GUIDELINES FOR DRAFTING PARTICIPANT INFORMATION SHEET AND CONSENT FORM (PICF)

The National Health & Medical Research Council (NHMRC) National Statement on Ethical Conduct in Human Research, 2007 (Updated 2018) advises "*Respect for human beings involves giving due scope to people's capacity to make their own decisions. In the research context, this normally requires that participation be the result of a choice made by participants – commonly known as 'the requirement for consent'. This requirement has the following conditions: consent should be a voluntary choice, and should be based on sufficient information and adequate understanding of both the proposed research and the implications of participation in it*". The researcher/investigator is responsible for providing the participant, at his/her level of comprehension (generally no greater than English at the comprehension level of a 12-year-old person), with information about the research, purpose and background, why they have been chosen, risks and benefits.

This guideline has been prepared to assist researchers in developing Participant Information and Consent Forms (PICF) for research being conducted at Mater Misericordiae Ltd (MML). For research being conducted at other organisations please consult with the relevant Research Governance Office for specific site requirements regarding formatting, use of institutional logos etc.

General Information

The PICF contains both participant information and the accompanying consent form and should be a combined document.

- At Mater the first page of the PICF should be printed with the Mater Research logo in the header. Please liaise with the Mater Research Governance Office regarding further site formatting.
- Employ version control in the PICF footer to include version number, date and page numbering in the format of Page x of xx.

  e.g. Mater PICF Version 1 dated 01 January 2020 *Page 1 of 4*
- For Mater PICF's that have been based on a Master PICF the versioning should read; Mater PICF, version number and date based on Master PICF, version number and date.

  e.g. Mater PICF Version 1 dated 01 January 2020 based on Master Version 1 dated 01 December 2019 Page 1 of 4
- Where the MML HREC has reviewed the research, the following statement should be included in the PICF:

  > "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 HREC 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."

- Where an external HREC has reviewed the research, the following details should be included in the PICF:

Mater Research Governance

Name	Research Governance Officer
Telephone	(07) 3163 3769
Email	research.governance@mater.uq.edu.au

Note: A signed copy of the PICF must be given to the participant and the original signed document kept in the research file in line with MML Research Governance requirements.

Specific Guidelines on Research on Humans of a Reproductive Age

As a Catholic Health Care Service, Mater Misericordiae Ltd is committed to reflecting the Church's teaching regarding respect for the personal dignity of human life in all stages. In reproductive health matters the responsibility of Catholic health care is to give counsel which is both accurate and a witness to the teachings of the church. It is acceptable within the Catholic teaching to counsel a woman and/or her partner to avoid becoming pregnant when either the woman or her partner is undergoing treatment that might affect an embryo/foetus. It is also acceptable to include a comprehensive statement of the risks, and the period during which pregnancy must be avoided as a consequence of participation in a study.

Regarding studies that may involve participants who are able to conceive, the MML HREC places paramount importance on the welfare of the research participants, and the welfare of any potential or actual unborn children. This is particularly the case in studies of interventions, such as drugs, that have the potential for harmful effects to a developing fetus, and/or an unborn child. All women participating in studies involving drugs whose effect on the unborn child are unknown are required to have a pregnancy test prior to entering the study and to be informed they could potentially be excluded from the study.

Recommended Catholic Health Australia Template for Catholic Institutions for PICFs where pregnancy must be avoided

The effects of *[Name of investigational product]* on the unborn child and on the newborn baby are not known. Because of this, it is important that research project participants are not pregnant or breastfeeding and do not become pregnant during the course of the research project. You must not participate in the research if you are pregnant or trying to become pregnant, or breast-feeding. If you are female and child- bearing is a possibility, you will be required to undergo a pregnancy test prior to commencing the research project. If you are male, you should not father a child or donate sperm for at least *[number]* months after the last dose of study medication.

Both male and female participants must avoid pregnancy during the course of the research and for a period of *[number]* months after completion of the research project. Your study doctor will discuss effective methods of avoiding pregnancy with you.

[For female participants] If you do become pregnant whilst participating in the research project, you should advise your study doctor immediately. Your study doctor will withdraw you from the research project and advise on further medical attention should this be necessary. You must not continue in the research if you become pregnant.

[For male participants] You should advise your study doctor if you father a child while participating in the research project. Your study doctor will advise on medical attention for your partner should this be necessary.

Structure and Guidelines for the PICF for Adults

Templates, instructions and advice on different PICF requirements for different types of studies can be found on the NHMRC website for Standardised Participant Information and Consent Forms or National PICF. PICF templates are available and can be used for Genetic, Interventional, Non-Interventional and Health and Social Science Studies. It is not compulsory to use these templates however they are useful tools and accepted by the MML HREC and Research Governance office.

Structure and guidelines for the PICF for children/young people

Research involving children and/or young people raises particular ethical concerns. *"Researchers must respect the developing capacity of children and young people to be involved in decisions about participating in research."* (NS 2007, Updated 2018). Please refer to National Statement Chapter 4.2 if you are developing a research project that involves children and young people and to the NHMRC website for Standardised Participant Information and Consent Forms for PICF templates that can be used for Genetic, Interventional, Non-Interventional and Health and Social Science Studies for Parents and Guardians.

For paediatric information sheet and consent form templates, we recommend those templates designed by Research Ethics and Governance at The Royal Children's Hospital, Melbourne. This information is provided to you with permission from Research Ethics and Governance, The Royal Children's Hospital, Melbourne. Access to these templates is available at: http://www.rch.org.au/ethics/researcher-resources/

References

Australian Code for the Responsible Conduct of Research 2018 - NHMRC
Code of Ethical Standards for Catholic Health and Aged Care Services in Australia 2001- Catholic Health Australia
National Statement on Ethical Conduct in Human Research 2007 (updated 2018) – NHMRC