From: Brown, Sheila (OGCP)
To: [redacted]
Subject: RE: GCP for survey research
Date: Thursday, October 13, 2016 2:47:00 PM
Attachments: [redacted]

Dear [redacted],
I was asked to respond to your question on behalf of the OC GCP mailbox.

In the United States, applicable GCP requirements depend on the regulations to which the study is subject. All FDA-regulated studies that involve human subjects must have IRB approval and informed consent of the study subjects, per 21 CFR 50 (informed consent) and 56 (IRB requirements). FDA's regulations do not allow for waiver of informed consent or of elements of informed consent (except 50.25(a)(6) for minimal risk studies); research-related injuries are included in the required elements. (There is a provision for an exception to informed consent but only in certain emergency situations, as described in 21 CFR 50.23 and 50.24.) If the survey is part of an FDA regulated study, informed consent of the subjects prior to completing the survey would be required, although written documentation (i.e. the subject's signature) may be waived if the IRB determines the study is minimal risk. FDA would not consider completion of the survey to imply informed consent of the subject. For your convenience, here are links to 21 CFR Parts 50 and 56:
Part 50: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50&showFR=1

Part 56: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=56&showFR=1

Studies with federal funding would need to comply with Health and Human Services (HHS) regulations at 45 CFR Part 46, which is overseen by the Office of Human Research Protections (OHRP). These regulations have provisions that allow the reviewing IRB to waive the requirement for obtaining informed consent or alter or leave out elements of informed consent (see 45 CFR 46.116(c) and (d)) in specific circumstances. You may want to review information on the provisions under 45 CFR 46 for waiving the requirement for obtaining informed consent or altering or leaving out elements of informed consent. This may provide you with an understanding of some of the situations where waiving consent may be considered appropriate. OHRP's website has some information about informed consent processes at http://www.hhs.gov/ohrp/regulations-and-policy/guidance/checklists/index.html . 45 CFR 46 can be found at http://www.ecfr.gov/cgi-bin/text-idx?SID=fe9a058721ddd01c22381ab2eff03891&mc=true&node=se45.1.46_1116&rgn=div8

If you have questions about these regulations, please contact OHRP. Contact information for OHRP is available at http://www.hhs.gov/ohrp/about-ohrp/contact-us/index.html .

It is possible for a study to be subject to both FDA and OHRP regulations; when these regulations conflict, those that provide stronger protections for human subjects should be followed; these are usually FDA's regulations, but please discuss this with your IRB. There may also be state or local laws that apply.

FDA's guidance, *A Guide to Informed Consent – Information Sheet*, may be helpful in understanding FDA regulations for informed consent. It can be found at http://www.fda.gov/RegulatoryInformation/Guidances/ucm126431.htm

We do not have enough information to determine which regulations apply to be able to address your question regarding "*who to contact in the event of a research related injury.*"; this would depend on which set of regulations you are required to follow. If you are under FDA's regulations, you must follow Part 50 and provide the subject with this information. If you are under HHS regulations, your IRB will determine whether or not any elements of informed consent may be waived. The injuries would be those associated with the study; for telephone surveys, this usually is associated with the risk to loss of personal identifiable information or identifiable health information, but you should discuss any foreseeable risks with the study sponsor and your IRB. Adding risk information should not unduly prolong the consent process, since it can be addressed in a sentence or two. We recommend that you ask your IRB which set of regulations they are applying to your study, and why those regulations apply to the study.

I hope this information is helpful to you. If you need further assistance, please feel free to contact the GCP mailbox at gcp.questions@fda.hhs.gov .

Best regards,

Sheila

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This communication does not constitute a written advisory opinion under Title 21 CFR 10.85, but rather is an informal communication under Title 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: Friday, October 07, 2016 7:36 PM
To: OC GCP Questions
Subject: GCP for survey research

Hi,

I'm wondering if you could please help me clarify GCP for our colleagues [redacted]