This document gives guidance on collecting data from participants by telephone when working remotely (at home). It outlines the issues to consider before contacting the participant, as well as the processes for collecting and recording the data. Before collecting data in this way, you should ensure that the study protocol allows for this type of data collection. If not, an amendment may be required; please check with your Sponsor.

1. Before contacting the participant – points to consider

   a) What data are you collecting?
   Is a whole questionnaire / form to be collected or just certain questions within the questionnaire / form? It may be sufficient to collect only the primary outcome data. It may depend on the time point/stage of the trial and whether this is a reminder, or a replacement call for an initial questionnaire. It may also depend on how long the questionnaire is. If the questionnaire is short, it might be reasonable to collect it all. If the questionnaire is long, try to collect only essential data.

   To decide these issues, please liaise with the trial's Project Management Group (PMG)/Chief Investigator (CI)/ Trial manager (TM).

   b) How are you collecting the data?
   Consider if sections of a questionnaire require set responses (e.g. all of the time, some of the time, none of the time etc), if so you may want to ask the participant to make a note of these responses before you ask the relevant questions.

   Before making the call, consider whether you are going to collect the data directly on to a database, via a copy of the questionnaire, on to a spreadsheet or in a notebook. This should have been agreed by the trial team on a study by study, or questionnaire by questionnaire, basis; although the method of documenting the data collected may change over time.
c) Length of phone call?
Is it reasonable to ask the participant to complete a large number of questions by telephone? Consider here whether participants are elderly, perhaps they are hard of hearing? If it is to be a long phone call, it might be best to arrange a suitable time in advance with the participant so you can ensure they do not feel rushed or distracted. Consider whether it would be easier to spread the data collection over a couple of calls, or it may be that you could collect the primary outcome by phone and the remainder online if they are happy to provide an email address (as long as online completion is already part of the protocol).

d) Security
In the UK use ‘141’ before dialling the participant’s telephone number so your telephone number remains anonymous. Consider however that some phones now will not accept calls from withheld numbers, and then decide whether or not you are happy for your personal number not to be withheld.

e) Use of other technologies
Contact made by text/email could be used to arrange a subsequent phone call. Please note that a protocol amendment, and Sponsor and Ethics (REC) approval, may be required if there is a change to the method of participant contact.

2. Making the phone call – if call is answered
• Ask to speak to the participant.
• State clearly who you are and that you are phoning from the <<XXX>> trial office.
• Let the participant know that the <<XX>> questionnaire timepoint has been reached and say you are ‘wondering how they are getting on’.
• With this approach the participant will generally start to chat and tell you how they are. Ask the participant if they would be happy to complete a questionnaire by telephone. Ensure you let the participant know how long this will take (might be a good idea to practice with one of your colleagues to estimate how long it might take; refer to section 1c). Let the participant know that this will be instead of receiving and completing the questionnaire by post.
• When you are speaking to the participant, it may be worth checking which contact details you already have for them (possibly on a trial database) and whether they are still correct and/or whether there are any additional contact details to add (e.g. mobile number, email address). If there are changes then these need to be updated accordingly.
• Once the questionnaire has been completed, thank the participant for their time and, if relevant, let them know when their next questionnaire will be due; and that it might be by telephone, post, email or text. If using email or text, ensure you have the appropriate approvals in place.
• If the participant is not happy to answer questions by telephone, thank the participant for their time and end the call. You may need to consider updating the participant’s contact preferences if he or she does not want to be contacted by phone.
3. Making the phone call – if call is not answered

Listed below are various scenarios to consider, some of these might be documented in the trial protocol otherwise they should be agreed with the trial’s PMG/CI/TM. *Note: it may be helpful when making multiple attempts at a call to try calling on different days and at different times of the day as participants may still be working or not at home.*

- Phone rang out and contact not made (a further X attempts should be made; *note: the number of attempts should be agreed with the trial team and may depend on whether this is the initial call or follow-up/reminder calls, or whether it is to collect primary outcome data*).

- Reached voicemail and message not left (a further X attempts should be made)

- Reached voicemail and message left. Please agree with your trial team as to whether you will use this option. Please note that ‘leaving a message’ may count as making contact and should only be used for the final attempt of that call. If you do, ensure the message is clear, short and to the point. Let the participant know who you are, why you are calling and if you will call back or are asking the participant to call you back.

  *Example message might be:*

  ‘This is a message for <<Participant name>>. I am calling from the <<XX>> Trial Office at the <<University of XXXX>>. You have reached the <<timepoint>> in the trial and would like to hear how you are getting on. I will call back again / please would you be able to call the trial office on <<01XXX XXXXXX>>. Thank you.’

- Phone number invalid/incorrect/wrong number (this can be followed up with site/GP/best contact). It may be worth considering following up by email if you have the participant’s email address and in the UK it’s also always worth checking ‘The Phone Book from BT’ ([https://www.thephonebook.bt.com/person/](https://www.thephonebook.bt.com/person/)).

- Contact made and primary outcome collected (record data collected)

- Contact made and participant asked to be called back – time given (follow-up and record any actions taken)

- Contact made and participant asked to be withdrawn from completing further questionnaires and/or telephone contact only (update participant's change of status appropriately) but they are happy to remain in the trial.

The result of each attempted call should be recorded ideally in a trial database with a note made as to whether the data was collected by phone rather than by post (or in a trial specific call log if the database does not have this functionality).

**Other points to consider**

- When making calls from a personal number, we would recommend withholding the number. We have not experienced many issues with this. However, a few participants have a call barring service that blocks calls from withheld numbers – and a personal decision can then be made as to whether the call is re-tried without withholding the outgoing number. If a call is made to a mobile number without withholding the outgoing number, a few participants have sent a text asking who is calling, and at this point, we have sent a text back explaining that we are calling from the <<XX>> study office to find out how they are doing.
• When speaking to the participant, they may ask for your advice about a clinical matter or medical treatment they have received. Advise the participant to contact their GP / hospital consultant (as appropriate) if they have concerns. It may also be appropriate to say that you will contact the trial's Chief Investigator (CI), Principal Investigator (PI) and/or Research Nurse (RN), depending on the query, for advice and will get back to them.

• Participants may say that they do not wish to complete a questionnaire as they have not had treatment or have no symptoms / problems. Please remind the participant that, despite this, it is important to find out how participants are, and how participants have been getting on since they joined the trial. It is important to collect data regardless of how the participant is doing (it may be useful to have a couple of scripted phrases at hand to address potential different responses that the participant may give).

• Sometimes a participant asks us not to send them any further questionnaires. Thank them for their help with the study to date and reassure them that further questionnaires will not be sent and confirm that they are still happy to remain in the trial; each trial will need to think about what this means? Is it about routine data, extraction of data from medical records etc.? Update the participant's trial record as appropriate.

MORE INFORMATION

1. If you have any questions contact info@trialforge.org.