PHONE SCRIPTS, QUESTIONNAIRES AND WAIVERS OF DOCUMENTATION

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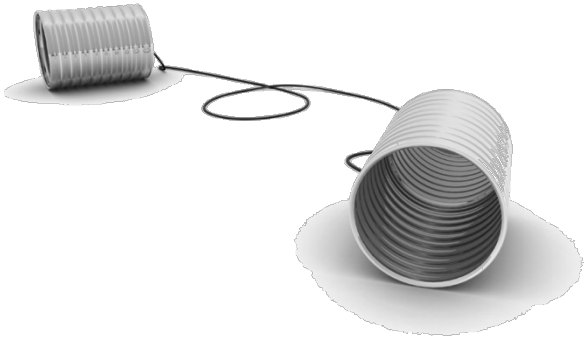


Today's objective:

To review phone screening scripts and questionnaire requirements, approved with a waiver of documentation, to ensure they do not contain language involving greater than minimal risk

Telephone Screening of Potential Subjects Guidance – GUI-15

- The **primary concern**…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 privacy laws **will require additional steps and protections** …before the screening can occur.

- …individually identifiable health information collected (must) be **kept to the minimum necessary.**

…the more sensitive and personal the information…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.

Sensitive information includes:

- potentially embarrassing/damaging info
- questions concerning illegal drug use
- attempts at suicide
- psychiatric conditions
- sexual orientation/practices
- contagious illness (e.g., HIV or hepatitis C)
- experiencing/committing any reportable event (e.g., child/elder abuse)

Waiver of Documentation

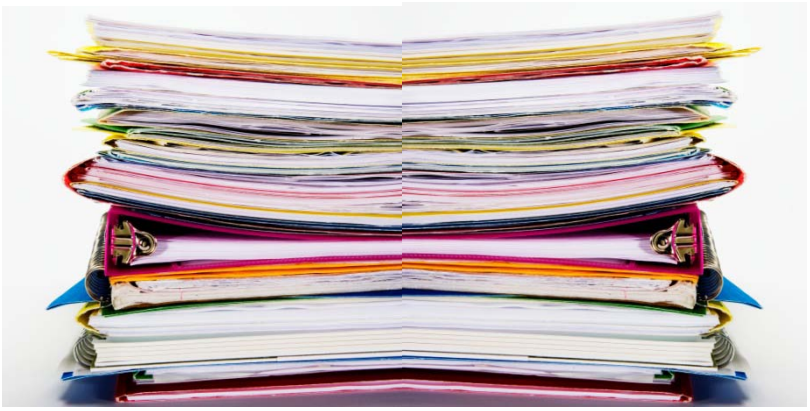
OHRP 45 CFR 46.117(c)(1)

For research not subject to FDA regulation, the IRB finds:

That the only record linking the subjects and the research would be the consent document and the principal risk would be potential harm resulting from **a breach of confidentiality**.

- Risk of criminal/civil liability
- Damage to financial standing
- Employability
- Insurability
- Reputation
- Stigmatizing

Waiver of Documentation



OHRP 45 CFR 46.117(c)(2); FDA 21 CFR 56.109(c)(1)

For research subject either to OHRP or FDA regulation, the IRB finds:

That the research presents **no more than minimal risk of harm** to subjects and involves no procedures for which written consent is normally required outside of the research context.

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Examples- Illegal Drug Use

Does NOT qualify as involving no greater than minimal risk

- Are you currently enrolled at the outpatient substance abuse clinic?
- Please rate your marijuana use in the past 30 days…
- Now I am going to show you a list of street drugs or medicines. Please tell me if you have taken any of the following to get high, feel better, or change your mood?

  List of drugs provided:

  Speed, crystal meth, cocaine crack, freebase heroin, ecstasy, LSD…

Examples: Harming self/others

Does NOT qualify as involving no greater than minimal risk

- In the past year, have you done anything to hurt yourself, such as cutting, burning, picking?
- Have you ever attempted suicide? If yes, when?
- Have you ever attempted to hurt or kill yourself? If yes, when was that? If no, are you currently thinking of hurting yourself? If yes, do you have a plan?
- Now you are going to make an oral contract with me that you are not going to hurt yourself. (if the person does not want to make the oral contract say, “Now the confidentiality requirement does not apply and I am going to call the police”).

IRB Considerations

Note: we are NOT denying the researcher the ability to ask the questions – we must ensure the criteria to approve the waiver of documentation are met

Provide guidance/reasonable alternatives:

NO	YES

Resources

- **GUI-15** Telephone Screening of Potential Subjects Guidance – contains flow chart
- **GUI-16** Advertisements: Appropriate Language for Recruitment
- **GUI-33** Recruitment
- **TEM-7 &TEM-8**

  Telephone Screening of Potential Subjects Template – Phone Screen Level 1a & 1b
- **HRPP Chapter 12.5.2** – Waiver of Documentation of Consent