



Institutional Review Board
Program for the Protection of Human Subjects

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Guidance on Screening Procedures for Research

I. Background:

Research studies generally have inclusion and exclusion criteria. Researchers must ensure that inclusion and exclusion criteria are adhered to by study personnel. Researchers can include in-depth screening activities that take place after obtaining informed consent. In studies where informed consent is obtained before screening, the informed consent document must contain a statement that indicates that if a subject does not qualify to continue in the research study after the end of screening, he/she will be withdrawn from the research. This statement is generally included in the section of the Informed Consent Document describing the Screening Visit and is followed by a statement stating that “If you continue to be eligible to participate in this study, the following will occur...” after which the rest of the study procedures are described. Note that subjects who sign a consent document, then do not pass screening are considered enrolled in the research study and are counted as withdrawn. When reporting to the IRB on enrollment numbers at the time of continuation, the total screen successes plus the total screen failures is the total number of subjects enrolled. The progress report should include the number of subjects who were withdrawn due to screen failure and the reasons for any other subject withdrawal.

Under certain circumstances, basic screening can take place prior to obtaining informed consent. In these cases, screening may be part of the recruitment activities of the study. Since screening involves interacting with subjects, it meets the regulatory definition of human research under the federal regulations.

II. Effective Date: 6/18/2014

Scope: This guidance applies to screening procedures involved in research conducted at Mount Sinai.

III. Guidance

In general, study participants must consent to any screening procedures that are part of a research study. The PI may choose to use two different consent documents (one just for screening procedures and one for the full research study) or use one consent document encompassing both elements. Participants are considered enrolled at the time of signing the consent form. Participants must be informed that they may be withdrawn if it is determined that they do not meet inclusion criteria. Participants who do not meet the screening criteria are to be reported as withdrawals from the study at the time of continuation.

Exceptions to obtaining full informed consent and HIPAA authorization prior to screening: Exceptions may be made, for example, if the screening is done through a phone call that does not involve extensive and/or sensitive questions. The screening script that will be used to introduce the study and the screening instrument to the potential subject must be submitted to the IRB for review. In these cases:

- **No identifiers can be retained with data from the screening procedure** unless informed consent has been obtained, or the IRB has granted a waiver of informed consent and waiver of HIPAA authorization for the screening procedure. Note that the accompanying documentation must be submitted to the IRB requesting a waiver.
- **No data, including aggregated data, can be used for research purposes** (i.e. to quantify selection bias) unless approved in advance by the IRB. However, potential subjects need to be informed that their information can be used for general reporting of how many people completed the screening, how many didn't meet inclusion criteria, and how many decided not to participate in the research study.
- **No sensitive questions can be asked directly.** The PPHS considers questions pertaining to mental health and substance use, illegal activities, STD and HIV, etc. as examples of questions that could reasonably place the subjects at risk of criminal or civil liability or be potentially damaging to financial standing, employability or reputation and therefore "sensitive".

This means that in order to use any data collected from the screening procedures for research purposes (outside of solely determining if inclusion criteria are met and to meet reporting requirements regarding screening and enrollment numbers) consent must be obtained from the potential research subject, and no sensitive or intrusive questions may be asked without first obtaining informed consent.

You cannot record name, MRN, or study ID# with the answers to the questions on the screener. The only information you will be able to record is eligible Y/N for each subject screened.

IV. Examples of Acceptable Screening Procedures

Telephone or Web-based Screening prior to a full informed consent process:

- a. *Screening procedures by phone that ask specific "non-sensitive" questions as long as the answers are not recorded or linked in any way with identifiers.*

Example: A screening instrument that asks questions about MRI exclusion criteria only, without any additional questions about drug use (prescription or other), mental health, or other study specific criteria.

- b. *Screening procedures by phone that review general information and make clear to potential participants that certain conditions are exclusionary for the research study, and thus a visit to the site would be a waste of time. Note: No sensitive questions can*

be asked or answered directly. Also, no information can be captured indicating which inclusion criteria is met for screen successes and no information can be retained on screen failures, other than noting screen fail or screen success.

Example 1: A screener that states “If any of the following apply to you, you do not qualify to be in the research study. It doesn’t matter which one applies to you: If you have high blood pressure, HIV, tattoos or use illicit drugs, you do not qualify for this research study. Do you think we should continue?” and is followed by setting up an appointment to go through the informed consent process.

Example 2: A screener that states “In order to qualify for this research study you need to have high blood pressure, HIV, tattoos or use illicit drugs. Don’t tell me which one applies to you. Do you think we should continue?” and is followed by setting up an appointment to go through the informed consent process.

- c. *With a properly designed web screener, eligibility can be assessed for a particular study.* Because of the evolving nature of web technology, this requires evaluation by the IRB to determine that adequate safeguards for ensuring anonymity and confidentiality of data are present (for example, identifiers such as a unique IP address, login ID, analytics tracker etc. will not be captured and/or retained). In the absence of clearly explained safeguards ensuring anonymity and confidentiality of data, the web screener may only be approved for use following a full informed consent process.

V. **References:** FDA “Screening Tests Prior to Study Enrollment - Information Sheet: Guidance for Institutional Review Boards and Clinical Investigators”