From: OC GCP Questions
To: [redacted]
Subject: RE: Telephone Pre-screening Inclusion in the Protocol
Date: Tuesday, November 08, 2016 8:14:00 AM
Attachments: [redacted]

Dear [redacted],

Protocols for INDs regulated under 21 CFR 312 require inclusion of information regarding "[t]he criteria for patient selection and for exclusion of patients and an estimate of the number of patients to be studied." 312.23(a)(6)(iii)(c)

312.23(a)(6)(iii)(d) requires "A description of the design of the study, including the kind of control group to be used, if any, and a description of methods to be used to minimize bias on the part of subjects, investigators, and analysts."

There are no specific regulatory requirements regarding inclusion of pre-screening materials or processes to be included in the protocol or investigational plan. When the regulations are silent, IRBs, institutions, sponsors, investigators are free to develop their own procedures and practices as long as applicable regulatory requirements are met.

However, telephone pre-screening is part of the informed consent process, and requires IRB approval, as you note in your email. The following information is from the guidance, *Recruiting Study Subjects - Information Sheet*, which can be found at http://www.fda.gov/RegulatoryInformation/Guidances/ucm126428.htm

- **Receptionist Scripts**
  The first contact prospective study subjects make is often with a receptionist who follows a script to determine basic eligibility for the specific study. The IRB should assure the procedures followed adequately protect the rights and welfare of the prospective subjects. In some cases personal and sensitive information is gathered about the individual. The IRB should have assurance that the information will be appropriately handled. A simple statement such as "confidentiality will be maintained" does not adequately inform the IRB of the procedures that will be used. Examples of issues that are appropriate for IRB review: What happens to personal information if the caller ends the interview or simply hangs up? Are the data gathered by a marketing company? If so, are names, etc. sold to others? Are names of non-eligibles maintained in case they would qualify for another study? Are paper copies of records shredded or are readable copies put out as trash? The acceptability of the procedures would depend on the sensitivity of the data gathered, including; personal, medical and financial.

You may wish to discuss any recruitment tools and informed consent processes with the Sponsor and/or IRB contacts for the IND. The Sponsor may wish to consult with their CDER contact for the IND, if they have any questions.

You may also wish to review the following FDA Information Sheet guidance:

Screening Tests Prior to Study Enrollment - Information Sheet
http://www.fda.gov/regulatoryinformation/guidances/ucm126430.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 the Commissioner (OC)
Office of Good Clinical Practice (OGCP)
U.S. Food and Drug Administration
Tel: 301-796-6563
sheila.brown@fda.hhs.gov

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This communication does not constitute a written advisory opinion under Title 21 CFR 10.85, but rather is an informal communication under Title 21 CFR 10.85(k), which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

From: [redacted]
Sent: Thursday, November 03, 2016 1:18 PM
To: OC GCP Questions
Subject: Telephone Pre-screening Inclusion in the Protocol

Hello,

If a sponsor requires investigator sites to conduct study specific telephone pre-screening of subjects (e.g. specific questions related to protocol inclusion/exclusion criteria) to assess potential eligibility for enrollment into a clinical trial for an investigational drug, should this step or process be included in the investigation plan (protocol)? The potential subject responses to the telephone pre-screening questionnaire will be entered into the eCRF database. The telephone pre-screening questionnaire was reviewed and approved by the central IRB. No pre-screening consent was required since there were no clinical procedures were required as a part of the pre-screening process (only a study specific telephone questionnaire).

Please advise at your earliest convenience. Thank you in advance for your response to this question.

Best regards,