Examples of Waivers of Documentation of Informed Consent: Survey and Telephone Screening

A Waiver of Documentation of Informed Consent is customarily requested for research where subjects will provide consent but not **written** consent for some or all of the research.

Criteria (2): OHRP regulation 45 CFR 46.117(c)(2) and FDA regulation 21 CFR 56.109(c)(1): *An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it 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.

Scenario 1 for Criteria (2) – A mailed survey:

A researcher conducting a survey (that does not qualify for an exemption) would like to mail a survey questionnaire to a random sample of adults. There will be no collection of medical records. The Invitation to Participate letter clearly states that by responding to the questions and mailing the survey back, the recipients have agreed to participate.

Justification:

- Do not: State that this is "just a mailing" or "just a survey" because some surveys involve greater than minimal risk to subjects.
- Try to: Focus on why the survey does not constitute greater than minimal risk, such as the nature of the questions. Explain how subjects are providing informed consent by reading the Invitation to Participate letter and taking an action (mailing the survey back.)
- Good example: Based on the nature of the survey and Invitation to Participate letter, this particular activity presents no more than minimal risk of harm to subjects. The survey does not ask the subject to answer any sensitive questions and the subject is not asked to perform other activities. Normally, there is no requirement for written consent for completion of surveys outside the research context. By completing and returning the survey, subjects have consented to participate in the research.

Scenario 2 for Criteria (2) – Telephone screening:

A researcher would like to screen prospective subjects by telephone to see if they qualify to participate in a research study. If they appear to qualify based on preliminary screening questions, these individuals will be asked to come to the institution to review the consent form.

The researcher has created a script that will be read to prospective subjects over the phone and the researcher has submitted this script for IRB review. In the script, prospective subjects will be informed about the purpose of the call, the nature of questions that will be asked, the plans to keep their responses confidential, and what will happen to their information if they don't qualify for the study based on telephone screening. Prospective subjects will then be asked to provide verbal consent to initiate the screening questions.

Justification:

- Do not … state that this is "just telephone screening" because some screening can involve greater than minimal risk to subjects—especially when asking about sensitive medical history or legal issues.
- Try to … focus on why the screening does not constitute greater than minimal risk. Most researchers focus on the non-sensitive nature of their planned screening questions. Describe the scope of the telephone script and explain that subjects will provide verbal consent.

Good example: Based on the nature of the telephone script and screening questionnaire, this screening activity presents no more than minimal risk of harm. The script informs prospective subjects about the types of questions that will be asked and that there are no plans to ask sensitive questions. There are robust confidentiality practices involving limiting access to the information obtained during screening. Prospective subjects will indicate willingness to participate in telephone screening by providing verbal consent. Normally, there is no requirement for written consent for telephone screening outside the research context.