1 PURPOSE

This document describes the submission requirements and review pathways for the ethical review of research involving human participants, human tissue or human data at Peter MacCallum Cancer Centre.

2 SCOPE

This guideline applies to new project submissions and all post approval amendment submissions. It applies to both single and multi-centre reviews.

3 RESPONSIBILITY

It is the responsibility of researchers and other staff involved in the submission and review of research proposals to follow the procedures set out in this guideline.

It is the responsibility of the Human Research Ethics & Governance office staff to be aware of, and adhere to the procedures set out in this guideline.

4 PROCEDURE

4.1 Ethical Review Pathways for New Research Projects

Human research is research conducted with or about people, or their data or tissue. The appropriate review pathway for your human research project depends on the level of risk and the type of project.

Ethical review may be carried out for projects running at multiple Australian sites as a single ethical review for the multiple sites or ethical review may be carried out for projects for the Peter Mac site only.

To determine the appropriate review pathway first the risk involved must be assessed. Risk is defined as a potential for harm, discomfort or inconvenience. It involves (a) the likelihood that a harm (discomfort or inconvenience) will occur; and (b) the severity of the harm, including its consequences. The risk may be to participants and/or to others e.g. family members, social group. Both the type of risk and the level of risk must be considered. The types of risks are well described in chapter 2.1 of the *NHRMC National Statement on Ethical Conduct in Human Research 2007 (updated 2018)*.

Levels of risk:

- Negligible Risk: Research where there is no foreseeable risk of harm or discomfort and any foreseeable risk is no more than inconvenience.
- Low Risk: Research where the only foreseeable risk is one of discomfort.
- High Risk: Research where the risk is more serious than discomfort.

Research with more than a low level of risk must be reviewed by the full Ethics Committee.

Research involving no more than a low level of risk may be delegated for review by other pathways.

Quality assurance and evaluation activities may require ethical review if they contain triggers for consideration of ethical review as listed in *NHMRC Ethical Considerations in Quality Assurance and Evaluation Activities (2014)*.

New projects approved via delegation are notified to the Ethics Committee.

The various review committees, sub-committees and panels are described in SOP001 Ethics Committee.

Submitted projects will be allocated for review to the most suitable pathway by the Human Research Ethics & Governance office staff. Research involving a physical intervention or projects using human biospecimens must be submitted per 4.1.1 below.

4.1.1 Submission Requirements for Clinical Research Committee or Tissue Research Management Committee or Ethics Committee Review of Projects

Required documents and submission instructions: Please refer to the Peter Mac Human Research Ethics & Governance website http://www.petermac.org/research

For more information refer to SOP001: Ethics Committee

NOTE GOVERNANCE REVIEW REQUIREMENTS: Prepare and submit an Application for Site Specific Assessment in accordance with Guideline001. Please refer to the Peter Mac Ethics Committee Secretariat website http://www.petermac.org/research

4.1.2 Submission Requirements for Low and Negligible Risk Ethical Review Committee (LNRR-ERC) Review

Required documents and submission instructions: Please refer to the Peter Mac Human Research Ethics & Governance website http://www.petermac.org/research

For more information refer to Guideline003: Low and Negligible Risk Research Ethical Review.

NOTE GOVERNANCE REVIEW REQUIREMENTS: Prepare and submit an Application for Site Specific Assessment in accordance with Guideline001. Please refer to the Peter Mac Ethics Committee Secretariat website http://www.petermac.org/research

4.1.3 Submission Requirements for Clinical Audit and Quality Assurance

Required documents and submission instructions: Please refer to the Peter Mac Human Research Ethics & Governance website http://www.petermac.org/research

For more information refer to Guideline004: Divisional Review.

4.2 Ethical Review Pathways for Ongoing Research (Post-Approval)

If the Peter Mac Ethics Committee provided the ethical review for a project then all subsequent amendments to the project must be submitted to the Peter Mac Ethics Committee for review.

Amendments are reviewed as per the new research project review pathway. However for high risk projects the ethical review of amendments can be delegated to the Clinical Research Committee, Tissue Research Management Committee or the Out of Session Review Panel. Amendments that are only administrative in nature can be reviewed by the Ethics Committee Secretariat. Amendments approved via delegation are notified to the Ethics Committee.

Note: some amendments implicating patient safety may be eligible for review and approval as an Urgent Amendment as described in 4.2.2. below. Urgent Amendments approvals are ratified by the Ethics Committee.

When the most appropriate mode of review has been established, the proposal may be submitted in accordance with the instructions outlined below.

4.2.1 Amendments

Required documents and submission instructions: Please refer to the Peter Mac Human Research Ethics & Governance website http://www.petermac.org/research

For more information refer to SOP004: Monitoring of Ongoing Research.

NOTE GOVERNANCE REVIEW REQUIREMENTS: For multisite ethical review applications prepare and submit a Governance Amendment, if required, in accordance with Guideline001.

4.2.2 Submission Requirements for an Urgent Amendment

Required documents and submission instructions: Please refer to the Peter Mac Human Research Ethics & Governance website http://www.petermac.org/research

For more information refer to SOP004: Monitoring of Ongoing Research.

5 RELEVANT DOCUMENTS

POLICY 21.1.1	Responsible Conduct of Research
SOP001	Ethics Committee
SOP002	Ethical Review Administration
SOP004	Monitoring of Ongoing Research
Guideline001	Governance Review Requirements for Human Research
Guideline003	Low and Negligible Risk Research Ethical Review
Guideline004	Divisional Review

NHMRC National Statement on Ethical Conduct in Human Research 2007 (Updated 2018)

NHMRC Ethical Considerations in Quality Assurance and Evaluation Activities 2014

6 FURTHER INFORMATION

For enquiries related to this Guideline please email ethics@petermac.org

7 VERSION AND APPROVAL HISTORY

Date	Version #	Author; Owner and Authoriser; Summary of Changes
January 2020	2.0	Author: Dianne Snowden, Manager Human Research Ethics & Governance; Owner: Human Research Ethics & Governance; Authorised by: Manager Human Research Ethics & Governance Summary of Changes: Updated due to release of new application form: Quality Assurance (QA) VIC, by Victorian Department of Health and Human Services and discontinuation of LNR VIC application form.

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