**From:** OC GCP Questions
**To:** [redacted]
**Subject:** RE: ICF question re procedure location
**Date:** Monday, June 09, 2014 4:18:00 PM

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Dear [Redacted]-

Thank you for your question. As you mentioned, the regulations at 21 CFR 50.25(a)(1) require the informed consent form to include:

> A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.

The location of the procedures is not a requirement. I recommend you talk to your IRB(s) about how you might address this scenario in the ICF. While not required, you could consider adding a statement that some subjects may have the follow up study procedures done at the study site while others may have a home health care visit. This way you are giving potential subjects an idea that this arrangement may affect some subjects but not all subjects. Your IRB is the best resource to discuss this with.

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:** Thursday, June 05, 2014 6:16 PM
**To:** OC GCP Questions
**Subject:** ICF question re procedure location

Hi,

In an upcoming study we expect some of the study lab procedures during follow up may be obtained via home health care nurses for some of the subjects who do not live in the vicinity of the site. The remaining subjects will have these labs obtained at the site. We would like to confirm that the location of these procedures is not a required component of the ICF. We will be providing a detailed list of what procedures are expected for the subjects within the ICF but are considering not adding the location of the procedures since it may differ from subject to subject.

In reviewing 21CFR 50, the FDA's Guide to Informed Consent-Information Sheet and ICH GCP E6 I do not see any ICF requirements relating to the location of the study procedures just that a description of the procedures is required. Can you confirm?

Thanks!

[Redacted]