From: OC GCP Questions
Sent: Friday, August 14, 2015 4:03 PM
To: [redacted]
Subject: RE: question pertaining to re-consenting and notifications

Dear [redacted]

Thank you for your question. FDA is responsible for protecting the public health by assuring that foods (except for meat from livestock, poultry and some egg products which are regulated by the U.S. Department of Agriculture) are safe, wholesome, sanitary and properly labeled; ensuring that human and veterinary drugs, and vaccines and other biological products and medical devices intended for human use are safe and effective; protecting the public from electronic product radiation; assuring cosmetics and dietary supplements are safe and properly labeled; regulating tobacco products; and advancing the public health by helping to speed product innovations. FDA has basic information that you might find interesting on our web site at http://www.fda.gov/AboutFDA/Transparency/Basics/default.htm - look under the Main Topics tab in the middle of the page. FDA does not generally oversee social or behavioral research.

You may also be aware of the Office for Human Research Protections (OHRP) who provides leadership in the protection of the rights, welfare, and wellbeing of subjects involved in research conducted or supported by the U.S. Department of Health and Human Services (HHS). OHRP helps ensure this by providing clarification and guidance, developing educational programs and materials, maintaining regulatory oversight, and providing advice on ethical and regulatory issues in biomedical and social-behavioral research. More information about OHRP can be accessed at their web site at http://www.hhs.gov/ohrp/index.html.

I recommend that you start by consulting the IRB at your institution for assistance in assessing whether subjects would need to be re-consented for the behavioral intervention study outlined below. Typically for FDA-regulated research (and it is not clear whether the research you have described below has FDA oversight) when additional information is added to a study that goes beyond what was identified in the original protocol and disclosed in the original consent form, obtaining informed consent for the additional information would be required (see 21 CFR 50.20 and 50.25) .

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.

Sincerely,

Bridget A. Foltz, MS, MT(ASCP)
Policy Analyst, Office of Good Clinical Practice
Office of the Commissioner, Food and Drug Administration

From: [redacted]
Sent: Thursday, August 13, 2015 2:17 PM
To: OC GCP Questions
Subject: question pertaining to re-consenting and notifications

Dear Sir or Madam,

I have a question pertaining to re-consenting. I understand that re-consenting and participant notification i mandatory if there is an increased risk.

My question to a behavioral intervention study. The study is a single group open trial. If anything as we have conducted the study, risk has proven to be lower than we anticipated.

The study is an intervention development study. Over time, we increased the number of intervention sessions from four sessions (N=10) to five sessions (N=5) and eventually settled on six sessions (N=95) as the optimum dosage. The consent signed by participants was specific to the number of sessions. This is to say that those who got 4 sessions had information that treatment consisted of four sessions and got four sessions. The change in number of sessions was done after a protocol modification (and consent form change) was approved by the IRB.

A couple of questions have arisen: (1) given that there were changes in the protocol in number of sessions do participants need to be re-consented? Do they need to be informed?

[redacted]