## **CASE STUDY**

## **Conversation Guide for conducting survival follow-up calls**

Many clinical trial protocols include a line item that study staff should conduct follow-up survival calls with participants at various timepoints, often twice or once a year, after the participant’s treatment period has finished. The data collected from these calls is commonly limited to participant survival. Follow up calls can be awkward for staff to conduct and potentially abrasive for participants to receive due to the long time between calls, staff turnover, and the delicate nature of the primary question. The protocol often does not have guidance for staff for how to conduct these calls.

A haematologist at Royal Prince Alfred Hospital saw this need and developed an optional conversation guide for their clinical trial staff undertaking survival follow up calls. The aim of this guide was to make these conversations easier by providing staff with a scaffolding of questions they might ask, and information that they might share with the participant. A secondary aim was to seek feedback on the participant’s experience while involved in the study.

Before conducting the call, staff are advised to review any information about the participants’ health status on file. For instance, if the participant has died, their family may have reported this to the study team, or this may have been shared with the study through the participants medical records. Staff should also find out if there are any updates about the progress or results from the project that they can share with participants, or when such updates might be available.

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| **Topic** | **Description** |
| Introduction | I’m [staff name] calling from [employer]  This is a scheduled call for [project name] that you participated in from [start date to end date]  The purpose of this call is to check on how you are going now that your active treatment in the trial was some time ago |
| Activities of daily living (ADL) | Has anything changed in your ability to conduct your activities of daily living since we last spoke?  Is there anything we can do to help? (e.g. booking a checkup appointment) |
| Study update | [If publicly available or provided by the sponsor, and the participant is interested, provide information about the outcome or status of the study drug] |
| Time during the study | What was your overall experience during the active treatment period of the study?  Did/do you feel supported by the study team?  Do you feel the study has had a positive/negative impact to your quality of life? |
| Questions or feedback | Is there anything we can do to assist you with your current treatment (e.g. hospital logistics)?  Is there anything we could do to improve the clinical trial experience for other participants? |

Staff reported that using a conversation guide made it easier for them to develop or maintain trusting relationships with the participants and made it easier for participants to feel comfortable with the clinical staff.

For sites looking to implement a similar guide, care should be taken to make sure that questions are limited to ones that the staff conducting the calls are able to respond to in the scope of their role. The example questions listed here were relevant to the role of the clinical staff conducting these calls in the original project. Questions should also be tailored to the needs of the research project and the capabilities of the participants.