1 PURPOSE

This guideline outlines the procedures related to the review and approval by Divisional Review Panels of negligible risk research e.g. clinical audit, quality assurance and evaluation activities at the Peter MacCallum Cancer Centre.

2 SCOPE

This guideline applies to negligible risk research e.g. clinical audit, quality assurance and evaluation activities at the Peter MacCallum Cancer Centre.

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 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 Low and Negligible Risk Research Ethical Review Committee (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

Negligible risk research	Research in which the only foreseeable risk is no more than inconvenience
Clinical audit	Analysis of data from previous treatment or investigations (e.g. imaging studies or laboratory tests) or of pre-existing research data and an intent to publish or otherwise present the data beyond the staff of this hospital.
Quality assurance	Activity where the primary purpose is to monitor or improve the quality of service delivered by an individual or an organisation
Evaluation activity	Systematic collection and analysis of information to make judgements, usually about the effectiveness, efficiency and/or appropriateness of an activity

5 PROCEDURE

5.1 Constitution of a Divisional Review Panel

Chair
- Senior Clinical Researcher

Membership
- Clinician researcher
- Representative with prior research experience of the specific area of study, (e.g. oncologist, a surgeon, a radiation therapist, a physicist, a pathologist)

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

The Panel will be responsible for:
- ensuring that projects at Peter Mac 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 projects
- evaluating and recommending approval of or rejecting applications

For more information refer to the *Divisional Review Panel Terms of Reference*.

5.2 Eligibility for Divisional Review

Divisional Review Panels will review projects that are:
- A single site application for the Peter MacCallum Cancer Centre only
- A project that will last no more than two years

The types of projects that may be reviewed by a Divisional Review Panel include:
- Negligible risk research: Research in which the only foreseeable risk is no more than inconvenience
- Clinical audit projects which are a medical record/database review of Peter Mac patient data with reference to a research hypothesis.
- Clinical audit projects that also collect prospectively anything that qualifies as clinical follow-up data. This could include survival/status at last contact, date of last contact, date and cause of death or other information related to the management of patient's disease.

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

Note: Projects that will last more than two years **or** could determine findings that may be clinically relevant to study participants **or** will include an intervention are **NOT** eligible for review by a Divisional Review Panel and will require Low and Negligible Risk Research Ethical Review Committee (LNRR-ERC) or Human Research Ethics Committee (HREC) review.

5.3 Submission Requirements for Divisional Review

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

5.4 Request for a waiver of the requirement for consent

A Divisional Review Panel can review a request for a waiver of the requirement for consent on behalf of the Ethics Committee for the following purpose:

- The collection of identified data from another individual or organisation involved in the treatment of the patient, in accordance with routine care/business practice

If the request is considered as acceptable by the Divisional Review Panel the approval will be issued by the Human Research Ethics & Governance office on behalf of the Ethics Committee. The approval will be limited to the collection of the information specifically described in the protocol.

5.5 Considerations of a Divisional Review Panel

A Divisional Review Panel should consider the following points when reviewing projects:

- Project design
- Patient eligibility
- Consent processes
- Requests for a waiver of the requirement for consent (see 5.4)
- Other scientific, statistical and resource issues relative to proposed project

5.6 Approval of Research

If the proposed project is approved subject to change or clarification, the researcher will be notified in writing of the changes or clarification(s) required. The Divisional Review Panel coordinator will forward the revised submission to the original reviewers for further review. Revised submissions must include a covering memo listing the changes or clarification requested and modifications made. Research that is approved by the Divisional Review Panel will be signed off by the Chair of the Panel.

A copy of the final approved protocol and Divisional Review Panel approval memo will be forwarded to the Human Research Ethics & Governance office by the Divisional Review Panel coordinator.

The Human Research Ethics & Governance office will issue an approval to the applicant and the approval will be noted by the Ethics Committee at its next meeting. The approval is for a period of two years. A Final Report must be submitted by the end of the two year approval period.

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

Projects are subject to monitoring of research conducted by the Human Research Ethics & Governance office.

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

SOP004 Monitoring of Ongoing Research

SOP001 Ethics Committee

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	2.0	Author: Dianne Snowden, Manager Human Research Ethics & Governance; Owner: Human Research Ethics & Governance; Authorised by: Manager Human Research Ethics & Governance Summary of Changes: Updated based on new Victorian Department of Health and Human Services application form: Quality Assurance (QA) VIC. Minor adjustments for consistency with Guideline 003 Low and Negligible Risk Research Ethical Review.

END OF DOCUMENT