Mass General Brigham Human Research Affairs

Guidance Document

PRE-SCREENING OF RESEARCH SUBJECTS DURING RECRUITMENT

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 in the recruitment process. When using this strategy, investigators must obtain informed consent of potential subjects prior to the collection of any information about them and adhere to the following guidelines to protect the privacy of the potential subject and the confidentiality of information collected about him/her. Generally, the IRB will waive the requirement for the investigator to obtain a signed consent form and allow verbal consent for the pre-screening activities.

I. Obtaining Potential Subject's Permission to be Contacted

The potential subject's permission to be contacted must be obtained prior to direct contact by study staff. Those subjects who respond to advertisements or recruitment letters have implicitly given their permission to be contacted. Refer to Mass General Brigham Human Research guidance on Recruitment of Research Subjects for other acceptable methods of obtaining an individual's permission to be contacted, particularly those who have been identified through their private medical information such as medicalrecords or patient databases.

II. Acceptable Information to Gather 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 at this point in the process to gather information that is not directly related to assessing eligibility and suitability (e.g. complete medical histories). Also refer to Conducting Pre-screening in Person (III.C.) below for guidance on performing very limited routine clinical procedures as part of pre-screening.

III. Methods for Conducting Pre-screening

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, asked whether this is an appropriate time for them to answer these questions, and told how long the phone call is expected to take. At a minimum, telephone scripts must include statements that address the following points:

- Thank you for your interest in our research study [*briefly describe purpose*].
- Is this a good time to talk?
- Would you be willing to answer questions about your health and medical history to find out if you might qualify for the study? Some of the questions may make you feel uncomfortable. You can stop at any time.
- I will record your answers in writing, but only collect detailed contact information if you qualify for the study and want to schedule an in person visit.

- **Optional Statement**: I will also ask you for your [*indicate what information will be collected, e.g., date-of-birth, social security number and medical record number*] to register you with the hospital before your in person visit.
- The risk of allowing us to record your name with your answers is a loss of confidentiality. We will take reasonable steps to protect the confidentiality of your information.
- May I begin?

The telephone pre-screening script and pre-screening questionnaires or screening tools that will be used must be submitted to the Mass General Brigham IRB Office for review. Subjects should be offered the option of completing the pre-screening in person, if they wish and if it is feasible.

In the interests of confidentiality, the researcher should record only the subject's first name at the beginning of the screening conversation; 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, Social Security number 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 of particular import in light of Health Insurance Portability and Accountability Act (HIPAA) privacy regulations. The collection of non-identifiable health information is not subject to the 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.

For the Collection of Identifiable Health Information: The following guidelines for handling identifiable new healthcare information became effective on April 14, 2003: Under the "preparatory to research" provision of the HIPAA Privacy Rule, an investigator may maintain identifying information at the end of the screening conversation until the subject meets with study staff to discuss the study further and sign the consent form. (If identifiable health information is collected on persons who are not enrolled, there are two options: (1) destroy the information or (2) if a failure log must be maintained, the PI must obtain informed consent and authorization in writing from each individual - see V. below). During this meeting, the subject must be asked to sign the written authorization to use and disclose his/her identifiable healthcare information and be given a copy of the hospital's Privacy Notice unless s/he has previously received one during interactions with the hospital. For subjects who do not ultimately pursue the study, the pre-screening information should be handled as outlined in Section V below (Retaining Information from Individuals who are Pre-Screened but not Enrolled).

B. Conducting Pre-screening over the Telephone utilizing Centralized Phone Banks

National advertisements are sometimes used to recruit subjects for large multi-center studies. Typically, centralized phone banks or operators receive calls from individuals who see such advertisements, and then screen subjects and refer those eligible and interested to local investigators. Phone screeners interacting with potential subjects in this setting are obviously not employees of our hospitals, are usually not healthcare providers, and typically work from a script or data collection tool which must be reviewed and approved by the Mass General Brigham IRB Office before use. Use of third-party screeners must be explicitly noted in the protocol. Under HIPAA privacy regulations, the use of such a centralized phonebank or operators requires a business agreement. Please refer to

(http://intranet.partners.org/finance/hipaa/Business_Associates.asp) for more information about these agreements. Potential subjects should be told they are speaking to a non-medical screener at a centralized phone bank, and not erroneously be led to believe they're speaking with a physician or member of the actual clinical research team at our hospitals. This is especially relevant to protocols involving depression or other psychiatric illness. Industry screeners should have policies on what will happen if subjects calling are found to be at serious risk of harm to self and others (e.g. suicidal) and provide such plans for Mass General Brigham Office review.

C. Conducting Pre-screening in Person

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. All of the questionnaires and checklists that would be used during phone pre-screens are appropriate in this setting as well. **Complete** medical histories and screening physical exams are not considered acceptable pre-screening activities but rather part of actual research procedures and should be conducted only **after** an individual has signed a consent form. That said, it is 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 would be acceptable to weigh an individual in order to ascertain whether s/he qualifies for a dietary study or briefly view a pigmented lesion or a subject's skin type to see whether s/he qualifies for a dermatology study. Such exceptions are made 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.

IV. Alternative Pre-screening Approaches

The guidelines listed above may not be applicable to every situation that arises in the research process. Carefully justified alternative approaches will be considered on a case-by-case basis. The Mass General Brigham IRB Office staff will offer guidance to investigators upon request.

V. Retaining Information from Individuals who are Pre-Screened but not Enrolled

It is acceptable to 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 even requested by industrial or academic 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 collected with verbal consent and authorization prior to enrollment (signing of informed consent form) may also be retained in research files, but must have segments containing identifiable information blacked out or cut off as soon as it is clear that the individual will not be enrolled. If identifiable health information is to be retained, the investigator must obtain informed consent and authorization from each of the persons screened.