Purpose:
This policy establishes that certain types of research activity that would pose a ‘low’ or ‘minimal’ risk to participants will be reviewed by the Expedited Review Committee (ERC) of Northeast Health Wangaratta Human Research Ethics Committee (NHW HREC). It articulates the submission and approval process for staff wishing to conduct low risk research or quality activities involving surveying patients or staff.

The ambit of the ERC will also include privacy legislation-related or other issues that are not components of research that do not require full HREC review.

This policy also describes the process for obtaining interim approval of eligible research project Amendments or other requests to the HREC.

The National Health and Medical Research Council (NHMRC) National Statement of Ethical Conduct in Research Involving Humans (National Statement) preamble (p.8) recognises that institutions should have policies indicating which activities require review by their HREC. Additionally, National Statement paragraph 2.27 authorises the delegation of authority by Human's for ‘expedited review of minimal risk research’ and other appropriate activities. For these activities, the HREC delegates its review authority to the ERC.

Policy:
Research posing any significant risk to participants must be reviewed in accordance with the established processes for review by the full HREC. In addition, there may be non-research activities that post ethical questions or implicate participant interests in ways that require full HREC review. However, for the activities defined below, the HREC delegates its reviewing authority to the ERC.

The ERC will assess proposals to conduct quality assurance activities or ‘low risk’ research. If the ERC determines that a specific proposal requires review by the HREC, it will recommend that level of review. In other cases, the ERC will review and approve the proposal according to the procedures set out below. The ERC will then report in summary to the Quality Council and the HREC on a regular basis.

The ERC consists of (the)

- HREC Chairperson or nominee

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No: NHW0000774 V 4.0  Approval Date: 29/11/2010  Review and Update by: 06/03/2020
• Three members of the HREC (one of whom to be a community representative)

A quorum of the ERC shall be 3 members, one of whom must be the HREC Committee Chairperson of Executive representative.

All proposals to engage in activities that are generally categorised as ‘quality assurance’, ‘quality improvement’ or ‘audit’ necessitating review (eg patient or staff surveys or focus groups) shall be submitted to the ERC via the HREC Secretary. Additionally, certain proposals to conduct research that can be anticipated as carrying ‘minimal risk’ to the participants may also be reviewed by the ERC and shall be submitted in the same manner. The types of research that may fall into this category include, but are not limited to

• Approving research projects that have previously been approved by another HREC
• minimal risk projects
• The discretion of the Chairperson of the HREC

In order to be approved by the ERC, a proposal must be

(a) an activity undertaken with the consent of the patients, carers, health care providers or institutions involved; OR

(b) consistent with National Privacy Principle 2.1 (a) which requires that disclosure of personal information about an individual may only be for a secondary purpose if it is (i) directly related to the primary purpose of collection; and (ii) the individual would reasonably expect the organisation to use or disclose the information for the secondary purpose AND an activity where participants, including patient, carers, health care providers or institutions are unlikely to suffer burden or harm (physical, mental, psychological, spiritual or social)

The ERC will assess submitted proposals and consider

• the merits of the proposed project/activity
• the adequacy of the methodology and relevant survey instruments;
• the expected outcomes and timeline; and
• whether the interest of the participants are sufficiently protected. This includes consideration of
  ➢ informed consent processes(es)
  ➢ risks and burdens
  ➢ privacy and confidentiality

The ERC will also consider the type of information to be gathered, the potential uses of that information and any relevant broader implication of the proposed project/activity.
For the purposes of publication or presentation requirements, a project or activity approved by the ERC will be considered approved by the NHW HREC.

For the purposes of obtaining information from third parties, approval by the ERC will be considered equivalent to approval by the NHW HREC.

**Definition:**

**Procedure:**

1. In addition to submitting the Core Application Form, and associated documents the applicant must submit an Expedited Review Application Form.

2. The ERC will review submissions within 2 weeks and make a recommendation to approve the project/activity, not approve the project/activity, or refer the project/activity to the HREC.

3. Once the proposal has been approved and the project/activity has commenced, the Applicant must:
   - Submit annual reports to the HREC (via the Secretary);
   - Report the results of the project/activity to the HREC Committee (via the Secretary).

4. The HREC Secretary will:
   - Maintain a database of projects/activities proposed and conducted
   - Make that database available to NHW upon request; and
   - Provide six-monthly regular reports on ongoing projects/activities to the Executive and Board, Quality Council and to the HREC.

**Interim Approval**

Requests for interim approval will be screened and facilitated by the HREC Secretary and, if interim approval is granted, the item will then be ratified at the next HREC Committee meeting.

**References:**

Adapted from the Peter MacCallum Cancer Centre’s Policies and Procedures *Expedited Review of Quality, Research & Privacy Matters*

NHMRC - [National Health and Medical Research Council | Working to build a healthy Australia](https://www.nhmrc.gov.au)

**Additional Information:**

**Keywords:**
## Authorised by

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