

## Section 17:

# Pre-screening Potential Trial Participants

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Once potential trial participants have been identified, a member from the study team may wish to establish contact, either by phone or in person, to determine initial eligibility for participation in the trial. The privacy and confidentiality of the individuals and all information collected regarding their medical history must be protected and maintained. Acceptable means of identifying and contacting potential trial participants are outlined in section on [Recruiting Trial Participants](#).

*The use of screening tests to assess whether prospective subjects are appropriate candidates for inclusion in trials is an appropriate pre-entry activity. Although an investigator may discuss availability of trials and the possibility of entry into a trial with a prospective subject without first obtaining consent, informed consent must be obtained prior to initiation of any clinical procedures that are performed solely for the purpose of determining eligibility for research, including withdrawal from medication (washout). When washout is done in anticipation of or in preparation for the research, it is part of the research.*

*Procedures that are to be performed as part of the practice of medicine and which would be done whether trial entry was contemplated, such as for diagnosis or treatment of a disease or medical condition, may be performed and the results subsequently used for determining trial eligibility without first obtaining consent. On the other hand, informed consent must be obtained prior to initiation of any clinical screening procedure that is performed solely for the purpose of determining eligibility for research. When a doctor-patient relationship exists, prospective subjects may not realize that clinical tests performed solely for determining eligibility for research enrollment are not required for their medical care. Physician-investigators should take extra care to clarify with their patient-subjects why certain tests are being conducted.*

(Source: FDA Information Sheets)

### 17.1 Appropriate Information to Gather

Only information pertaining to the specific inclusion/exclusion criteria for the trial should be obtained during the pre-screening session. Information regarding the feasibility of the individual's participation in the trial is also appropriate. For example, if the trial requires frequent visits to the clinic and the individual resides out-of-state, it may be appropriate to ask whether he or she would be willing to commit to the protocol requirements.

Information that does not specifically relate to the trial's eligibility criteria should not be sought.

### 17.2 Pre-screening Procedures

All pre-screening activities (i.e., scripts, questionnaires, screening tools) are considered part of the subject selection and recruitment process and, therefore must be reviewed and approved by the IRB *prior* to initiation. Such procedures should be outlined in the protocol document or research application.

#### Telephone

Once a member of the study team has identified himself or herself as such, he or she should immediately express the possible sensitive nature of the questions to be asked and the expected length of the conversation and then confirm that this is an appropriate time to conduct the pre-screening interview.

Only upon deeming the participant eligible for enrollment and ascertaining the individual's interest in enrolling should any contact or identifiable information (i.e., name, address, date of birth, social security number) be recorded. Until then, only the participant's initials should be documented. Per the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the historical medical information from identifiable participants obtained during a pre-screening assessment constitutes "Protected Health Information." Collection of such information requires researchers to provide participants with the institution's privacy policy and also obtain a separate authorization to use and disclose the information. However, if only the participant's initials are recorded during the pre-screening, prior to establishing eligibility, the information is not considered "Protected Health Information."

### **In-Person**

Participants may prefer to conduct the pre-screening interview in person. The questionnaires, scripts, and checklists used for phone interviews are also appropriate for in-person interviews. As stated earlier, only information pertaining to the participant's eligibility should be gathered. Administering eligibility tests and medical exams is considered trial activity and may not be conducted during a pre-screening visit but rather only after the participant has been deemed eligible, agreed to participate, and has signed a consent form.