required to include the statement at 21 CFR 50.25(c) in the informed consent document.

You may also wish to review FDA's guidance document related to the requirements of 21 CFR 50.25(c) at 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.

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Office of Good Clinical Practice
Food and Drug Administration



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**From:** [REDACTED]

**Sent:** Friday, September 05, 2014 10:19 AM
**To:** OC GCP Questions
**Subject:** 510(k) approved products - need for clinicaltrials.gov statement in consent form

Does the informed consent document need the required clinicaltrials.gov statement if the device being studied in a post-market clinical trial has already received 510(K) approval?

[REDACTED]

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While just about all new trials are required to be registered on the website, not all are required to have the statement in their ICFs! At least, that's what one sponsor informed me of when I asked about a site lacking the statement (for a study investigating a 510(k) approved device, so the study is considered post-market).

It was their understanding that (almost) all studies need to be registered on clinicaltrials.gov, but not all studies need this statement about clinicaltrials.gov in their site's informed consent forms. In order for this statement to be required, one of the major criteria is that the device is subject to 510(k), PMA, or HDE requirements.

In the study we were discussing, the device has already been 510(k) cleared and is a post-market approved study, so it was felt that this statement was not required in the site's consent forms.