

Suggested Format for Telephone Scripts to Screen Potential Subjects
When Identifiable Private Information,
Including Protected Health Information, Will be Recorded or Written

8/30/2007

(Note that the investigator must request a waiver of documentation of consent and an alteration of authorization to record or write identifiable private information, including protected health information, for research purposes. For further details, see the DUHS IRB policy on telephone and mail questionnaires on the IRB website.)

1. Introductory remarks: who is calling and reason for the call.
2. Brief description of the proposed study, including the name of the PI, purpose of the research, procedures for subjects, risks, and benefits.
3. Basic elements of consent and authorization before asking the screening questions, because verbal consent is being obtained by telephone. This section can be worded something like the following:

ADULTS

I would like to ask you some questions that would help us determine if you qualify to be in this research study. This will take about ___ minutes. These questions will involve your giving information about your medical history. Answering these questions is voluntary. You are under no obligation to answer them, and not answering them will have no effect on your health care at Duke. Not answering the questions, however, means that you will not be eligible to participate in this research study. If at any time during this prescreening you would like to stop and not participate or if you have any questions, just let me know.

Here is some information about the confidentiality of the information I collect today. If you do not qualify for the study or decide not to participate, we will not keep the information we collect today. If you do qualify for the study and decide to participate, we will ask you to sign a consent form at your first appointment. The personal information you give me today will become part of your research record and will be reviewed by Dr. _____ and the research staff. Your name will not appear on this screening information. We will assign a code number and the key to the code will be kept in a locked file separate from the other information I collect today. If you change your mind at any time and decide that you do not want to participate, you can call us and we will immediately destroy the private information that we collect today.

Would you like to continue now with the screening questions?

MINORS

I would like to ask you some questions that would help us determine if your child qualifies to be in this research study. This will take about ___ minutes. These questions will involve your giving information about your child's medical history. Answering these questions is voluntary. You are under no obligation to answer them, and not answering them will have no effect on your or your child's health care at Duke. Not answering the questions, however, means that your

child will not be eligible to participate in this research study. If at any time during this prescreening you would like to stop and not participate or if you have any questions, just let me know.

Here is some information about the confidentiality of the information I collect today. If your child does not qualify for the study or you decide for him/her not to participate, we will not keep the information we collect today. If your child does qualify for the study and you decide for him/her to participate, we will ask you to sign a consent form at his/her first appointment. The personal information you give me today will become part of your child's research record and will be reviewed by Dr. _____ and the research staff. Your child's name will not appear on this screening information. We will assign a code number and the key to the code will be kept in a locked file separate from the other information I collect today. If you change your mind at any time and decide that you do not want your child to participate, you can call us and we will immediately destroy the private information that we collect today.

Would you like to continue now with the screening questions?

4. Provide telephone contact for study staff in case the potential subject has further questions.
5. Closing remarks regarding whether or not the potential subject is eligible for the study, and further instructions.