

Phone Screen Guidance

In early November 1998, the FDA issued guidelines regarding telephone screens in its updated FDA Information Sheets, dated September 1998. FDA's proposed telephone screen guidelines recommend that the reviewing IRB consider several questions about the use of the information obtained as a result of the telephone screen. In addition, Schulman feels that an appropriate confidentiality disclosure to the caller should be part of the telephone screen process. The caller should be alerted to the following:

1. The purpose of the phone screen
2. The type of information that will be requested during the phone screen
3. The caller's permission to go forward with the telephone screen questions
4. Notify the caller what will be done with the information that is obtained during the telephone screen and who will have access to that information
5. If the caller does not qualify for the study that is the focus of the phone screen, request the caller's permission to use the information obtained from the phone screen to contact him/her on other studies.

Please consider the following in relation to the phone screen:

1. What happens to the personal information if the caller ends the interview or simply hangs up?
2. Does a marketing company gather the data? If so, are the names, etc, sold to others?
3. Are names of non-eligibles maintained in case they would qualify for another study?
4. Are paper copies of phone screen documents shredded or readable copies put in the trash?

Schulman recommends the following script, incorporating the above noted FDA guidelines, to be used in conjunction with your intended telephone script.

Opening: *In order to determine if you qualify for this research study, we are going to ask you some confidential questions about your health history and present condition.*

Do we have your permission to proceed? _____ Yes _____ No

Closing: *Based upon the information you have given us, it appears that you do not qualify for this research study. With your permission we will keep this information about your health on file for your possible qualification in a future research study.*

*Do we have your permission to retain in our files the information we collected in this telephone conversation? _____ Yes _____ No**

**[If No]: We will destroy this information at the conclusion of this call.*