

## GUIDANCE ON SCREENING RESEARCH SUBJECTS FOR RECRUITMENT

### **DEFINITIONS**

**SUBJECT PRE-SCREENING:** “Subject Pre-screening” for IRB purposes is the term used to describe the activities associated with selecting research participants prior to obtaining Informed Consent to determine who may potentially be eligible to be enrolled in a study. Since there is no informed consent, research procedures or interventions may not take place during subject pre-screening.

**SUBJECT SCREENING:** “Subject Screening” is the term used to describe research activities performed on participants after obtaining their informed consent. It is usual that “subject screening” activities are done to ensure subjects are eligible to be enrolled in the study.

**SCREEN FAILURE:** This is the term used to describe the circumstance wherein subjects who have provided consent have subsequently failed to meet eligibility criteria for participation in the study based on screening procedures performed after informed consent was obtained.

**ENROLLED:** A subject is considered enrolled in a research study once the subject signs the consent form.

Note -- Some studies have both a screening consent form (to determine subject eligibility for the study) and an intervention consent form (to consent to study activities following the screening procedures). If a subject signs a screening consent form but does not meet study inclusion criteria, the subject is considered enrolled for the screening component but is not considered enrolled in the study’s intervention component.

**WITHDRAWAL:** A subject is considered to be withdrawn from a study if he/she leaves the study after randomization or assignment to study treatment. Withdrawals are different than screen failures since screen failures occur as the result of failure to meet eligibility criteria while withdrawals occur as the result of actions taken by the PI or by voluntary cessation of participation by the subject.

Note -- A subject may voluntarily cease participation at any time after the consent document is signed.

### **OVERVIEW**

Pre-screening and Screening of potential subjects to assess whether they are appropriate candidates for inclusion in a research study are components of the recruitment and enrollment process, and require IRB oversight. It is imperative that these activities be clearly described in the study submission forwarded to the IRB for review and approval.

### **PRE-SCREENING ACTIVITIES**

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 approach in the recruitment process. When using this approach, investigators should indicate their plans to protect the privacy of the potential subject and the confidentiality of information collected about him/her.

Alternative Pre-screening Approaches: alternative pre-screening approaches will be considered on a per study basis by the IRB.

- a. Conducting Pre-screening over the Telephone: At the beginning of a phone pre-screening conversation, potential subjects should be informed of the nature and sensitivity of the questions and asked whether there might be a more appropriate time for them to answer

these questions. They should also be told how long the phone call is expected to take. Subjects should be offered the option of completing the pre-screening in person, if they wish and if it is feasible.

**NOTE -- The questionnaires, pre-screening tools and screening script of what will be said by study staff must be approved in advance by the IRB.**

- i. For confidentiality, phone screeners should record only the subject's first name or initials at the beginning of the pre-screening conversation. Screeners should explain to the subject that s/he will be asked a set of questions to determine eligibility and that at the end, only if s/he appears to be eligible and is interested in pursuing the study, will s/he be asked to provide contact/identifying information (e.g. last name, address, birth date or hospital medical record number). By following this procedure, identifiable healthcare information is only created for those persons who likely meet eligibility criteria. And for those persons who do not meet entry criteria, only non-identifiable health information is created. This distinction is important since the collection of non-identifiable health information is not subject to the privacy regulations (HIPAA). But, the collection of identifiable, historical medical information (even by telephone) creates **new** "Protected Health Information" and obligates the researcher to provide all of the HIPAA Privacy protections.
- ii. For the Collection of Identifiable Health Information: An investigator may maintain identifiable **new** protected health information at the end of the pre-screening conversation until the subject meets with study staff to discuss the study further, (if eligible for enrollment in the study) the study staff must obtain consent and have the subject sign the consent form.

If identifiable health information is collected on persons who are not enrolled, there are typically two options: (1) destroy the information or (2) if a failure log must be maintained, the PI must obtain authorization from each individual screened (see c. below).

Alternately, the researcher may request a waiver of authorization from the IRB to maintain this information without obtaining a signed HIPAA authorization (in such cases if circumstances permit, if the individual is disqualified while in contact with research personnel the potential subject should be informed that the Waiver was granted only after the investigator assured the institution that they would appropriately safeguard the protected health information and be offered the option of signing an authorization so they can be made aware of all the ways their information may be used or disclosed or alternately given the option to verbally instruct the researcher to destroy any PHI collected during the pre-screening). For subjects who do not ultimately pursue the study, the pre-screening information should be handled as outlined below (Pre-Screening Records).

- iii. Waiver of documentation of informed consent: The collection of data from or about a person during pre-screening constitutes a research interaction or intervention and is subject to informed consent requirements. Although pre-screening activities do not necessarily result in data that are used to evaluate study outcomes, such procedures must be reviewed by the IRB during its review of the protocol in order to ensure appropriate informed consent is obtained, when required, and so that all potential risks to subjects may be evaluated. The IRB may waive the requirement for informed consent or documentation of (signed) informed consent for pre-screening activities if:
  1. the screening activities are deemed to be minimal risk, and
  2. the screening activities do not involve procedures for which written informed consent is normally required outside of the research context.

For FDA-regulated research, the IRB may only waive the requirement for signed informed consent for pre-screening activities in accordance with 21 CFR 56.109(c)(1) for the purposes of minimal risk activities only.

If the IRB determines that pre-screening activities for a particular research study qualify for a waiver of signed informed consent, the investigators must develop a consent script in order to conduct the pre-screening activities for the research study. The pre-screening script will be reviewed and approved by the IRB and will be considered as a tool to be used for the oral informed consent process.

b. Conducting Pre-screening in Person:

- i. Investigators may choose to conduct pre-screening in person, for example, if potential subjects are finding out about research during routine clinical care or while visiting the hospital. The questionnaires and checklists used during phone pre-screens may be appropriate in this setting as well. Complete medical histories and screening physical exams which are part of the research study are not considered acceptable pre-screening activities and should be conducted only after an individual has signed a consent form. However, 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 before signing a consent form for a study. For example, it may be acceptable to weigh an individual in order to ascertain whether s/he qualifies for a dietary study or acceptable to briefly view a pigmented lesion or a subject's skin type to see whether s/he qualifies for a dermatology study. Such exceptions may be submitted to the IRB for review and consideration as part of the study.

These types of activities during pre-screening may be approved by the IRB in certain specific circumstances in the interest of the convenience of the research subject, if s/he agrees. Complete physical exams, full body skin exams and any sample collection or laboratory testing must not be undertaken until a subject has given informed consent and has signed the consent form (as approved by the IRB).

c. Pre-Screening Records

- i. The Investigator must assure the confidentiality of the potential participant's information, whether or not s/he actually enrolls in the research study. The investigator may maintain a record of the screening data if this is represented in the IRB approved study to assess and revise the recruitment plans or to document time and effort spent on screening efforts by study staff provided the appropriate process is followed.
- ii. Pre-screening sheets from individuals who did not provide identifying information can be retained with no further action.
- iii. Pre-screening sheets with identifying information gathered in order to obtain written authorization and prior to enrollment (signing of informed consent form) of the potential subject may also be retained in research files, but must have segments containing identifiable information blacked out, redacted or cut off as soon as it is clear to the PI and/or study team that the individual will not be enrolled.
- iv. If identifiable health information is to be retained, the investigator must inform each of the persons screened of the intended use and obtain HIPAA authorization.
- v. Investigators who plan on creating a database with the purpose of using it to aid in recruitment for future research must obtain prospective IRB review and approval. Informed Consent and HIPAA authorization must be obtained for the creation of such research databases.

**SCREENING ACTIVITIES**

Screening activities include any interaction or intervention with potential subjects to determine eligibility that would not otherwise have been performed if not for the study, or collecting data directly from subjects through written screening tools or oral responses to questionnaires. Investigators must describe screening procedures in the IRB study submission used in the recruitment process including:

- a. The screening instruments to be used or procedures to be done.
- b. A description of the data, if any, that will be collected...
- c. How the data collected during the screening procedures will be stored.
- d. Whether the investigator intends to retain or destroy data collected from subjects who are deemed ineligible upon completion of the screening process.

### **SAMPLE SCREENING SCRIPT**

#### **Introductory Statement:**

- The script must include an introductory statement that informs the subject of the purpose of the questions and that they do not have to answer any questions they do not want to answer.
- The script must not describe the type of questions that will be asked as “confidential;” i.e., rather than saying “we would like to ask you some *confidential* questions,” say “we would like to ask you some questions.” It is acceptable to say “personal questions” or “sensitive questions.” The purpose of this policy is to prevent any possible misunderstanding that the answers will be held in complete confidence.
- When appropriate, the script must include an introductory statement warning the subjects of the sensitive nature of the questions that might make the subject uncomfortable, and preferably include an example (for instance, “We are going to ask you about drug or alcohol use.”) This will generally be limited to questions about mental illness, substance abuse, and sexual abuse. For these types of screening scripts, it is preferable to not collect any identifying information until after the questions are asked (i.e., collect the name and other identifying information at the end of the conversation and the form).

Here is a sample introductory statement:

[Thank you for calling] (or) [We are returning your call] about a research study we will be doing. The purpose of the study is [briefly describe study - e.g., “. . . to evaluate the safety and effectiveness of an investigational drug for arthritis”]. Participation in this study would last about [number of days, weeks, etc.] and (if applicable) would require up to [number] of visits to our office.

To see if you might qualify for this study, I need to ask you some questions about your health history and present condition. Some of these questions may be sensitive, such as questions about [give examples - e.g., drug use, birth control, mental health, sexual activity, etc.] You do not have to answer any questions you do not want to answer. You may stop this interview at any time. If you do not qualify for this study, the information you give me will be [e.g., “destroyed immediately” or “stored (where and for how long)”]. Do I have your permission to proceed? "

#### **Body of Screening Form**

- The IRB expects to see the actual questions that will be asked, not just a general statement such as “inclusion/exclusion criteria addressed.”

#### **Closing Statement**

- The script must include a closing statement informing the subject of whether or not they have met the preliminary screening requirements.
- The script must address in the closing statement whether the information received from the subject will be destroyed immediately, or whether it will be stored, and if so for how long and where.

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- Note: When seeking to obtain/retain information about individuals who refuse to participate in the proposed research, it is recommended that the script detail what information will be obtained/retained. Informed consent may still be required but can be given verbally with an IRB-approved waiver of signed consent.
- If the site would like to keep information for future contact for new studies, this must be described to the subject as well, and the subject must have an opportunity to decline.

**Additional Issues**

- The screening script must be in language understandable by lay people. If complicated medical terms must be included in the screening script, please provide the IRB with an explanation of how they will be explained to the subjects.
- The IRB realizes that the script may not be followed verbatim, as subjects may ask additional questions or stray from the topic. This is acceptable, but it is expected that the interviewer will keep as closely as possible to the spirit and letter of the script.
- It is useful to the IRB if the investigator informs the IRB of the use of the recruitment screen; e.g., if it is going to be used with subjects calling in from advertisements, for calling patients listed in a database, or for conducting cold calls, etc.