Telephone Script for Recruiting Subjects

Modified: January 2017

Background:

If you want to contact potential study subjects to recruit or screen them, you must submit a phone script to the IRB for approval.

Q: What should be included in a telephone script?

1. Introduce yourself

2. Ask if “targeted” person is present, if not, offer to call back later. Remember to be discrete regarding the purpose of the call (eg. We are calling about a research study”) and not present anything about the specific study that might reveal sensitive inclusion criteria. Releasing PHI to a family member is still in violation of HIPAA.

3. Indicate to targeted person the purpose of the study (eg. “we are conducting a study on diabetes), and how you came to have their name and telephone number.

4. Ask early on if the potential subject wants to hear more about the study, if no, thank them and you’re done

5. Tell them participation is entirely voluntary, and that if they say no, it will not affect their care in any way.

6. Explain the study in 8th grade-type language

7. At the end, thank them for their time

Q: If screening a subject over the phone, can you collect PHI?

Yes, however, if screening subjects over the phone, and you will be collecting PHI, make sure that those collecting the PHI have taken the appropriate HIPAA training.

Please include in your phone script the following information you will be telling the potential subject:

a. The type of questions and/or information you are going to collect (particularly if it is sensitive)

b. Any potential consequence of the information (ie: we are trying to find out if you might qualify for this study, we will inform you if you may or may not qualify)

c. They can choose not to answer any question they are asked
d. If they screen in or out, then tell them what will happen to the information they just gave you:

i. If the potential subject screened out, then example statements are:

1. The data collected will be destroyed

2. We will record why you screen out, and provide summary data to the PI without any information that could identify you.

ii. If the potential subject screens in, then tell them something like “their data will be given to the PI or someone from the study team, who will be in contact with you. If you have any questions, you can contact <list name and phone number>”

Q: Should I minimize the collection of PHI during the screening, and if so, how?

Yes, you should always try to minimizing the collection of PHI

a. To collect the minimum necessary PHI, you can group the screening questions\answers (ie: you can ask the potential subject, “if you have any of the following conditions, please let us know after we have listed them all).”

b. In this way you will know if the potential subject screens out, but you will not know the specific reason, and thus you are not collecting PHI that you don’t need to have.

Q: What about other potentially sensitive information?

Even if the screening attributes don’t constitute PHI (e.g., you’re not in the covered entity vis-à-vis HIPAA, and the information won’t reside in a covered entity unit or database; engagement in risky behaviors, etc.), the information sought should be the minimum necessary for study goals, as outlined above.

a. The script and protocol should be clear about what information will be maintained and associated with their identity and with any other study information to be collected.

b. The script and protocol should be clear on whether any information will be maintained about a person if they don’t qualify for the study.

Q: What should potential participants be told when they are excluded from participation?

Unless there is a specific reason for informing potential subjects about the basis of exclusion, the default recommendation is to merely tell them that based on their responses, they don’t qualify for inclusion in the study, and thank them for their time.