**TELEPHONE/TELEMEDICINE SCRIPT (Talking to prospective participants)**

This template is to assist in developing a telephone script for phone screening of potential subjects and review telephone consent best practices.

**BEST PRACTICES**

**What should I be aware of when presenting study information over the phone?**

* People can easily multi-task and pay less attention while speaking to you on the phone
* There are no body language cues to give you an indication of how the conversation is going

**What should I be aware of when using telemedicine?**

* Restrictive US licensure laws may require a practitioner to be licensed to use telemedicine. Study teams should review and comply with local laws and institutional policies for credentialing and training of research staff members to be able to perform telemedicine.
* Information transmitted may not be sufficient (e.g. poor resolution of images) to allow for appropriate decision making by the participant. Whenever possible, each party should use the most reliable connection method to access the Internet as determined by the health professional or IT team. Be sure to have a back-up plan for lost connectivity.
* In rare instances, security protocols could fail, causing a breach of privacy of personal medical information. Be sure to follow all security policies and procedures to reduce this risk.
* Software platforms should not be used when they include social media functions that notify users when anyone on a contact list logs on.

**What can help?**

* Ask the potential subject if this is a good time to discuss the research study. IF it is not, ask when a better time to reach them would be, then follow up.
* Let the potential subject know how long you expect the conversation to be and OVERESTIMATE!
* On average telephone conversations should not last more than 30 minutes.
* Set the agenda…review with the potential subject what your plan is for the conversation.
* Encourage the potential subject to interrupt with questions.
* Talk slowly!
* Assess understanding: Pause and check-in with the potential subject to check that they are still following along with you. This is always critical but becomes even more essential when there are no physical cues to pick up on.

**How can I use this script?**

* The script is meant to guide a thoughtful and consistent conversation that a study team plans to have with a potential subject.
* This script is intended to be used for Study Introduction/Recruitment, Screening or as part of an IRB approved consent process via telephone.
* The script may contain more information than what is necessary for your study or it may not contain enough information. Please select the appropriate sections to complete for your study.

**What should I consider when developing my consent process?**

* Cold calling can turn off your potential subjects. You will likely need to develop a letter to participants introducing the study and setting the expectation of future contact.
* Consider providing the consent or information sheets along with an introductory letter to allow the potential subject to fully consider their interest in participation prior to you phoning them. This process is also more respectful of subject’s time and likely a more efficient use of yours.
* If you need to document consent, mail two copies of each form. One copy is for participants to keep and one copy is for participants to sign and send back. The mailed forms should NOT already be signed by the research team. Include a self-addressed stamped envelope to make it easier for the subject to return the signed form to the study team.
* If minors will be approached to give assent, you will need to discuss the study with the minor as well as the parent/guardian. The team should approach the parent first and ask for their permission prior to approaching their child about participating in the study.
* Both the witness and person obtaining consent must sign the consent form used during phone conversation.Research teams must document in the consent note and on the form itself that a consent conference was held via phone and record the date.
* When the signed form is received back from participant, then the two forms (the one signed by the subject and the one signed by the witness/study team member) can be combined and copy be given to the subject for their records.
* It is required to have appropriate forms signed by subject prior to starting study procedures, including starting to ask study-related questions while the subject is on the phone. If there is a need to speed up the process, consider exchanging the forms electronically - either by email or fax.

**Instructions on how to edit the script for IRB approval:**

Fill in the yellow sections with as much information as you have. Delete what sections are not required. Provide this to the IRB for approval.

Note some blanks may need to remain blanks since you won’t have that information at the time of IRB approval. For example, the subject’s name when asking, “May I speak to \_\_\_\_?”. These can remain blanks when obtaining IRB approval.

**Step 1: Calling the Potential Participant**

Hello, I am [study team member’s first and last name], from [site name]. May I please speak to \_\_\_\_\_\_\_\_?

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| **When desired person gets on the phone** | Hello (Mr./Ms). \_\_\_\_\_\_\_\_. I am [study team member’s full name] from [site name].  I am calling about our research study XX [**OR** I am calling you about XX study].  **Explain how you received the individual’s contact message**[e.g.) “You left a message on our study line with your telephone number” or “Two weeks ago we sent you a letter letting you know we planned to give you a call” or “Your child is a patient in our clinic and we are contacting all patients to see if they would like to take part in a research study” or “You were a past research participant and you indicated you would like to know about other opportunities for research.”]  Joining a research study is completely voluntary. If it's alright with you I'd like to take about XX minutes to explain the basic idea of the study and to see if you would be interested in taking part. Is now a good time?  **IF NO, GO TO immediate refusal**  **IF YES, GO TO STEP 2** |
| **If desired person is not available** | Is there a better day and time to reach (Mr./Ms). \_\_\_\_\_\_\_\_\_?  **Note days and times and enter into XX.**  Thank you. I will try to call back then.  **End call** |
| **If immediate refusal** | **IF NO/NOT INTERESTED**, Okay, thank you for your time. **End call.** |

**Step 2: Describing the Project**

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| **STEP 2a**  **Introduce the Study** | First, I’d like to tell you more about the study. As I explain the basic idea of the study, please feel free to stop me at any time with questions.  As I said the research study is called XX. All research studies ask a question. In this study we are asking… XX [describe the study purpose in lay terms, e.g. “Does a new treatment for teens struggling with depression work better than treatments that are currently available.”]  <Add text to Give a basic explanation of what study participation would entail including the number of visits and essential procedures>.  Now that I've given you a basic idea of what the joining the study would look like, what questions do you have?  Are you still interested in being a part of the study?  **IF NO/NOT INTERESTED**, Okay, thank you for your time. **End call.**  **IF YES and SCREENING/ Eligibility (i.e. finding out if the potential participant’s situation meets criteria to participate in the study) IS INCLUDED, GO TO STEP 3**  **IF YES and SCREENING IS NOT INCLUDED, GO To STEP 4** |

**Step 3: Assessing Eligibility**

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| **STEP 3a**  **IF YES to eligibility questions** | Great, thanks. Please feel free to stop me any time if you have any questions**.**  **<Fill in appropriate screening questions according to your study requirements, i.e. are you over 18 years old?>**  1) [Question 1]?  2) [Question 2]?  **Meets criteria** Based on your answers, it appears that this study might be a good fit for you.  **To Schedule a future consent conference on the phone or in- person**  **GO TO STEP 4 to schedule a consent conference**  **To continue and complete presenting the study over the telephone**  **GO TO STEP 5**  **DOES NOT meet criteria** Unfortunately, this study is not a good fit for you. (If possible add a positive, e.g. “You are too healthy for this study.”) For scientific reasons we are not allowed to include people in the study who have/don’t have [insert criteria].  We may have other studies that you might qualify for. Would you be ok with us contacting you in the future to discuss these other studies? **Record permission for future contact.**  We appreciate your interest. Thank you for taking the time to talk with me today.  **End call.**  **MAY NOT meet criteria** Because [criteria] might not fit with the scientific rules for this study, I’m not  sure if this study will be a good fit for you. I will need to check with Dr. XX to be sure. [If appropriate] Let’s continue with our conversation and I will call you to let you know what Dr. XX says about this issue. |

**Step 4. Scheduling a Consent Conference [in person or over the phone]**

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| **Step 4a**  **Scheduling Face-to-Face** | Let’s find a time for you to have a detailed [phone or in-person] conversation with a research team member. What day and time works best for you [or we have XX dates available]?  **Continue to STEP 5** |
| **Step 4b**  **If sending information to subject ahead of consent conference** | Before meeting with a research team member, I’d like to send you some study information to review, including a consent form.  Could I please get/confirm [if already in the database] your mailing address? [Record address in the database]  And your home phone number is…? [Record home number in the database]  Do you have a cell phone or alternate number? [Record phone in the database]  Which is the best number to reach you at? [Record phone preference in the database]  **Ensure that this is approved by the Institutional Review Board to record**  Do you have an email address you would like us to use? [Record email address in the database]  To whom does this email address belong to? [e.g., family, parent, work] [Record name/owner in database]  Would you prefer to receive the forms and information via postal mail or email? [Record preference in database]  Would you like to receive a reminder call or email before their meeting?  Great. So just to confirm, [review any study specific information such as directions and parking etc].  **Continue to STEP 5b** |
| **5c Confirm Information** | Cover logistic details such as directions, parking, what to bring, etc.  Thanks again for your interest in XX study. Are there any other questions I can answer for you?  Again, my name is \_\_\_\_\_\_\_\_ (first name). If you have any questions or concerns before the meeting, please feel free to call me at \_\_\_\_\_\_. We look forward to seeing you on \_\_\_\_\_\_\_ (meeting date) at (meeting time). Thanks for your time today.  **End call.** |

**Step 5. Presenting the Study in Full**

**\*\*\* Step 5 is only appropriate if you have prior IRB approval to conduct consent processes via telephone. \*\*\***

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| **Step 5a Phone Consent** | Since you are interested in the study, the next step would be for me to walk through the consent form with you.  **Go through the consent form just as you would during an in-person process. Make sure you ASSESS YOUR COMMUNICATION using open-ended questions. See Best Practices BASICS for Consent Process.** |

**Step 6. Documenting Consent**

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| **STEP 6a**  **Document Consent** | **After all questions are answered, and the research staff feels confident that the participant understands the study. Have the participant sign and date the appropriate research forms and mail back the signed copies. Encourage them to keep the extra copy for their records.**  Please sign and date [list appropriate form] and mail the signed copy back to us. The second copy is for you to keep and reference.  **The person obtaining consent and the witness to the telephone consent should sign a copy of the consent form.**  **Once all the appropriate signatures are completed:**  Please [mail, fax, scan/email] the signed copy of the form back to us at [address]. Thank you very much for your time and for volunteering. The next step will be: XX [fill in as is study appropriate].  Thank you very much for you time. **End Call.** |

**Step 7. End Call**

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| **STEP 7** | Thanks again for your interest in XX study. Are there any other questions I can answer for you?  Again, my name is \_\_\_\_\_\_\_\_ (first name). If you have any questions or concerns before the meeting, please feel free to call me at \_\_\_\_\_\_. We look forward to seeing you on \_\_\_\_\_\_\_ (meeting date) at (meeting time). Thanks for your time today.  **End call.** |

**No research procedures can begin until you have received the signed copy from the participant in the mail or by email.**

**Once the signed version is received, staple it with the version signed by the person obtaining consent and witness.**