



Title **RESEARCH AND ETHICS**

Document type **Policy**

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 Director of Education and Research
Accreditation Standard (<i>Office use only</i>)	National Standard 1
Related documents	
Variations from previous versions	July 2020 Refresh links and minor changes

Purpose:

To ensure that research undertaken involving staff, clients or systems of Northeast Health Wangaratta (NHW) and/or other external research activities reviewed by the NHW Human Research Ethics Committee (HREC) is supported by sound research governance and adheres to a transparent and ethical research approval process in accordance with the NHMRC Australian Statement (1) and Code (2).

Definition:

Research covers three activities: basic research, applied research and experimental development.

- **Basic research** is experimental or theoretical work undertaken primarily to acquire new knowledge of the underlying foundation of phenomena and observable facts, without any particular application or use in view.
- **Applied research** is also original investigation undertaken to acquire new knowledge. It is, however, directed primarily towards a specific practical aim or objective.
- **Experimental development** is systematic work, drawing on existing knowledge gained from research and/or practical experience, which is directed to producing new materials, products or devices, to installing new processes, systems and services, or to improving substantially those already produced or installed.

Quality Improvement or Assurance are activities whose primary purpose is to monitor or evaluate the quality of service provided. Most quality improvement activities do not require ethics approval however there are times when QA activities may be of such design or intent that they require HREC review (diagram below, 3).

Human research ethics and **level of risk** are both defined in the *National Statement on Ethical Conduct in Human Research (2018) (1)*.

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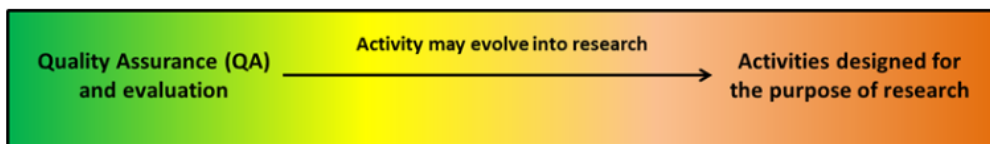
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Ethical review and approval not necessary where:	Triggers for ethical review and approval include:
Data being collected and analysed is coincidental to standard operating procedures with standard equipment and/or protocols.	Where the activity potentially infringes the privacy or professional reputation of participants, providers or organisations.
Data is being collected and analysed expressly for the purpose of maintaining standards or identifying areas for improvement in the environment from which the data was obtained.	Secondary use of data - using data or analysis for QA or evaluation activities for other purposes.
The data being collected and analysed is not linked to individuals.	Gathering information about the participant beyond that which is collected routinely. Information may include biospecimens or additional investigations.
None of the triggers for consideration of ethical review (see right) are present.	Testing of non-standard (innovative) protocols or equipment.
	Comparison of cohorts.

Policy statement:

The research program at NHW is directed through the Education and Research Unit and forms part of the organisational clinical governance through its support of evidence-based medicine (EBM).

NHW HREC may receive applications for ethics approval from internal or external researchers.

Internal Research and Ethics:

Research conducted onsite at NHW is required to have both Research Governance and HREC approval prior to commencement. (See NHW Ethics Application Procedure)

Ethics application and approval by NHW HREC will be registered in the statewide Ethical Review Manager (ERM) database and reported monthly via the Research Governance Officer to the Director of Education and Research.

All research undertaken at NHW must comply with:

- a. National Statement on Ethical Conduct in Human Research (2018)
- b. Australian Code for the Responsible Conduct of Research (2018)
- c. NHW policies and procedures including those related to ethics and research governance
- d. relevant legislation, regulations, codes and guidelines.



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External Research and Ethics:

NHW HREC is registered with the National Health and Medical Research Council (EC00256) (4).

External researchers may submit ethics applications to NHW HREC for consideration and approval provided that they comply with:

- a. National Statement on Ethical Conduct in Human Research (2018)
- b. Australian Code for the Responsible Conduct of Research (2018)
- c. NHW policy and procedures related to the submission of ethics applications
- d. Relevant legislation, regulations, codes and guidelines

Additional Information:

NHW Research Application Procedure

HREC Expedited Review Policy

HREC Complaints Process Policy

References:

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

(2) [Australian Code for the Responsible Conduct of Research](#)

(3) [Ethical Consideration in Quality Assurance and Evaluation Activities](#)

(4) [List of Registered HRECs](#)

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