PROMISE-Carers Participant Information Sheet & Consent Form

Title	PROMISE Optional Partners and Carers Substudy
Short Title	PROMISE-Carers
Coordinating Principal Investigator	Professor Penelope Webb
Site Principal Investigator	*[Institute Principal Investigator]*

1. What is the PROMISE Partners and Carers study about?

We are inviting you to take part because you have been nominated as the partner/carer of someone who is participating in the PROMISE Trial.

This document tells you about the PROMISE-Carers study and what is involved. This will help you decide if you want to take part.

Please read this information carefully and ask questions about anything that you don't understand or want to know more about (see Section 12 for who to contact). Before you decide whether or not to take part, you might like to talk about it with a relative, friend or your doctor.

Participation in this research is voluntary. If you do not want to take part, you do not have to.

2. What is the purpose of this research?

During clinical appointments there is not always much time for patients and their doctors to discuss how things are going. These discussions are usually the only opportunity for the doctors to find out how the patient is feeling. We are testing a new method of monitoring people during and after their cancer treatment. We hope this may help their doctors work out what is most important for them and that this will improve how they feel and may also make things easier for their partners/carers.

The PROMISE study is being conducted by QIMR Berghofer Medical Research Institute with the Queensland University of Technology, the University of Queensland, the Princess Alexandra Hospital, Royal Brisbane and Women's Hospital, Gold Coast Hospital and Townsville Hospital.

3. What will I have to do if I agree to take part in the study?

If you agree to participate, you will first be asked to complete an electronic questionnaire to tell us a bit about yourself, your relationship to the PROMISE study participant who nominated you for this study, and your wellbeing. You will then be asked to complete similar questionnaires 3, 6, 12, 18 and 24 months after joining the study. This is so that we can find out about your quality of life and need for support. At each time-point, you will be sent an electronic link to the questionnaire by email or text message and it will take about 20 minutes to complete. If you do not complete a questionnaire within one week of being sent the link a research assistant from QIMR Berghofer Medical Research Institute will send you a reminder or contact you by telephone to help you complete it. This information will go to the researchers at QIMR Berghofer. It will be stored separately from your personal information using a unique Participant ID number.

This information will not be reviewed by a health practitioner so you should contact your doctor if you have any concerns about your health. However, if you do report something on your questionnaire that suggests you are severely distressed we will contact you or your general practitioner, if you nominate them on the consent form.

Optional interview: A member of the research team may contact you to invite you to take part in a one-off, individual interview to find out about your experience of participating in the trial. This interview is completely voluntary and can be stopped at any time. It will be audio-recorded to allow the research team to reflect and analyse the interview data later. The interview should take no longer than about 30 minutes.

4. Do I have to take part in this research project?

No, you do not. Participation in any research project is voluntary so if you do not wish to take part, you do not have to. If you do decide to take part, you will be asked to sign the Consent Form at the end of this Information Sheet and will be given a copy of this to keep. If you decide to take part but change your mind later, you are free to withdraw from the project at any stage.

5. What are the possible benefits of taking part?

We cannot guarantee that you will personally receive any benefits from this research. Possible benefits for partners/carers of participants randomly assigned to the intervention group include improved health and experience of care from the new approach that we are testing. Those assigned to the control group may also benefit as we will be monitoring your responses to the study questionnaires and will take action if we identify any major concerns.

6. What are the possible risks and disadvantages of taking part?

There are minimal risks associated with participation in this project.

7. What if I withdraw from this research project?

If you decide to withdraw, please talk to a member of the research team so that we can arrange this. If you withdraw we will not ask you to complete any more study questionnaires but we will keep the information we have already collected about you unless you ask us to destroy this.

8. What will happen when the research project ends?

We will not contact you again after the 2 year research period for this study. If you would like to receive a copy of the results at the end of the study, please indicate this on the consent form or contact the study team (see Section 12) and we will send this with our compliments.

9. What will happen to the information collected about me?

By signing the consent form you consent to relevant research staff collecting and using your personal information for the research project. Any information that can identify you will remain confidential. All of your data will be coded with a unique Participant ID number and stored separately from personal information, such as your name and address. No personal information will be used outside this research study or in any reports from the study.

All the information we collect will be kept for at least 15 years after the end of the study. After this your identifying information will be permanently deleted from the computer system and any hard copies will be destroyed. This will ‘de-identify’ the data and make it impossible for anyone to link the information back to you. Your information will only be used for the purpose of this research project and it will not be disclosed without your permission, except as required by law.

Any information obtained during the research project is subject to inspection (for the purpose of verifying the data) by the relevant authorities. This includes authorised representatives of the Sponsor, Professor Penelope Webb, Princess Alexandra Hospital, or as required by law. By signing the Consent Form, you authorise release of, or access to, this confidential information for the relevant study personnel and regulatory authorities as noted above.

The results of this research project may be published and/or presented in a variety of forums,but information will be provided in such a way that you cannot be identified, except with your permission. For example, we will only report results for groups of people and not for individuals

In accordance with relevant Australian and Queensland privacy and other relevant laws, you have the right to request access to your information collected by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

10. Who is organising and funding the research?

This research project is being conducted by Professor Penelope Webb at the QIMR Berghofer Medical Research Institute and the PROMISE Study Group. It is funded by a research grant from the Cancer Council Queensland and QIMR Berghofer. No member of the research team will receive a personal financial benefit from your involvement in this research project.

11. Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the Metro South HREC (at the Princess Alexandra Hospital).

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2018)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

12. What if I have a question or want to make a complaint about the study?

If you want any further information concerning this project you can contact one of the following:

For general questions about the study:

- The Principal Investigator – Professor Penelope Webb (07) 3362 0281 or penny.webb@qimrberghofer.edu.au
- The Project Manager – Ms Karen Martin (07) 3845 3550 or karen.martin@qimrberghofer.edu.au or Freecall 1800 222 600

If you wish to discuss the study with someone who is not directly involved, particularly in relation to matters concerning complaints about the conduct of the study, or your rights as a participant, you can contact:

- Metro South Hospital and Health Service Human Research Ethics Committee (EC00167) Contact: Metro South HREC Coordinator 07 3443 8047 or MSH-Ethics@health.qld.gov.au
- *[Institute Name]* Governance Office: *[Add name, phone number & email]*

STUDY ID ☐

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Declaration by Participant

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

- I freely agree to participate in this research project as described and understand that I am free to withdraw at any time.
- I understand that I will be given a signed copy of this document to keep.

Please also indicate below whether you are willing to be contacted for a 30 minute interview or about future research studies. Also indicate if you would like us to send you a copy of the main results at the end of the study (these will be results for the groups, individual results will not be available).

I agree to be contacted for a 30 minute interview	Yes ☐	No ☐
I agree to be contacted for future research	Yes ☐	No ☐
I would like a copy of the main study results	Yes ☐	No ☐

If the information I provide suggests a potential health concern, I wish to be informed via the following medical practitioner:

_____ (name & address)

Name of Participant (please print) _____

Signature _____ Date _____

Declaration by Researcher

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name (please print) _____

Signature _____ Date _____

Note: All parties signing the consent section must date their own signature.