From: OC GCP Questions
Sent: Monday, August 24, 2015 4:53 PM
To: [redacted]
Subject: RE: using email addresses with subjects

Dear [redacted]:

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."

In determining which written communications with already enrolled subjects require IRB review and approval prior to use, the IRB should consider whether such communications would bear directly on the rights and welfare of the subject. Written communications that clearly have no effect on the conduct of the research, its underlying science or methodology, associated risks and benefits, or the potential willingness of subjects to continue participation would not require prior review and approval by the IRB.

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.

In conclusion, an IRB may wish to consider developing policies and procedures that address which communications with subjects, as part of ongoing research, require IRB review and approval and which do not.

I hope that this information is helpful. Please contact us at gcp.questions@fda.hhs.gov if you have further questions. Since many questions and concerns regarding good clinical practices have been addressed over time, some individuals may find it useful to access a set of redacted GCP inquiries found at the following web address: http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriestoFDAonGoodClinicalPractice/default.htm .

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: Monday, August 24, 2015 1:35 PM
To: OC GCP Questions
Subject: using email addresses with subjects
Importance: High

I need to create an SOP for our site on the use of contacting subjects via email to remind them of upcoming follow appoints. By chance is there any guidelines addressing this?

[redacted]