From: Brown, Sheila (OGCP)
To: [redacted]
Subject: RE: Extent of IRB review
Date: Wednesday, September 30, 2015 12:58:00 PM

Dear [redacted],
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.

The advertising you mention in your email is considered the start of the informed consent process; it appears that the phone number provided in the advertisements is for this call center. If the IRB has not already been made aware of the call center and its role in patient recruitment, updated information should be provided to them for their review. If any data are collected via the call center, its disposition, storage, and means of protecting confidentiality should also be included. If no data will be collected, this should be made clear in the submission. If it was not already submitted to the IRB, the screening script should also be submitted for review, as part of the informed consent process.

You may find FDA's guidance, *Recruiting Study Subjects - Information Sheet* helpful; part B refers to receptionist scripts. It can be found at http://www.fda.gov/RegulatoryInformation/Guidances/ucm126428.htm

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

Sheila Brown, RN, MS
Policy Analyst, Office of Good Clinical Practice
Office of Special Medical Programs, Food and Drug Administration

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From: [redacted]
Sent: Monday, September 28, 2015 8:27 AM
To: OC GCP Questions
Subject: Extent of IRB review

Dear FDA GCP questions,

We are going to have a call center to direct potential cancer subjects, to institutions proximal to their residence, who are conducting one of our trial protocols, if applicable.

This potential subject may have come across one of our Facebook or journal or Twitter ads (etc.), all of which have been centrally IRB approved, which lists a phone number to the above call center.

The intent of the call center is for this subject to interact with a “live” person, rather than leaving a voice mail message (which is usually the case), and then being warm transferred to a participating trial center..usually to the institutions clinical trial office.

The extent of the information exchanged on the call center may be

a) What type of cancer [redacted] does this patient have and
b) What is their ZIP code.

The two pieces of data would be reviewed and if a local site were available, subject could be transferred to speak with someone from that site.

My questions is therefore, does any part of the call centers’ participation need to be IRB approved?

If the patient does ask other questions, of the call center, the only further information that the call center would supply would be directly from the clinicaltrials.gov website.

Thanks so much, in advance, for your assistance with this clarification.

[redacted]