From: OC GCP Questions
To: [redacted]
Subject: RE: ICH-GCP, 4.8.10, section "m"
Date: Monday, January 25, 2016 2:21:00 PM

Dear [redacted] -

Thank you for your question. As you noted, the ICH GCP E6 Good Clinical Practice: Consolidated Guidance, (which is recognized as official FDA guidance – see http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073122.pdf) states the following:

> 4.8.10 Both the informed consent discussion and the written informed consent form and any other written information to be provided to subjects **should include explanations of the following**: [emphasis added]
> ---
> (m) That the subject's participation in the trial is voluntary and that the subject may refuse to participate or withdraw from the trial, at any time, without penalty or loss of benefits to which the subject is otherwise entitled.

I emphasized the phrase "…**should include explanations of the following**:" to point out that the guidance is recommending that the consent discussion and form include an explanation so subjects understand that participation is voluntary, that they can refuse to participate altogether or withdraw from the trial at any time, and that these decisions will not result in any penalty or loss of benefits for them. This recommendation for an explanation is not the same as a requirement for the informed consent form to include the exact wording "without penalty or loss of benefits to which the subject is otherwise entitled". So while the guidance does not require you to use those exact words in the consent form, I suggest you discuss how best to address this explanation in the consent discussion and consent form with the investigator and the IRB/IEC.

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

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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: Thursday, January 21, 2016 10:20 PM
To: OC GCP Questions
Subject: Re: ICH-GCP, 4.8.10, section "m"

Dear All,

Re: Informed consent discussion and the written informed consent

ICH-GCP, 4.8.10, section 'm' states the following;

That the subject's participation in the trial is voluntary and that the subject may refuse to participate or withdraw from the trial, at any time, without penalty or loss of benefits to which the subject is otherwise entitled.

Is it expected that the Informed consent given to subjects actually shows the above underlined sentence?

e.g. you may withdraw from the trial at any time and your decision to withdraw will not result in any penalty or loss of benefits to which you may be entitled.

Please guide.

Thanks and Kind Regards
[redacted]