

**Mater Patient Information and Consent Form (PICF) template**

**STOP!** This document is:

* A basic PICF template most suitable for LNR applications.
* For catholic wording guidelines, please refer to our Guidelines for drafting PICF available via this [link](https://www.materresearch.org.au/MaterResearch/media/Content/Researchers/Guidelines-for-drafting-PICF-V3-02072021_1.pdf).

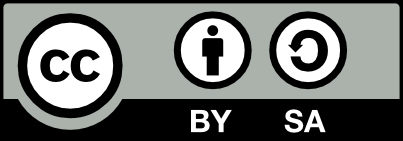
* If your project is **Greater than Low Risk**, please refer to the **NHMRC PICF** templates available via this [link](https://www.nhmrc.gov.au/research-policy/ethics/ethical-issues-and-resources) for further guidance.

***All light blue italicized text in the template document is instructive information only and should be removed from the template prior to submission.***

* Highlighted text indicates where you should enter study specific information. Please ensure you remove the highlighting once appropriate text has been entered.
* Ensure you update the footer of the document with the **correct document title, version number and date** of your final document.
* Texts in dark blue font are sample wordings that can be used in this PICF.

**Investigators can customise this document for their research project as appropriate.**

**NOTE:** The PICF template starts on page 2. Please **delete this page** when your document is complete and ready for submission with your research ethics application.



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Mater Misericordiae Ltd – Mater Research 2021

**Participant Information Sheet and Consent Form**

**Mater Misericordiae Limited**

|  |  |
| --- | --- |
| **Title** | XX |
| **HREC Number** | HREC/MML/XXX NOTE: This is the project number of your ERM application |
| **Coordinating Principal Investigator** | *NOTE: CPI is only application for multi-centre research. Remove if not* |
| **Principal Investigator** | NOTE: There should only be 1 PI for a research study, all other investigators should be AI |
| **Location** | (i.e. Mater Hospital Brisbane) |

***NOTE: Remove any light blue italicized text, this is information text only.***

1. **Introduction**

You are invited to take part in this research project. This is because you have [Name of condition]. The research project will be conducted at [name of site/s] in conjunction with (name of other collaborators as appropriate and / or clinical department).

This Participant Information Sheet and Consent Form tells you about the research project. It explains the processes, tests and treatments involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don’t understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local 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 take part.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

• Understand what you have read

• Consent to take part in the research project

• Consent to have the processes, tests and treatments that are described

• Consent to the use of your personal and health information as described

You will be given a copy of this Participant Information Sheet and Consent Form to keep.

1. **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 study and its significance*
* *How your project intends to fill any gap in knowledge*
* *How it may contribute to care or education or research in the future,*
* *Any relevant background including what is already known*
* *Whether the research is for the purposes of obtaining a degree or other educational qualifications, is funded by a grant, or has sponsorship of some other sort.*

*Sample wording if research is to obtain a degree/ other education qualification:*

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

*Sample wording where the research project is investigator-initiated:*

This research has been initiated by the researcher, Dr/Professor [name].

*Sample wording where the research project is funded by a grant:*

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

1. **Why have I been invited to participate in this study?**

You are invited to take part in this research because [provide a brief description of the reasons for why the participant is invited in simple lay language. This section can include the inclusion criteria]

1. **Do I have to take part in this research?**

Participation in any research project is voluntary. If you do not wish to take part, you do not 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 routine care, your relationship with those treating you or your relationship with [Institution e.g. Mater Misericordiae Ltd.].

*Sample wording for general research project:*

If you do decide to take part, you will be given this Participant Information Sheet and Consent Form to sign and you will be given a copy to keep.

Sample wording for **survey only research** where access to medical records is **NOT** required:

If you do decide to take part, completion of the survey/questionnaire will be taken as your informed consent.

1. **What does participation in this research involve?**

*You should explain the study process, procedures and/or tasks, the number of times the task/procedure will be repeated, the amount of time required, and the purposes of the procedures should be clearly explained in lay terms. You can use visual aids such as tables, diagrams and images to make it easier for participants to understand the study requirements.*

***NOTE:*** *If your application involves access to medical records, this should be clearly stated here. It should be specified what type of information will be collected from the participants medical charts.*

1. **What are the possible benefits of taking part?**

*You should outline any definite benefits the participant might expect from taking part in the research. It is important, however, not to build up participant hope in this section. Reference to the potential benefit for future patients may be appropriate but should not be exaggerated.*

*Sample wording for research that may have a direct benefit to the participant:*

We cannot guarantee or promise that you will receive any benefits from this research; however, possible benefits may include [describe any likely benefits to participants or other people in the future].

*Sample wording for research with no direct benefit to the participant:*

You may not benefit directly from participating in this study, but you will be providing a valuable contribution to the scientific knowledge in this field.

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

*It should be explained in simple lay terms any possible harm that the participant may experience as a result of the research procedures/tasks. This section should use short uncomplicated sentences.*

*Things to consider when describing the possible risks and disadvantages:*

* *If applicable, state any non-medical risks (e.g. emotional distress, fatigue or potential risk to privacy)*
* *Include any services/support that is available in the event the research procedures might be upsetting to the patient*

1. **What will happen to my information?**

By signing the consent form, you consent to the research team collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. *[Insert how it will be confidential and, if it is identifiable, where it will be kept and who will have access to it].* Your information will only be used for the purpose of this research study and it will only be disclosed with your permission, except as required by law.

Information about you may be obtained from your health records held at [enter details of which health services records will be accessed] for the purpose of this research. By signing the consent form, you agree to the study team accessing health records if they are relevant to your participation in this research project.

If you withdraw from the study, we will not collect any more information about you. We would like to keep the information we have already collected about you to help us ensure that the results of the research project can be measured properly. Please let us know if you do not wish for any information to be kept.

1. **How will the results of the study be distributed?**

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 expressed permission.

You can indicate on the consent form if you wish to receive a lay summary of the study findings.

1. **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 reviewed and approved by the Mater Misericordiae Ltd HREC. This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

1. **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 medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the following person:

**Clinical contact person**

|  |  |
| --- | --- |
| Name |  |
| Position |  |
| Telephone |  |
| Email |  |

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

**Complaints contact person**

|  |  |
| --- | --- |
| Name | Mater Research Governance Officer |
| Telephone | 07 3163 3769 |
| Email | research.governance@mater.uq.edu.au |

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

This study has been reviewed and approved by the Mater Misericordiae Ltd Human Research Ethics Committee (EC00332). Should you wish to discuss the study in relation to your rights as a participant, or should you wish to make an independent complaint, you may contact the Liaison Officer or Chairperson, Human Research Ethics Committee, Mater Misericordiae Ltd Level 2 Aubigny Place, Raymond Terrace South Brisbane 4101 or telephone (07) 3163 1585, email: research.ethics@mater.uq.edu.au

**Consent Form**

|  |  |
| --- | --- |
| **Title** | XX |
| **HREC Number** | HREC/MML/XXX NOTE: This is the project number of your ERM application |
| **Coordinating Principal Investigator** | *NOTE: CPI is only application for multi-centre research. Remove if your study is not multi-centre* |
| **Principal Investigator** | NOTE: There should only be 1 PI for a research study, all other investigators should be AI |
| **Location** | (i.e. Mater Hospital Brisbane) |

*[Please refer to the ‘Guide to writing research protocols’ for other examples of wording and whether a ‘withdraw from consent’ form is also needed].*

**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 health care.

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

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | |
|  | Name of Participant  (please print) | |  |  |  |  |
|  | | | | | | |
|  | Signature |  | | Date |  |  |
|  | | | | | | |

*Under circumstances when participants are unable to read (see Note for Guidance on Good Clinical Practice CPMP/ICH/135/95 at 4.8.9) a witness to informed consent is required.* [This may or may not be necessary depending on your project]

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | |
|  | Name of Witness\* to Participant’s Signature  (please print) | |  | | |  |
|  | | | | | | |
|  | Signature |  | | Date |  |  |
|  | | | | | | |

*\*Witness is not to be the investigator, a member of the study team or their delegate. If an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.*

**Declaration by Study Doctor/Senior 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 Study Doctor /Senior Researcher†  (please print) | |  | | |  |
|  | | | | | |  |
|  | Signature |  | | Date |  |  |
|  | | | | | | |

† A senior member of the research team must provide the explanation of, and information concerning, the research project. [This may or may not be necessary depending on your project]

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

Please provide me with a research summary when this is available. □

Email address \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Form for Withdrawal of Participation**

|  |  |
| --- | --- |
| **Title** | XX |
| **HREC Number** | HREC/MML/XXX NOTE: This is the project number of your ERM application |
| **Coordinating Principal Investigator** | NOTE: CPI is only application for multi-centre research. Remove if your study is not multi-centre |
| **Principal Investigators** | NOTE: There should only be 1 PI for a research study, all other investigators should be AI |
| **Location** | (i.e. Mater Hospital Brisbane) |

*[This form may or may not be needed depending on your project]*

**Declaration by Participant**

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with Mater Misericordiae Ltd.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | |
|  | Name of Participant  (please print) | |  |  |  |  |
|  | | | | | | |
|  | Signature |  | | Date |  |  |
|  | | | | | | |

*In the event that the participant’s decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.*

|  |
| --- |
|  |

**Declaration by Study Doctor/Senior Researcher†**

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | |
|  | Name of Study Doctor /Senior Researcher†  (please print) | |  | | |  |
|  | | | | | |  |
|  | Signature |  | | Date |  |  |
|  | | | | | | |

† A senior member of the research team must provide the explanation of, and information concerning, the research project. [This may or may not be necessary depending on your project]

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