



INVESTIGATOR GUIDANCE: Phone Screen Procedure

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Instructions:

IRB requires that the initial contact, regardless of method, must come from a person who can be expected to be reasonably familiar to the potential research participant, such as a physician or health care provider directly engaged in the patient's clinical care or an acceptable representative or a physician or healthcare provider from the clinical unit in which the patient has been seen, or a referring physician.

Phone scripts should inform the potential participants of the following:

- Name and address (department) of the investigator;
- How their names were obtained, e.g., seen in a particular clinic or had a specific type of surgery in the past;
- Why they are being contacted about participation in a research study, e.g., medical diagnosis or history, or age criteria; (Use the word "research");
- Summary of the purpose of the research with a brief listing of major eligibility criteria;
- Factual description of the benefits to the participant from participation in the study, if applicable;
- Compensation if provided, but do not state dollar amount;
- The location of the research and contact information;
- That participation will not affect current or future care;
- Whether results of the research will be released to the participants;
- Plans to recontact individuals again by phone or mail, and outline the conditions under which recontact will happen, if applicable.

Example: Phone screening script when no identifiable health information is recorded

IRB Protocol No.

Date:

Phone Screen Script

1. A phone call will be placed by ____ (i.e., Explain how the contact complies with IRB initial contact requirements above, or explain if subjects will call in response to an advertisement.)
2. We give a synopsis of the study:
 - a. Purpose of the study
 - b. Procedures
3. We answer any questions that the subject may have.
4. We then ask them, "Does this sound like something you would like to do?"
5. If they answer yes, we ask them some basic eligibility questions but no identifiable information is recorded at this time.
6. If they are eligible based on these screening questions, we schedule them for a visit.

Example: Phone screening script when identifiable information is recorded

1. A phone call will be placed by ____ (i.e., Explain how the contact complies with IRB initial contact requirements above, or explain if subjects will call in response to an advertisement.)
2. We give a synopsis of the study:



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- a. Purpose of the study
- b. Procedures
3. We answer any questions that the subject may have.
4. We then ask them, "Does this sound like something you would like to do?"
5. If they answer yes, we read the following statement: "I will be asking you some questions about your health information and medical history to determine if you are eligible for this research. By answering these questions, you are consenting to allow us to use this information to pre-screen you for the study. With your permission we will retain this information in the locked research office, and if you are interested in participating in additional studies in our department, we will contact you for future studies. This information will not be shared with anyone outside of the (department name) research team. If you do not want us to keep your information, we will destroy it following the study.
Do you want me to go ahead with the questions? _____
(If yes) Do you want us to keep your information at the end of this study so that we can contact you for future studies? _____"
6. We then go through our phone screen form that is based on the general inclusion/exclusion criteria for that study.
7. If at any point during the process the subject doesn't meet the criteria, we tell them that and stop asking questions unless he/she is interested in being contacted for future research studies.
8. We keep a screen fail notebook (to show sponsors how many potential subjects we have talked to). We enter in the notebook: "male caller, saw ad in the Orlando Sentinel"
9. If the subject meets the initial phone screen criteria, we schedule them for a visit.

Example: Phone screening script when screening for sensitive issues

1. Subjects will be called after we have received a referral from a physician.
2. We read the following statement: "I will be asking you some questions about your health information and medical history to determine if you are eligible for this research. But before I begin, I want to let you know that because of the nature of the research that is conducted we do not enroll people who are HIV positive, people who have abused alcohol or drugs within the past 2 years, people who have pre-existing psychiatric disorder including moderate/severe depression, suicide ideation/attempts. If you have a history of any of the above simply say you are not interested in participating when asked."
3. We give a synopsis of the study:
 - a. Type of drug to be used
 - b. Purpose of the study
 - c. Procedures
 - d. Study visits (how many, time of day, time commitment from subject)
4. We answer any questions that the subject may have
5. We then ask them, "Does this sound like something you would like to do?"
6. If they answer yes, we read the following statement: "I will be asking you some questions about your health information and medical history to determine if you are eligible for this research. By answering these questions, you are consenting to allow us to use this information to pre-screen you for the study. With your permission we will retain this information in the locked research office until the completion of study; your information will then be destroyed. This information will not be shared with anyone outside the XXXX research team."
Do you want me to go ahead with the questions? _____



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7. We then go through our phone screen form that is based on the general inclusion/exclusion criteria for that study.
8. If at any point during the process the subject doesn't meet the criteria, we tell them that and stop asking questions.
9. We keep a screen fail notebook (to show sponsors how many potential subjects we have talked to). We enter in the notebook: "initials, age, reason for exclusion."
10. If the subject meets the initial phone screen criteria, we schedule them for a visit.