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 Codes (1).

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 in order 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 (2).
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

Quality Assurance (QA) and evaluation → Activity may evolve into research → Activities designed for the purpose of research

Ethical review and approval not necessary where:
- Data being collected and analysed is coincidental to standard operating procedures with standard equipment and/or protocols.
- 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.
- The data being collected and analysed is not linked to individuals.
- None of the triggers for consideration of ethical review (see right) are present.

Triggers for ethical review and approval include:
- Where the activity potentially infringes the privacy or professional reputation of participants, providers or organisations.
- Secondary use of data - using data or analysis for QA or evaluation activities for other purposes.
- Gathering information about the participant beyond that which is collected routinely. Information may include biospecimens or additional investigations.
- Testing of non-standard (innovative) protocols or equipment.
- Comparison of cohorts.


Human research ethics and level of risk are both defined according The National Statement on Ethical Conduct in Human Research (2007).

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 HREC and Research Governance approval appointed prior to commencement. (Refer Appendix for Governance Review Form)

Ethics application and approval by NHW HREC will be registered by the Secretary of the HREC and reported monthly via the Research Governance Officer to the Director of Education and Research.

All research undertaken at NHW must comply with:
External Research and Ethics:
NHW HREC is registered with the National Health and Medical Research Council (EC00256) (3).

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

c. NHW policy and procedures related to the submission of ethics applications
d. Relevant legislation, regulations, codes and guidelines

Additional Information:

References:

