From: OC GCP Questions
To: [redacted]
Subject: Ethics Committee Related Queries: Kindly Opine on the Same
Date: Monday, February 03, 2014 10:47:47 AM

Good morning –

Speaking from an FDA perspective only, one purpose of the ICF is to provide potential subjects with information that they need to decide whether or not to participate in the study. If all the relevant information (including the required elements of consent) is not contained in the form at the time of consent, then it may not be provided to the subject. When an IRB reviews the protocol and ICF, it generally reviews the completed (but unsigned) form to ensure it adheres to the requirements of 21 CFR part 50. The specific contact information is important and it is for that reason it is a required part of the ICF. Altering an IRB-approved ICF by inserting information to blank sections (other than signatures and dates) during or after consent has been obtained is not consistent with FDA's regulations.

In particular, the required basic element of informed consent found in the regulations at 21 CFR 50.25(a)(7) requires that each subject be provided with information regarding an explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject. If each site is left to fill this required information in to the document each time an ICF is used, I see other potential problems with this practice that may result in a determination that the IRB-approved ICF is inadequate. For example, what if the site forgets to fill in this required information for a particular subject? What if the site fills in the name of a contact that is different from that expected by the IRB (e.g., the site fills in the name of the study coordinator instead of the investigator as called for in the ICF)? What if the site transcribes the information incorrectly and by mistake provides the wrong phone number for a particular subject?

I recommend that you discuss this issue with your institution and the IRB/EC of record.

Please see link to FDA guidance documents that also might assist you with your ICD questions. The meaning of “explanation” is mentioned in the second link.
Guidances > Institutional Review Boards Frequently Asked Questions - Information Sheet
Guidances > A Guide to Informed Consent - Information Sheet

I hope this informaton is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [Redacted]
Sent: Friday, January 31, 2014 11:46 PM
To: OC GCP Questions
Cc: [Redacted]
Subject: RE: Ethics Committee Related Queries: Kindly Opine on the Same

Dear Sir/Ma'am

Need an urgent feedback on the Informed Consent Document:

1. 21-CFR Part 50.25 (Elements of ICF)
   (7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.
   - What does the word explanation means ?
     - ✓ Is it the verbal explanation which we need to provide to the patient or subject.
     - ✓ Or all the above stated contact details must be printed on the ICF before we submit the Informed Consent Document to Ethics Committee for approval.

2. If for the section " Whom to contact" the ICF has blank fields as given below, can this be approved by EC based on 21 CFR Part 50.25. The bank fields reflect that the section will be completed by Principal Investigator or coordinator during the consent process.
   e.g. Whom to contact (this is ICF section)
   If you have additional questions during the course of this study, or in the event of a research related injury or if any problem arises, you may address them to _____ (PI Name) at _____ (Contact No.).
   If you have any additional question about your rights as a research subject, you may contact to:

Ethics Committee Chairperson Name	
Ethics Committee Address	
Ethics Committee Chairperson Contact No	

3. Is there mandatory requirement that ICF's be site Specific. Site Specific ICF's means all the details of the site are listed on title page, footer and whom to contact section. On this I have following questions?
   a. Can a generic ICF be used in the study. Generic ICF is an ICF where the fields for name and contact details is left blank to be completed by site Principle Investigator or coordinator- Generic ICF's are easy to be controlled. Even when the translations are made these are easy to be managed when compared with site specific ICFs.
   b. If the Informed Consent Document with blank fields as mentioned in question 2 is approved by Ethics Committee can this be used for the study?

Your views and feedback will be highly appreciated as these will help us in recommending regulatory agency for necessary changes or for development of new regulations. Together we will be able to develop a research environment which will be more protective towards the human subjects, participating in the biomedical research.

Thanks & Regards,
[Redacted]