Title	**NHW ETHICS APPLICATION**		
Document type	**Guideline/Procedure**	Document owner / Responsibility for review	**Director of Education and Research**
Department	**Chief Executive Officer**	Authorised by	**Chief Executive Officer**
Section	**Education and Research**		

Individuals/Groups consulted in review and approval of this document	NHW HREC, Research Committee
Accreditation Standard ***(Office use only)***	National Standard 1
Related documents	Research and Ethics Policy Expedited Review Committee Policy HREC Complaints Process Policy Research Governance Review Form
Variations from previous version	2015 V 2 – June 2017. • Previously policy - Research Ethics • Moved from CEO Ethics March 2019 • NEAF replaced by HREA and ERM system • Section 5 updated with new policy and procedure June 2020

Purpose/Objectives:
To ensure research undertaken at NHW or involving data gathered at/by NHW is conducted according to sound methodological principles and complies with the ethical standards as outlined in the *National Statement on Ethical Conduct in Human Research 2007 (Updated 2018)* (1), the Australian Code for the Responsible Conduct of Research (2), the NHMRC Ethical Guidelines for Research with Aboriginal and Torres Strait Islander Peoples (3) and DHHS requirements (4).

Personnel involved:
HREC Committee
Research Development and Governance Officer
Research Committee
Researchers
Higher Degree Students
Clinical Trial Coordinators

Equipment required:
NHW has adopted the on line ethics application process Ethical Review Manager (ERM) through the Victorian Department of Health and Human Services. All ethics applications must now be submitted via this portal. https://au.forms.ethicalreviewmanager.com/

Process:

1 Initial Assessment

1.1 Research not involving NHW

Ethics applications pertaining to research proposed for sites or contexts *not involving NHW* data or participants will proceed directly through the HREC secretariat.

1.2 Research involving NHW

Persons planning to undertake research projects *at NHW* or involving data obtained from NHW are required to contact the NHW Research Development and Governance Officer (RDGO) **before** submitting an ethics application and/or before ethics applications will be considered by NHW HREC in order to confirm:

a) If the project is feasible, resourced appropriately, aligns with current strategic direction and appropriate approvals have been provided.

b) If an ethics application is required and if so - if the project qualifies as a Quality Improvement or Clinical Audit for Publication or External Dissemination or a Low or Negligible Risk application (LNR) or if it requires completion of a full Human Research Ethics Application (HREA).

c) If an ethics approval for a multisite project or clinical trial involving NHW has already been granted at another HREC – and if so - ensure Site Specific Assessment (SSA) details for NHW and accompanying documentation such as cover letter, copy of approval letter and number from the approving HREC and researcher CVs are added.

d) If a research proposal should be recommended for peer review through NHW Research Committee or other means.

The RDGO will complete the Research Governance Review form to be attached to the ethics application.

2 Ethics Applications

2.1 **Full ethics applications** should be completed using the HREA and the Victorian Specific Module (VSM) and submitted via ERM.

2.2 **Low or Negligible Risk Applications** (LNR) applications do not require a separate VSM and are submitted via ERM.

2.3 **Multisite applications – Site Specific Assessment**. In line with the National Statement and the National Mutual Acceptance Scheme, NHW HREC is committed to a review process that eliminates any unnecessary duplication of ethical review. All multisite research projects including clinical trials shall in consultation with the RDGO complete the relevant SSA online form in ERM for their specific project to ensure sound research governance and appropriate assessment of project feasibility is confirmed for each site. These applications will then be registered with the NHW HREC and tabled for information only at the next available meeting.

2.4 Quality audits and activities requiring ethics application

Quality Improvements and Clinical Audit projects (QI/CA), and Case Reports, where the project team intend to publish or disseminate results externally to NHW should follow the Quality Improvement or Clinical Audit for Publication or External Dissemination policy and procedure and guidance from the NHMRC on ethical considerations (5). QI/CA projects are submitted via the Quality Assurance form on ERM and Case Reports directly to the RDGO.

2.5 Requests for review and comment on ethical questions

Matters related to patient care and/or practice with complex ethical considerations can be referred to HREC for comment and recommendation.

2.6 Timelines for submission and feedback

HREA and LNR applications must be fully completed, signed and submitted via ERM to the NHW HREC by the submission date prior to the next scheduled HREC meeting. Meeting and submission dates will be advertised on the NHW internet page. Completed and signed SSA and QI/CA applications can be submitted via ERM and assessed by the RDGO at any time.

3 Reporting expectations

Researchers undertaking projects approved at NHW under the multisite approval process from another HREC must notify NHW HREC of any amendments, delays or adverse events and must send a *copy* of the annual and final project report to NHW HREC.

Researchers undertaking research activities with NHW HREC approval are required to report on their progress annually and/or at the completion of their research analysis.

Reports should take the form of a brief executive summary including a brief outline of the

- research activity undertaken
- any changes to the methodology or ethics application in the reporting period
- status of the research project (ongoing, completed, suspended).

For a final report include a brief summary of:

- findings
- recommendations
- intention to and/or successful publication and /or presentation of project.

Refer to the Research Governance Procedure flowchart for a summary of this procedure.

References:

(1) NHMRC National Statement on Ethical Conduct in Human Research

(2) Australian Code for the Responsible Conduct of Research

(3) Ethical Guidelines for Research with Aboriginal and Torres Strait Islander Peoples

(4) https://www2.health.vic.gov.au/about/clinical-trials-and-research/clinical-trial-research

(5) Ethical Considerations in Quality Assurance and Evaluation Activities

Additional Information:
Northeast Health Wangaratta (NHW) has a fully constituted Human Research Ethics Committee (HREC), NHMRC code: EC00256.

Key words:

Ethics
Research:
HREC
Low or Negligible Risk (LNR)
Site specific assessment (SSA)
Clinical trial
Multisite
Human Research Ethics Application (HREA)
Ethical Review Manager (ERM)