PROMISE Participant Information Sheet & Consent Form

[Insert site name]

Title	**P**atient **R**eported **O**utcome **M**easures in cancer care: a hybrid effectiveness-**I**mplementation trial to optimise **S**ymptom control and health service **E**xperience
Short Title	**PROMISE**
Protocol Number	*[Protocol Number]*
Project Sponsor	QIMR Berghofer Medical Research Institute
Coordinating Principal Investigator	Professor Penelope Webb
Site Principal Investigator	*[Institute Principal Investigator]*

1. Would you like to take part in the PROMISE trial?

We are inviting you to take part because you are starting treatment for cancer and we want to test a new way to monitor patients during and after their cancer treatment. This Information Sheet tells you about the trial and it will help you to 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 13 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 don't wish to take part, you don't have to. You will receive the best possible care whether or not you participate.

2. What is the purpose of this research?

During normal clinical appointments there may not be enough time for you and your doctors to discuss how things are going and how you are really feeling. We want to test a new way of monitoring people during and after their cancer treatment.

This will involve people filling out a quick electronic 'checklist' about their current symptoms at home before attending their hospital appointments. By having this information beforehand, the doctors will have a better understanding of an individual's needs and what is most important for them in their ongoing treatment and care. The aim is to improve how people feel and reduce the chance that they will have bad symptoms or side-effects from their treatment.

This research 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 does participation in this research study involve?

Sometimes we need to compare different treatments or procedures to find out which is the best. To do this, we put people into groups and give each group a different treatment. We can then compare the groups to see if one treatment is better than the other. To make sure the groups are the same, each participant is put into a group by chance (random). This is called a randomised controlled study and it is designed to make sure we can interpret the results in a fair and appropriate way and to avoid doctors or participants jumping to conclusions about what is best.

In the PROMISE study, we will randomly allocate about 580 participants to use either the new electronic symptom checklist (the PROMISE group) or to normal best-practice care (the USUAL CARE group). We will follow everyone for up to five years to compare the two groups.

If you decide you would like to take part, you will be asked to sign the Consent Form at the end of this document and the separate Services Australia Consent Form. By signing them you are telling us that you:

- Understand what participation in the PROMISE study will involve
- Consent to take part in the study as described
- Give permission for the research team to access your medical records during the study
- Consent to the use of your personal and health information as described.

There are no costs associated with participating in this research project, nor will you be paid.

4. 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 about yourself and how you are feeling. You will then be randomly allocated to one of the two study groups: PROMISE or USUAL CARE.

- If you are randomly allocated to the **PROMISE** group, a study nurse will show you how to fill out the electronic 'checklist'. You will then receive an electronic link via email or text message every 1-2 weeks or once a month, depending on the hospital you are attending, so that you can complete the checklist. Your answers to the questions in the checklist will go to your cancer doctors to help them plan your care. You will also be able to see your own answers and how they have changed over time.
- If you are randomly allocated to the **USUAL CARE** group you will continue to receive the current best-practice care.

Questionnaires: Everyone who takes part in the PROMISE study will be asked to complete a questionnaire at 3, 6, 12, 18 and 24 months (two years) after joining the study. This is so that we can find out about your quality of life and experiences of care. You will be sent an electronic link to the questionnaire by email or via a text message and it will take about 20 minutes to complete. If you have not completed the 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 directly to the researchers at QIMR Berghofer and will be stored separately from your personal information using a unique Participant ID number. It will not be reviewed by a health practitioner and will not go to your healthcare team so you should contact your treating doctors 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 pass this information on to your treating doctors.

Health data: Everyone will be asked to give consent to allow the researchers access to their medical records held by public and private hospitals and health services during the two year research period and for up to 3 years after this (a total of 5 years). This will include information from the Queensland Hospital Admitted and Non-Admitted Patient Data Collections (QHAPDC, QHNAPDC) and the Emergency Department Collection (EDC) held by Queensland Health.

You will also be asked to sign a separate consent form authorising the study to access your complete Medicare Benefits Schedule (MBS) and Pharmaceutical Benefits Scheme (PBS) data as outlined in the Services Australia consent form. Medicare collects information on your doctor visits and the associated costs, while the PBS collects information on the prescriptions for medications that you have filled at pharmacies. This consent form will be sent securely to Services Australia which holds MBS and PBS data confidentially.

We ask for permission to access this health information so that we can measure the long-term health effects of the PROMISE intervention after the end of the two year research period and to assess whether the intervention is cost-effective to the healthcare system. All of this information

will be stored securely on a server at QIMR Berghofer and will be identified only by your unique Participant ID number.

There will also be 3 additional opportunities for involvement in this project, as follows. These are all optional.

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

(ii) PROMISE–Carers: We know that it can also be hard for partners/carers when their loved one has cancer. If you agree to take part in the PROMISE study, we will invite you to nominate your partner or someone else who is close to you and gives you help, to take part in the PROMISE-Carers study. If they agree to take part, we will send them electronic questionnaires to complete at the same time that you complete your own questionnaires. *This is optional* – you do not have to nominate anyone and, if you do nominate someone, they do not have to take part. We will give them a separate Information Sheet explaining what their participation would involve.

(iii) PROMISE–Genetics: If you agree to take part in the PROMISE study you may also be invited to provide two small blood samples for genetic research. *This is optional* and you will be given a separate Information Sheet that will explain what it is all about.

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

No, you do not have to take part in the PROMISE Study. *Participation in any research project is voluntary* so if you do not wish to take part, you do not have to. You will still receive the best possible care whether or not you take part.

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 for your own records. If you decide to take part but change your mind later, you are free to withdraw from the project at any stage.

Your decision whether or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with *[Institution]*.

6. What are the possible benefits of taking part?

We cannot guarantee that you will personally receive any benefits from this research; however, possible benefits for those randomly assigned to the PROMISE group include improved health and experience of care as a result of the new approach that we are testing. Participants randomly assigned to the USUAL CARE group may also benefit because we will monitor all responses to the study questionnaires and will take action if we identify any major concerns.

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

There are minimal risks associated with participation in this project.

It is possible that you may experience some psychological distress because the questionnaires cover personal questions. If you do become upset as a result of the research you should contact the research team (see Section 13) or talk to your doctors who will be able to arrange appropriate help. This help will be provided by qualified staff who are not members of the research team.

8. What if I withdraw from this research project?

You can withdraw from any aspect(s) of the project at any time; for example, if you do not want to complete any more questionnaires or no longer want to allow access to your MBS and PBS data. If you withdraw, you will still receive your regular healthcare at *[Name of Institution]*.

If you decide to withdraw from a part or all of the study, 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; however, we will keep the information we have already collected about you and we will continue to collect information from your medical records and by linkage to other health databases (Queensland health and Services Australia) unless you ask us to stop this and/or to securely destroy the information we have already collected.

9. What will happen when the research project ends?

We will not contact you again after the 2 year research period but we will continue to collect information from your medical records and Queensland Health for up to 3 years after this (a total of 5 years) including the data mentioned in section 4. Your ongoing care will continue according to your hospital's policy. If you would like to receive a copy of the results at the end of the PROMISE study, please indicate this on the consent form or contact the study team (see Section 13) and we will send this with our compliments.

10. 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, including MBS and PBS information, will be coded with a unique Participant ID number and stored separately from personal information, such as your name and address. It will be stored on a secure server at QIMR Berghofer Medical Research Institute and will only be accessible to approved study personnel. 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. Data will be destroyed securely by the IT Department at QIMR Berghofer according to their standard protocols. In addition to this research project, we may also use your information for future projects related to cancer. Any such projects will have to be approved by the relevant scientific and ethics committees. Your information will not be disclosed to anyone else without your permission, except as required by law.

Your health records and any information obtained during the research project are subject to inspection (for the purpose of verifying the data) by the relevant authorities. This includes authorised representatives of the Sponsor, Professor Penelope Webb, *[Institution]*, 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.

Information about your participation in this research project will be recorded in your health records.

The results of this research project may be published and/or presented in a variety of forums but information will only 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.

11. 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.

12. 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.

13. 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

To talk to someone at your hospital:

- The Site Principal Investigator – *[Add name & phone number]*
- The Site Nurse / Trial Coordinator – *[Add name & phone number]*

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]*

If you have a privacy complaint in relation to the use of your MBS/PBS data you should contact the Office of the Australian Information Commissioner. You will be able to lodge a complaint with them.

Website: www.oaic.gov.au
Telephone: 1300 363 992
Email: enquiries@oaic.gov.au
Mail: GPO Box 5218, Sydney NSW 2001

PROMISE Consent Form

Title	**P**atient **R**eported **O**utcome **M**easures in cancer care: a hybrid effectiveness-**I**mplementation trial to optimise **S**ymptom control and health service **E**xperience
Short Title	**PROMISE**
Protocol Number	*[Protocol Number]*
Coordinating Principal Investigator	Professor Penelope Webb
Site Principal Investigator	*[Institute Principal Investigator]*

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 without affecting my future health care.
- I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to the project team concerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential.

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 ☐

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.