From: OC GCP Questions
To: [redacted]
Subject: Websites for Recruitment Question
Date: Thursday, November 05, 2015 8:22:00 AM

Dear [redacted],
The advertising/recruitment material you mention in your email is considered the start of the informed consent process. If any data are collected via the web site, its disposition, storage, and means of protecting confidentiality should be included in the submission to the IRB. If no data will be collected, this should be made clear in the submission. The screening script, including the questions asked, that will appear on the website should also be submitted for review, as part of the informed consent process.

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 information you quote from FDA's guidance, Recruiting Study Subjects - Information Sheet http://www.fda.gov/RegulatoryInformation/Guidances/ucm126428.htm , may or may not be appropriate in this situation. In any case, it should be reviewed by the IRB for their determination as to whether or not consent is required for the screening information. The primary study may still require informed consent, even if the IRB determines that the screening questions do not.

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

From: [redacted]
Sent: Tuesday, November 03, 2015 2:22 PM
To: OC GCP Questions
Subject: Websites for Recruitment Question

Good afternoon,

I'm hoping that you can help me with a question regarding websites that advertise clinical trials and solicit information to facilitate recruitment which may include screening questions.

Because this is a recruitment and screening activity, not passive review of records,

would consent be required? If consent is required, would the below guidance (excerpted from the information sheet on screening tests) be applicable?

The IRB may find it appropriate to limit the scope of the screening consent to a description of the screening tests and to the reasons for performing the tests including a brief summary description of the study in which they may be asked to participate. Unless the screening tests involve more than minimal risk or involve a procedure for which written consent is normally required outside the research context, the IRB may decide that prospective study subjects need not sign a consent document [21 CFR 56.109(c)].

Sincerely,