From: OC GCP Questions
To: [redacted]
Subject: RE: GCP Question on referencing text across ICFs
Date: Tuesday, February 25, 2014 10:34:00 AM
Attachments: [redacted]

Dear [Redacted]-

Thank you for your question. Have you consulted your IRB with your question? For studies that are subject to the requirements of the FDA regulations, the informed consent documents should meet the requirements of 21 CFR 50.20 and contain the information required by each of the eight basic elements of 21 CFR 50.25(a), and each of the six elements of 21 CFR 50.25(b) that is appropriate to the study. IRBs have the final authority for ensuring the adequacy of the information in the informed consent document.

You state in your question that the study has two informed consent forms (one for participation in the study and one for participation in an optional component of the study) and it appears that each consent form is a stand-alone, self-contained consent document. As required by the regulations, the informed consent documents must contain the information required by each of the eight basic elements of 21 CFR 50.25(a), and each of the six elements of 21 CFR 50.25(b) that is appropriate to the study.

I understand that several sections of each consent form may be identical, but since these are separate consent documents, each consent form must meet the regulatory requirements for content.

As suggested, you may wish to discuss your question with your IRB as they will be familiar with potential options that may be available to you to address your issue (e.g., a single consent document that incorporates the optional component of the study into the main study consent form).

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

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From: [Redacted]
Sent: Thursday, February 20, 2014 4:11 PM
To: OC GCP Questions
Subject: GCP Question on referencing text across ICFs

Dear FDA GCP Representative,

I would be grateful for your expert GCP guidance on the following scenario:

A clinical trial includes two informed consent forms (ICFs):
1. one ICF for participation in the trial
2. one ICF for participation in an optional component of the study (e.g., DNA or biomarker sample collection for research).

There are several sections of text that are identical in both forms (e.g, What happens in the case of injury, Protection of privacy, Use of samples for future research, Handling of data).

In the interest of reducing the amount of text that a subject must read, we would like to know if it is it appropriate in the Optional ICF to simply reference the sections in the main clinical trial ICF that would otherwise would be identical. For example, using a statement such as, "Your information will be handled in the same manner as described in Section X of the main clinical informed

consent form”.

If applicable, it would be helpful if you could provide supporting references to your response.

Thank you in advance for your advice.

Best regards,

[Redacted]