From: OC GCP Questions
To: [redacted]
Subject: Mailing/Emailing consents
Date: Thursday, January 22, 2015 3:40:04 PM

Good afternoon –

This information is for FDA-regulated studies. As stated in the FDA Information Sheet Guidance, "Recruiting Study Subjects" (available at http://www.fda.gov/RegulatoryInformation/Guidances/ucm126428.htm), "FDA requires that an Institutional Review Board (IRB) review and have authority to approve, require modifications in, or disapprove all research activities covered by the IRB regulations [21 CFR 56.109(a)]. An IRB is required to ensure that appropriate safeguards exist to protect the rights and welfare of research subjects [21 CFR 56.107(a) and 56.111]. In fulfilling these responsibilities, an IRB is expected to review all the research documents and activities that bear directly on the rights and welfare of the subjects of proposed research."

Based on the information in your email and that the covered letters may contain new information in the consent, the cover letter might need IRB review and approval prior to use. For example, IRB review and approval would not be necessary for a written communication that simply reminds a subject of his/her next appointment, including communications that provide reminders that are consistent with the written informed consent and protocol, such as the need to fast prior to the appointment. However, a letter that included information on study results (new information) or solicited interest in another research project (recruitment) would require IRB review and approval prior to use. Additionally, written communications providing results notifications (new information) would also require IRB review and approval prior to use.

It is best to seek guidance from your REB.

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

Kind regards,

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

From: [redacted]
Sent: Thursday, January 22, 2015 11:57 AM
To: OC GCP Questions
Subject: Mailing/Emailing consents

Hi There,

I have a question regarding reconsenting of the subjects for study related changes.

Once the consents are approved by the REB and the site has been requested to start with the reconsenting of the subjects sometimes the site emails or else mails out the consent forms to the subject. Prior to this the Nurse informs the subjects that the consents have been mailed out to them and to give a call once they receive them. Once the subject receives the new consent and calls the Nurse a discussion regarding the changes in the consents take place. All these conversations are documented in the consent process.

However there is a question that we have regarding the cover letter that we send out to the subject while mailing out or emailing the subject with the new consent. The cover letter basically provides information such as the study title, protocol # and instructions related to the handling of the consents. Sometimes the cover letter might also contain information related to the changes in the consent but the subject is still mandated to call the Nurse after receipt of the consents.

Our question today is whether the cover letter which consists information as provided above should be approved by the REB. There is no REB policy that requests the site to get the cover letter approved.

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Thanks & Regards
[redacted]