Telephone Consent Guidelines

The IRB encourages that whenever possible the informed consent process be done in person and not over the telephone. However, when the research can not reasonably be conducted in person, a telephone consent may be deemed appropriate. When the proposed research poses minimal risk to subjects, and you plan an initial contact with subjects by phone, or if you plan to conduct the research using a phone questionnaire, a telephone consent script is needed. In this script, you need to concisely describe the study, tell what participants will need to do, tell them how confidentiality will be maintained, and in the case of a telephone interview, explicitly ask for their consent to participate. Specifically you must include in your script the following:

1. Statement that the study involves research
2. Explanation of the purpose
3. Duration of the subject's participation
4. Description of the procedures
5. Description of risks/discomforts
6. Description of benefits
7. Confidentiality
8. Whom (and how) to contact for questions regarding the actual study (researcher) and their rights as participants (IRB)
9. The voluntary nature of participation in the research and her/his ability to withdraw without any penalty
10. The approximate number of subjects.

Federal regulations at 45 CFR 46.117 require ***written*** informed consent (meaning the use of an IRB-approved written consent form which is signed by the subject or the subject's legal representative) unless the IRB has determined that the research meets the criteria for waiver of written informed consent.

- If obtaining only oral/telephone consent, you must explain that you are requesting a waiver of written informed consent in the Informed Consent portion of your protocol (see below)
- You must also submit a Waiver of Authorization form.

Example (from Protocol Summary guidelines/ Informed Consent Process section):

- *If written informed consent, assent or permission will not be sought or documented, provide justification for this by describing how the research meets each of the following criteria:*
  - *the research involves no more than minimal risk to the subjects*
  - *the waiver or alteration will not adversely affect the rights and welfare of the subjects*
  - *the research could not practicably be carried out without the waiver or alteration of the written informed consent, assent or permission requirements*
  - *whenever appropriate, the subjects will be provided with additional pertinent information after participation*

Sample Script for Telephone Consent:
This is only an example and can/should be expanded to meet the needs of your study. The script should be followed by the actual survey/questions you will be asking, as well as the signature page (see below). Include Version Dates.

Study Title:
Principle Investigator:

Hello, my name is _____ from _____. We are asking you to volunteer to take part in a phone interview/survey as part of a research study about_ (briefly explain the study) __. The interview/survey will take approximately _____ minutes of your time. Your participation in this survey is completely voluntary. This means you do not have to participate if you don't want to. If you agree to participate, you have the right to only answer the questions you choose to answer. This phone interview is being conducted to determine _____. The phone interview will consist of questions pertaining to your child's _____. The potential risks of this research are minimal and confidentiality of private health information that you share with us will be maintained to the highest level. You have the right to stop participation at any point during the interview if you so choose. If you have questions or concerns regarding this research, you can contact the PI _____at _____ or the Children's Healthcare of Atlanta IRB, the committee that works to protect your rights and welfare at _____"
"Do you have any questions?"
"Do you agree to voluntarily participate in this survey process?"

[ ] Yes If Yes..... Continue
[ ] No If No... Good-bye.

Follow with list of specific questions you will be asking. You can only collect information provided in the script, so be specific and thorough.
The last page is your record of your telephone/oral consent. This must be kept, just as a written Informed Consent would be kept. See sample.

Script to introduce telephone interview- EXAMPLE.

Hello, Mr./Mrs./Ms. This is *Interviewer name,* calling from the Louis Stokes VA Medical Center.

I talked to you last *day that respondent had office visit* about being part of our study on sleep problems.

When I talked to you at your doctors office, you said that you would be willing to answer a telephone questionnaire for the research study.

Are you still willing to do that? The interview should take between a half hour and an hour of your time.

Would you like me to remind you about the types of questions that I am going to ask.

If patient say yes –

The questions will be about problems that you might have with falling asleep, staying asleep, or waking up too early. There are questions about how sleepy you feel during the day, and questions about uncomfortable feelings that you might have in your legs. There are also some questions about your general health and how you are able to get things done during the day. There are also some questions about whether you feel depressed or anxious and about your use of drugs or alcohol or tobacco.

Would you be willing to answer those questions?

If no, ask , Is this a bad time? Could I call you back at another time?

If yes, read below --

As I told you the other day, you are not required in any way to answer these questions. You can skip any questions that you don't want to answer or you can end the interview at any time if you choose.

Your doctor at the VA will not know if you are in the study. Your choice about being in the study will not effect the medical care that you will get from the VA Medical Center.

Do you have any questions before we begin?

Answer patient questions. If interviewer is not able to answer all questions, give phone number for Dr. Bourguet or Dr. Ober.