1 PURPOSE

This guideline outlines the procedures related to the review and approval of research by the Low and Negligible Risk Research Ethical Review Committee (LNRR-ERC) and outlines the types of research which are eligible for review and approval by the LNRR-ERC.

2 SCOPE

This guideline applies to all research that is considered 'low' or 'negligible' risk to participants.

3 RESPONSIBILITY

The *NHMRC National Statement on Ethical Conduct in Human Research* 2007 (updated 2018) recognises that institutions should have procedures indicating which activities require review by their Human Research Ethics Committees (HREC). Additionally, the *National Statement* provides guidance on assessment of risk, and establishes categories of "low risk research" and "negligible risk research". The *National Statement* authorises the delegation of authority by HRECs for review of low risk research and exempts some negligible risk research from ethical review. For review of these activities, the Peter Mac HREC delegates its reviewing authority to the LNRR-ERC and Divisional Review Panels.

It is the responsibility of researchers and other staff involved in the submission and review of research proposals to be aware of and comply with this guideline. It is the responsibility of the Human Research Ethics & Governance office staff to be aware of, and comply with, the procedures set out in this guideline.

4 DEFINITIONS

Low risk research	Research in which the only foreseeable risk is one of discomfort
Negligible risk research	Research in which the only foreseeable risk is no more than inconvenience

5 PROCEDURE

5.1 Constitution of the Low and Negligible Risk Research Ethical Review Committee

The LNRR-ERC consists of:

- Human Research Ethics & Governance office representative
- Two or more representatives from across Peter Mac's Clinical Divisions e.g. from Cancer Nursing, Allied Health, Familial Cancer Centre, Radiation Therapy
- One or more Community Representatives

Proxy members are acceptable and the Chair may co-opt individuals with specific research expertise as required for review.

A quorum of the LNRR-ERC shall be four members, one of whom must be the Chair (or their delegate). The Chair will determine if there is sufficient representation to make an appropriate decision.

The LNRR-ERC will be responsible for:

- ensuring that projects are conducted according to appropriate standards and guidelines
- considering study design, patient eligibility, consent processes and other scientific, statistical and resource issues relative to proposed studies
- evaluating and recommending approval of or rejecting applications

For more information refer to the *Low and Negligible Risk Research Ethical Review Committee Terms of Reference*.

5.2 Eligibility for Low and Negligible Risk Research Ethical Review

Risk is defined as a potential for harm, discomfort or inconvenience. It involves (a) the likelihood that a harm (or 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. The risk may be physical, mental, psychological, spiritual or social. Both the type of risk and the level of risk must be considered. The types of risks are well described in the *NHMRC National Statement on Ethical Conduct in Human Research* (see Chapter 2.1, Introduction).

Any 'low' or 'negligible' risk research is eligible for review by the LNRR-ERC.

The types of research include, but are not limited to:

- research that involves surveying patients and does not involve a clinical intervention or survey questions or processes that have the potential to cause significant distress;
- staff research (i.e. research in which staff members are the only projected participants;
- best practice research identified through the 'evidence based medicine' process;
- clinical audits which are a medical record/database review of patient data with reference to a research hypothesis

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).*

- quality assurance where the primary purpose is to monitor or improve the quality of service delivered by an individual or an organisation
- evaluation activities involving systematic collection and analysis of information to make judgements, usually about the effectiveness, efficiency and/or appropriateness of an activity

5.3 Submission of Research Proposals to the Low and Negligible Risk Research Ethical Review Committee

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

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

5.4 Approval of Research

If the proposed project is approved subject to changes or clarification, the researcher will be notified in writing of the changes or clarification(s) required. The Human Research Ethics & Governance office will review the revised submission and consult the LNRR-ERC members as required. Revised submissions must include a covering memo listing the changes or clarification requested and modifications made.

When a project is approved by the LNRR-ERC the Human Research Ethics & Governance office will issue an ethical approval certificate and the approval will be noted by the Ethics Committee at its next meeting.

For the purposes of publication or presentation requirements, a project or activity approved by the LNRR-ERC will be considered approved by the Peter MacCallum Cancer Centre Human Research Ethics Committee (Ethics Committee).

For purposes of obtaining information from third parties, approval by the LNRR-ERC will be considered equivalent to approval by the Ethics Committee.

5.5 Post Approval

After the approval of a project by the LNRR-ERC, further monitoring is conducted. The LNRR-ERC requires the following to be submitted to the Ethics Committee Secretariat throughout the course of a project:

- Any amendment to the project protocol or associated documentation
- Annual Progress Reports
- A Final Report at the completion of the project

For more information about post approval monitoring, refer to *SOP004 -Monitoring of Ongoing Research*.

6 RELEVANT DOCUMENTS

POLICY 21.1.1 Responsible Conduct of Research
SOP001 Ethics Committee
SOP004 Monitoring of Ongoing Research
Guideline001 Governance Review Requirements for Human Research
Guideline002 Ethical Review Pathways and Submission Requirements
NHMRC National Statement on Ethical Conduct in Human Research 2007 (Updated 2018)
NHMRC Ethical Considerations in Quality Assurance and Evaluation Activities 2014

7 FURTHER INFORMATION

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

8 VERSION AND APPROVAL HISTORY

Date	Version #	Author; Owner and Authoriser; Summary of Changes
January 2020	2.1	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. Minor adjustments for consistency with Guideline 004 Divisional Review.

END OF DOCUMENT