

Hunter New England Local Health District

Checklist: Ethical Considerations in Quality Improvement, Service Evaluation and Audit Activities

If you are undertaking a quality improvement, service evaluation, or audit project (see definitions below), and not research (see definition below), please complete the checklist below. Research projects will require a submission in REGIS, <https://regis.health.nsw.gov.au/>.

If you answer 'yes' any question below, please complete the details on the reverse of this form and submit via email to HNELHD-ResearchOffice@health.nsw.gov.au for advice on ethical review. If responses below are all 'no', ethical clearance is not required, and you may proceed with the activity provided you have the approval of your direct line manager.

Does the activity involve:	Yes	No
Extraction of direct or indirect identifiers from medical records (see definition below).		
Sensitive data (see definition below).		
Any risk of harm or distress beyond standard care.		
The potential to infringe on the rights, privacy or professional reputation of participants, providers, or organisations.		
Information about the participant beyond that which is collected routinely.		
Testing of non-standard (innovative) protocols or equipment.		
Randomisation, use control groups or placebos.		
Targeted analysis of data involving minority/vulnerable groups whose data is to be separated out of that data collected.		
Aboriginal and/ or Torres Strait Islander peoples are to be examined in the results.		
Rare conditions or small communities/ cohorts.		
Contact with patients or their relatives.		

Definitions:

Audit: Consist of describing or measuring a clinical outcome or a process, often against well-defined standards set on the principles of evidence-based medicine.

Direct Identifiers: Data that can be used to quickly, and easily identify someone such as name, address, date of birth or MRN.

Health Data: Records of information that relate to the health of an individual, which are held by NSW state data collections and held by the NSW Ministry of Health, including those data collections that are managed by an external agency on behalf of the Ministry.

Indirect identifiers: Can be a range of data, depending on context, such as age or having a rare chronic condition for example. In the context of seeking to adequately de-identify data for research purposes indirect identifiers is data that makes it technically possible for re-identification to occur (whether from the information itself, or in combination with other information that may be available in the data access environment).

Quality Improvement: An activity where the primary purpose is to monitor or improve the quality of service delivered by an individual or an organisation.

Research: Research is a systematic investigation designed to develop or contribute to generalizable knowledge.

Sensitive Data: Information or an opinion about an individual's ethnic or racial origin, political opinions, or memberships, religious or philosophical beliefs, membership of a trade union or professional association, sexual orientation or activities, criminal record, genetic and /or biometric information.

Service Evaluation: Evaluation is a term that generally encompasses the systematic collection and analysis of information to make judgements, usually about the effectiveness, efficiency and/or appropriateness of an activity. The term is used in a broad sense to refer to any set of procedures, activities, resources, policies and/or strategies designed to achieve some common goals or objectives.

For further information click on the following link:

<https://www.oaic.gov.au/privacy/privacy-guidance-for-organisations-and-government-agencies/handling-personal-information/de-identification-and-the-privacy-act>

[Data Collections – Disclosure of Unit Record Data for Research or Management of Health Services \(nsw.gov.au\)](#)

Please complete the following details if you responded yes to any of the above:

Applicant Name	
Department	
Email	
Contact Number	
Supervisors Name, Role & Department	
Site of project	
Brief Title	
Aim of project	
Brief description of the activity including any data to be accessed	
Intended use of data including if unit level data will be shared outside of LHD	

Declaration:

- The information contained within this application is true and accurate.
- There are no actual or potential conflicts of interest.
- No identifiable data will be included in any presentations or publications.
- Agree to take all reasonable steps to prevent access to the information or data by those who are not authorised.
- All related data:
 - Only be used for the purpose as outlined in this form.
 - Be stored in a secure location at a HNELHD site.
 - Not to be taken off site in any format.
 - Be promptly and securely destroyed five years after publication.

Name, signature, date

Applicant

Head of Department

Research Office Use Only

Recommended level of ethical review

No ethical risks identified & no ethical review required	
Ethical submission required in REGIS https://regis.health.nsw.gov.au/	

Title:

Reference number:

Authorised by:

Manager, Research Ethics
Hunter New England Local Health District

Signature, date