GUIDANCE: SCREENING PROCEDURES FOR RESEARCH

1. **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. Limited screening activities can occur without formal informed consent in certain situations (See Section 4 below for examples).

1. **Scope:** This guidance applies to screening procedures involved in human subjects research conducted at Mount Sinai.
2. **Guidance**
   1. In general, study participants must consent to any screening procedures that involve interactions with the prospective participant. 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 Participants must be informed that they may be withdrawn if it is determined that they do not meet inclusion criteria
   2. Screening for potential participants by chart review does not require consent nor a waiver of informed consent. The type, manner and extent of the chart review has to be spelled out in the application to the PPHS and should be limited to the minimal amount of information that is needed to accomplish the task. A HIPAA waiver will be needed if identifiers are accessed, which is the most likely scenario.
   3. If screening activities are limited to participants answering questions or completing a questionnaire, their formal informed consent will not be needed. However, since there is direct interaction with participants there must be enough information shared to allow the person to make an intelligent decision to take part. Essentially, they have to give assent for screening. This information should be included in the script that introduces the project and will have to be approved by the IRB.
      1. **No identifiers can be linked with data from the screening procedure** unless HIPAA authorization for the screening procedure was obtained or a complete waiver of HIPAA authorization or a waiver of signature (aka a HIPAA alteration) is granted. Note that the accompanying documentation must be submitted to the IRB requesting a HIPAA waiver.
      2. **No data, including aggregated data, can be used for research purposes** (e.g., to quantify selection bias) unless approved in advance by the IRB. However, if use of aggregated screening data for research purposes is indicated in the approved research design, 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. A screening form should make clear if the reporting will include data of those who screened out or decided against full participation in the study.
3. **No identifiable sensitive questions should be asked directly without consent.** The PPHS considers questions pertaining to mental health and substance use, illegal activities, STDs 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 count as “sensitive”. The PPHS may require full consent in these circumstances, but there are acceptable “work arounds” that most researchers find acceptable.

# 4. Examples of Acceptable Screening Procedures

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

1. *Screening procedures by phone that ask specific “non-sensitive” questions as long 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.

1. *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 of the inclusion criteria were 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 exclusion criteria 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.

1. *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.
2. **References:** FDA “Screening Tests Prior to Study Enrollment - Information Sheet: Guidance for Institutional Review Boards and Clinical Investigators”