

The primary concern with the telephone screening of potential subjects for research protocols is the degree to which sensitive personal information is solicited and collected. The more sensitive and personal the information, the more likely that the federal human subjects regulations and other privacy laws will require additional steps and protections (e.g., Common Rule and FDA informed consent/ HIPAA authorization from the subject, or waiver of documentation of consent and waiver of authorization for recruitment) before the screening can occur. These privacy laws require that individually identifiable health information collected be kept to the minimum necessary.

Sensitive personal information includes potentially embarrassing or damaging information, responses that are self-incriminating for criminal or civil liability, information that could adversely affect financial standing or employability, disclosure of a serious or potentially fatal medical condition or of a matter that might be considered deeply personal, etc. Examples include screening questions concerning illegal drug use, attempts at suicide, psychiatric conditions, sexual orientation or practices, contagious illness such as HIV or hepatitis C, and experiencing or committing any reportable event such as child or elder abuse. Whenever possible, draft screening questions in a manner that will NOT elicit such sensitive information.

Additionally, the more sensitive and personal the information solicited and collected, the more likely the screening would not meet the definition of "minimal risk." A key criterion for waiver of consent documentation under the Common Rule and FDA, and waiver of authorization under HIPAA, is that the screening constitutes no more than minimal risk.

Finally, if identifiable health information will be collected and kept for recruitment under a future protocol (see Phone Screen Level 1b), the Protocol Director must include that use as a recruitment step in the IRB application. A request for a Waiver of HIPAA Authorization for Recruitment and waiver of documentation of informed consent should also be included for the use of the information in recruitment.

TELEPHONE SCREENING TEMPLATES AND RELATED GUIDANCE

[Screening Script Decision Tree](#) - for guidance on determining which level of screen to use

Stanford University Sample [Phone Screen Level 1a](#)

Stanford University Sample [Phone Screen Level 1b](#)

Guidance: Advertisements: [Appropriate Language for Recruitment Material](#)

Stanford University : Research Compliance Office

SCREENING SCRIPT DECISION TREE

