Pre-Screening Potential Subjects During Recruitment

Background

Pre-screening of potential subjects over the telephone or in person to determine their initial eligibility for and interest in a study is a common strategy. All pre-screening activities are considered to be part of the subject selection and recruitment process. When using this strategy, investigators must protect the privacy of the potential subject and the confidentiality of information collected about him/her.

What is the difference between screening and pre-screening?

"Pre-screening," for IRB purposes, is the term used to describe activities before obtaining informed consent (i.e., before enrollment). Pre-screening may not include any research procedures. "Screening" is the term used to describe activities performed after obtaining consent to ensure subjects are qualified for the study.

What information can I collect during pre-screening?

Questions appropriate for pre-screening address the specific inclusion/exclusion criteria for the study and other issues of suitability, for example, an individual's ability to come to the research site multiple times. It is not appropriate to gather information that is not directly related to assessing eligibility and suitability. Administering eligibility tests and medical exams is considered research activity and may not be conducted during a pre-screening but rather only after the participant has been deemed eligible, agreed to participate, and has signed a consent form.

How should pre-screening over the telephone be done?

To begin a phone pre-screening conversation, the study team member should identify himself or herself as such. Then, potential subjects should be:

- Informed of the nature and sensitivity of the questions,
- Told how long the phone call is expected to take,
- Asked whether there might be a better time for them to answer these questions, and
- Offered the option of completing the pre-screening in person, if possible.

Next, the study team member should explain that a set of questions will be asked to determine eligibility.

Whenever possible, the potential subject should be asked to indicate if s/he appears to be eligible only after all questions have been asked. Sometimes this is not possible, for example, when pre-screening for specific medications or levels of activity. The investigator should consider this carefully when designing pre-screening procedures.

In the interest of confidentiality, only the potential subject's first name or initials should be recorded at the beginning of the pre-screening conversation. After the screening conversation, if s/he appears to be eligible and is interested in pursuing the study, contact/identifying information can be recorded - e.g., last name, address, birth date, and Social Security number.

How should pre-screening in person be done?

Pre-screening is done in person usually when potential subjects are finding out about research during routine, non-research activities. This is most often applicable in the clinical care setting, but may be used for non-clinical research.

The guidelines for the conduct of pre-screening in person are the same as those for conducting pre-screening over the telephone.

Regardless of the setting, only information pertaining to the participant's eligibility should be gathered during pre-screen. It may be acceptable to perform very limited routine clinical procedures as part of a pre-screen if they directly relate to eligibility determinations and an individual verbally consents to have them performed. For example, it may be acceptable to weigh an individual in order to ascertain whether s/he qualifies for a dietary study. Such exceptions may be made by the IRB in certain specific circumstances in the interest of the convenience of the research subject. Complete medical histories, physical exams, full body skin exams and laboratory testing cannot be done until a subject has given informed consent and has signed the consent form.

Can I conduct pre-screening online?

Yes. In many cases, potential subjects prefer online pre-screening. The guidelines for the conduct are the same as those described above for other methods. However, because online survey tools have different privacy policies and terms of use, it is up to the investigator to provide documentation regarding privacy and confidentiality protections. This documentation must be included in your eRA submission.

Can I retain information from individuals who are pre-screened but not enrolled?

Yes, you can retain non-identifying information about individuals who are pre-screened for a study, but do not actually pursue the study or enroll. In fact, this is often desirable or requested by sponsors to obtain information about the entire pool of individuals interested or potentially eligible for the study.

Pre-screening sheets from individuals who did not provide identifying information can be retained with no further action.

Pre-screening sheets with identifying information may also be retained in research files. Fields containing identifiable information must be blacked out or cut off as soon as it is clear that the individual will not be enrolled.

What do I need to include in my submission for IRB review?

Protocol: All pre-screening activities are considered part of the subject selection and recruitment process and must be reviewed and approved by the IRB prior to initiation. Pre-screening procedures should be described in the protocol document. In addition, the specific inclusion/exclusion criteria for the study should be stated. The IRB will compare the screening tools with these inclusion/exclusion criteria, to ensure that the questions asked during pre-screening are not beyond the scope of the criteria.

Screening tools: The questionnaires, checklists, or other screening tools that will be used must be submitted for IRB review. If pre-screening is to be done over the telephone, investigators should provide a script for IRB review. The script should follow the points outlined above (How should pre-screening over the telephone be done? section).

Consent form: Pre-screening does not need to be described in the consent form because it is done before the consent discussion and documentation of consent takes place.