**NOTE: You should delete any headings and sections that are not relevant to your study and/or modify paragraphs so that they are relevant to your study.**

**Participant Information Sheet/Consent Form**

|  |  |
| --- | --- |
| **Title** | *[Project Title]* |
| **Project Number** | *[Insert Peter Mac Ethics Project number]* |
| **Project Sponsor** | Peter MacCallum Cancer Centre *[Insert correct Project Sponsor if not Peter Mac]* |
| **Principal Investigator** | *[Insert Principal Investigator name only]**DO NOT LIST ASSOCIATE INVESTIGATORS* |

**1 Introduction**

You are being invited to take part in a research project that *[finish sentence with a plain language explanation of purpose of the project]*. You are being invited to take part because *[finish sentence with the reason for invitation e.g. you are currently undergoing treatment for …]*.

This Participant Information Sheet/Consent Form tells you about the research project. Please read this information carefully. Ask questions about anything that you don’t understand or want to know more about.

Participation in this research is voluntary. If you don’t wish to take part, you don’t have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage. Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your care or your relationship with staff or the Peter MacCallum Cancer Centre.

If you decide you want to take part in the research project, you will be asked to sign the consent section and you will be given a copy of this Participant Information and Consent Form to keep.

**2 What is the purpose of this research?**

*Briefly describe the following aspects of your project in simple terms and in only a couple of sentences for each point:*

*• Aim of the project and its significance*

*• How many people will be taking part in the project overall and at this site*

*• If applicable, the size or scope of a project e.g. number of hospitals or countries involved*

*• If applicable, whether the project involves researchers from a number of organisations working in collaboration*

*Where the research is for the purpose of obtaining a degree or other educational qualification:*

The results of this research will be used by the researcher *[insert name of researcher]* to obtain a *[insert full name of degree]* degree.

*Where the research project is funded by a grant:*

This research has been funded by *[insert name of granting body]*.

*Where the research is being coordinated outside the institution:*

This research is being conducted by *[insert name of collaborative research group or other]*.

**3 What does participation in this research involve?**

*Include information and clear explanation of the following:*

*⮞ Procedures:*

*• Nature, number, timing and time commitment of visits and questionnaires*

*• Nature of any follow-up*

*• Duration of participant’s involvement (including follow-up)*

*• Duration of the research project (if this is different from their involvement)*

*• Whether there are different groups e.g. case/control groups, different types of focus groups*

*⮞ The commitment required by the participant*

*⮞ Access to personal records that may be required*

*⮞ Whether any part of the research project will be recorded (video/audio)*

*⮞ Details on the use of interpreters in the consent and/or data collection process*

*⮞ Venue details and a statement whether participants may choose the venue*

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

*Provide information on how the participant will find out about the success of the project. State how, and approximately when, participants will be provided with a summary of the results when the research project is completed.*

**4 What are the possible risks and disadvantages of taking part?**

*Provide information on the possible risks with taking part in this research project.*

*Psychological distress*

You may feel that some of the questions we ask are stressful or upsetting. If you do not wish to answer a question, you may skip it and go to the next question, or you may stop immediately. If you become upset or distressed as a result of your participation in the research project, the research team will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified staff who are not members of the research team. This counselling will be provided free of charge.

*Group discussions*

Whilst all care will be taken to maintain privacy and confidentiality, you may experience embarrassment if one of the group members were to repeat things said in a confidential group meeting.

**5 What if I withdraw from this research project?**

If you do consent to participate, you may withdraw at any time. If you decide to withdraw from the project, please notify a member of the research team.

You should be aware that data collected up to the time you withdraw will form part of the research project results. If you do not want your data to be included, you must tell the researchers when you withdraw from the research project.

*OR where appropriate, explain that if a participant withdraws part-way through a research project that data collected to that point may not be able to be deleted.*

**6 What will happen to information about me?**

By signing the consent form you consent to the research team collecting and using personal and health information about you for this research project. The personal information that the research team collect and use is *[insert types of information, e.g. information from questionnaires]*.

*Information should be provided regarding the following:*

*• Whether the data collected or used is individually identifiable, re-identifiable (coded) or non-identifiable*

*• Where the data will be kept and who will have access to it e.g. only the project team*

*• How long it will be stored and what will happen to the data at the end of the storage period*

*If it is likely that additional health information relating to participants will be sought from their health records, the following should be included:*

Information about you may be obtained from your health records held at this and other health organisations for the purpose of this research. By signing the consent form you agree to the research team accessing health records if they are relevant to your participation in this research project.

*If it is anticipated that the results will be published include the following paragraph:*

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your express permission.

*Indicate whether the participant can access their own information/data.*

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

**7 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 HREC of the Peter MacCallum Cancer Centre.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2023)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

**8 Further information and who to contact**

The person you may need to contact will depend on the nature of your query. If you want any further information concerning this project or if you have any problems which may be related to your involvement in the project, you can contact the researcher on *[Phone number]* or any of the following people:

*List the names and contact phone numbers of other appropriate persons involved in the project including researchers and study coordinators.*

 **Research contact person**

|  |  |
| --- | --- |
| Name | *[Name]* |
| Position | *[Position]* |
| Telephone | *[Phone number]* |
| Email | *[Email address]* |

The details of the Peter MacCallum Cancer Centre complaints person are:

**Complaints contact person**

|  |  |
| --- | --- |
| Position | Consumer Liaison |
| Telephone | (03) 8559 7517 |

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

|  |  |
| --- | --- |
| Reviewing HREC name | Peter MacCallum Cancer Centre Ethics Committee |
| HREC Executive Officer | Ethics Coordinator |
| Telephone | (03) 8559 7540  |
| Email | ethics@petermac.org |

**Reviewing HREC approving this research** **and HREC Executive Officer details**

**Consent Form**

|  |  |
| --- | --- |
| **Title** | *[Insert Project Title]* |
| **Project Number** | *[Insert Peter Mac Ethics Project number]* |
| **Project Sponsor** | Peter MacCallum Cancer Centre *[Insert correct Project Sponsor if not Peter Mac]*  |
| **Principal Investigator** | *[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 in the project.

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 during the project without affecting my future care.

I understand that I will be given a signed copy of this document to keep.

|  |
| --- |
|  |
|  | 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 of Researcher† (please print) |  |  |
|  |  |
|  | Signature |  |  Date |  |  |
|  |

† An appropriately qualified member of the research team must provide the explanation of, and information concerning, the research project.

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