# Ethical Considerations and Appropriate Oversight for Retrospective Data Analyses

NNSW LHD QA Guideline for Retrospective Data v7

Research is encouraged within Northern NSW Local Health District (NNSW LHD) as a means of informing the safe, effective and efficient delivery of health services. Quality Activities including Quality Improvement, Quality Assurance and Service/Program Evaluation can also be used to monitor or improve the quality of health services. Attempts to differentiate Quality Activities as separate to research by way of definition are generally unhelpful because they often utilise similar methods and pose similar risks and benefits to participants. Definitions for each activity are available [online](https://nnswlhd.health.nsw.gov.au/our-organisation/research/research-governance#quality-activities).

The Northern NSW LHD Research Office has established a [review pathway for Quality Activities involving a non-Human Research Ethics Committee](https://nnswlhd.health.nsw.gov.au/our-organisation/research/research-governance#quality-activities) (HREC) level of review. This document provides guidance on ethical considerations and appropriate oversight for Quality Activities proposing to analyse existing, deidentified data collected during standard/routine care in the form of retrospective data analyses and details the process of submitting an application to the Research Office. **This review pathway can only be used by lead project officers who are** **employees of Northern NSW LHD *and* for projects that pose no more than low risk to participants (i.e. no more than discomfort)**. NNSW LHD supports a range of alternative ethical review pathways for projects which do not meet these criteria. Further information about NNSW LHD Research Ethics and Governance processes and review pathways is available [online](https://nnswlhd.health.nsw.gov.au/our-organisation/research/research-governance#quality-activities). Also described on this page is the standard process for other types of Quality Activities (e.g. **projects involving primary data collection such as surveys, focus groups and interviews**, and **projects involving mixed methods**) and **case study/series**. If required, please contact the NNSW LHD Research Office for further guidance by email: NNSWLHD-Ethics@health.nsw.gov.au or telephone: (02) 6672 0269.

To submit a retrospective data analysis Quality Activity application for review by the Research Office, please complete the following:

1. Quality Activity Proposal for retrospective data analyses,
2. Ethical Considerations checklist, Appendix A,
3. Obtain the signature and endorsement for the conduct of the project from your relevant Head of Department, and
4. Submit the form (in word format) *with* HoD endorsement and signature (electronic signature or scanned PDF document accepted) and supporting material by email to: NNSWLHD-Ethics@health.nsw.gov.au

If you are planning on **engaging the services of a Health Information Manager** (HIM) to obtain retrospective data, please provide evidence that the HIM is aware of the project and is willing to support it conditional on ethical and scientific review approval (e.g. providing a copy of the email correspondence with a HIM is sufficient as evidence).

To **submit an amendment to an approved QA project**, please follow the instructions on the [Research Governance website](https://nnswlhd.health.nsw.gov.au/our-organisation/research/research-governance#quality-activities).

# Quality Activity Proposal for retrospective data analyses

### The Quality Activity template is designed to help you define the scope of your project and develop a plan for how you will undertake your project. This process helps to ensure that any subsequent findings align with the aims, the methods used meet an acceptable standard of scientific quality and any ethical and safety considerations are identified and addressed. The protocol template is designed for projects that plan to use routinely collected data and where *possible provides details of the type information* *required (in italics)* as well as sample responses.

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| **Project title:**  | *Use a descriptive, informative title that succinctly describes the study including the main project idea, study site, and the study design (e.g. retrospective analysis of routinely collected data, medical record review, chart audit, cohort study, case-control study). For example, Evaluating smoking status screening, assessment and management in NNSW LHD emergency departments: a retrospective analysis of routinely collected data* |
| **Short title (if any):** | *Sometimes referred to as a running title* |
| **Site(s):** | *Please list all site(s) the project will be undertaken* |
| **Version Control:**  | Version 1, dated xxxx |
| **Purpose:** | *What is the main purpose for undertaking the activity? Please select all that apply.*

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| [ ]  Clinical Leadership Program | [ ]  Fellowship Training Program |
| [ ]  Coursework excluding higher degree research programs | [ ]  Program evaluation  |
| [ ]  Clinical practice improvement project e.g. clinical audit, quality improvement project |
| [ ]  Other, provide a description in your own words: |

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| **Project Team:** | **Lead Project Officer**: The lead project officer must be an employee of Northern NSW LHD for the duration of the project.

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| Name: |  |
| Position: |  |
| Department: |  |
| LHD Employee Number:  |  |
| Telephone: |  |
| Email: |  |

**Project Officer**

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| --- | --- |
| Name: |  |
| Position: |  |
| Department: |  |
| LHD Employee Number:  |  |
| Telephone: |  |
| Email: |  |

*Copy and paste the table to add additional project officers.* |
| **Head of Department Endorsement:** | * I confirm that I am the relevant Head of Department for the above-named Project Lead including the service/data relevant to this project OR I have sighted evidence of approval from the relevant Department.
* I confirm that the lead project officer is, and will remain, an employee or agent of NNSW LHD for the duration of the project.
* I confirm I have read the QA Proposal and Ethical Considerations Checklist, and I agree with the assertions made by the Project Lead.

**Head of Department**

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| --- | --- |
| Name: |  |
| Position: |  |
| Department: |  |
| LHD Employee Number:  |  |
| Telephone: |  |
| Email: |  |
| SIGNATURE: |  |
| DATE: |  |

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| **Student involvement** | [ ]  Yes, I would be interested in having a medical or other student involved in this project (Please note that this cannot be guaranteed but you may be contacted at a later date when projects are required)[ ]  No, I am not interested in having a medical or other student involved in this project |
| **Background & Rationale:** | *Provide an introduction to the project, this may include a description of the problem and brief literature review of the area and rationale/justification for the project (why is it important that you undertake this project, what is the evidence-practice gap you are trying to address)* |
| **Aims & Objectives:**  | *State the aim of the project (an aim describes the overall goal/intention of the project) and objectives of the activity/project (the objectives are the specific steps you will take to achieve your aim. These can be outlined as dot points).* |
| **Outcomes & Relevance:** | *Provide information on the potential benefits of the project (e.g. to inform future research, policy, planning and/or practice) and how the findings will be used to improve or inform service improvement.* |
| *Dissemination plan* | Where do you plan to disseminate the findings of the project*: (check all that apply and provide details as appropriate)*[ ] Internal report (please provide details): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_[ ] External report (please provide details): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_[ ]  Presentation (please provide details e.g. unit/department/organisation level, scientific conference): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_[ ]  Publish in a peer-reviewed journal (please provide details): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_[ ]  Other (please provide details): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  |
| **Methods:** | **Study Design** (check box)[ ] Cohort study (Identify patients and follow them overtime)[ ]  Case-control study (Selecting cases and controls)[ ]  Cross-sectional study (Identify patients and describe their characteristics at one point in time)**Setting***Describe the setting (e.g. ED/inpatient/outpatient/community), locations (e.g. hospital site(s)) and relevant dates (e.g. timeframe/years of interest).***Participants (including eligibility criteria)***Give the eligibility criteria (inclusion/exclusion criteria), the data sources (e.g. electronic medical records, FirstNet, SurgiNet) and methods of selecting participants (i.e. describe how you will identify participants e.g. specify the codes or algorithms used to identify subjects*). **Variables** *List and define ALL the variables you plan to extract including any exposures, predictors, potential confounders, and effect modifiers. This may include demographic information (e.g. age, sex, socioeconomic status), clinical information (e.g. diagnosis, disease or condition, specific treatment or procedure provided; give diagnostic/treatment codes if applicable) and potential confounders (e.g. comorbidities, other treatments received).*

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| **Variable** | **Definition** | **Source of data**  | **Measured** |
| *e.g. Age* | *e.g. Age at recruitment* | *e.g. electronic medical record* | *e.g. Years and months* |
| *e.g. Triage category* | *e.g. Triage category on presentation to ED (Cat 1 immediate; Cat 2 emergency; Cat 3 urgent; Cat 4 semi-urgent; Cat 5 non-urgent)* | *e.g. FirstNet* | *e.g. Number 1 to 5* |
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*Add additional rows as required***Main study outcome variable(s)***Provide information on the main outcome variable(s), how it is defined (e.g. diagnostic/treatment codes, descriptive definition), the source of data and how it will be assessed/measured.*

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| **Main study outcome variable** | **Definition** | **Source of data**  | **Measure** |
| *e.g. Smoking cessation management* | *e.g. Smoking cessation provided* | *e.g. electronic medical record* | *e.g. Yes or No, if yes details of treatment provided including mode, dose* |
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*Add additional rows as required***Study procedure***Provide a description of the steps you will take to identify, extract and clean the data in preparation for analysis including who will be involved in data extraction and preparation.* **Sample size***Provide a justification for the sample size you have chosen. This could include a sample size calculation, if applicable, considerations for precision, or justification related to a generalisable sample.* **Statistical analysis***Provide a description of the statistical methods that will be used (e.g. descriptive statistics: count, percentage, frequency, median, mean, standard deviation; significance tests: student-tests, chi-square tests etc). It is good practice to express your results as a point estimate and 95% confidence intervals, as appropriate, and describe how you will calculate each.* |
| **Ethical Considerations and Standard Conditions** | *Consult the checklist at* [*Appendix A: Ethical Considerations Checklist*](#EthicalConsiderationsChecklist)*. If any risks are identified, indicate how they will be mitigated and/or addressed.* *By submitting this proposal for review by the Research Office, you agree to adhere to the standard conditions for retrospective data analyses as follows:*1. *Data are to be kept in a secure physical and electronic environment that is accessible only by persons directly involved in the project;*
2. *Northern NSW LHD is to be acknowledged in any publication or report that arises from the use of the data;*
3. *Complete the* [*approvals form*](https://intranet.nnswlhd.health.nsw.gov.au/clinical-governance/human-research-ethics-and-governance/publications/) *for submission of abstracts for conference presentations or manuscripts for review in peer-reviewed journals if appropriate;*
4. *A copy of any publication or report is to be provided to the Northern NSW LHD at least two weeks prior to public release (emailed to –* *Alexandre.Stephens@health.nsw.gov.au**, Director of Research);*
5. *The data are to be destroyed after 5 years (after project completion);*
6. *No information will be released with which it may be possible to identify an individual person;*
7. *Individuals identified in the data are not to be personally identified in any publication or report;*
8. *The use of information on Aboriginal and Torres Strait Islander status is subject to the approval of the Aboriginal Health and Medical Research Council Ethics Committee if one or more of the following apply:*
	1. *Aboriginality is a key determinant*
	2. *Data collection is explicitly directed at Aboriginal peoples*
	3. *Aboriginal peoples, as a group, are to be examined in the results*
	4. *The information may have an impact on one or more Aboriginal communities*
	5. *Aboriginal health funds are a source of funding*
9. *This authority continues until and unless it has been revoked in writing;*
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| **Governance**  | *Standardised answers have been provided to assist you completing this section in accordance with data management policies and guidelines. Please provide additional details or revise as required.* **Data storage:** *NOTE: storage on portable media, laptops and desktop computer hard drives is not acceptable.*Electronic data will be stored on a physically secure NNSW LHD file server that is password protected. If applicable, hardcopy material will be stored in a secure file. **Data access:** *specify how data will be accessed by investigators.*Data and project material will only be accessible to the project team.**Data retention:** Records will be retained for a minimum of 5 years after project completion in accordance with the *State Records Act 1998* (NSW). **Data disposal**: Records will be deleted from the secure NNSW LHD file server 5 years post project completion. Hardcopy material will be securely destroyed or shredded.  |
| **Additional Material:** | *If required, provide a list of the study material(s) (e.g. data extraction sheet)* |
| **Applicable National Safety and Quality Health Service Standards:** | *Select the Applicable NSQHS Standard/s. See:* [*https://www.safetyandquality.gov.au/standards/nsqhs-standards*](https://www.safetyandquality.gov.au/standards/nsqhs-standards)

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|[ ]  Clinical Governance Standard |[ ]  Partnering with Consumers Standard |
|[ ]  Preventing and Controlling Healthcare-Associated Infection Standard |[ ]  Recognising and Responding to Acute Deterioration Standard  |
|[ ]  Comprehensive Care Standard |[ ]  Communicating for Safety Standard |
|[ ]  Blood Management Standard |[ ]  Medication Safety Standard |
|[ ]  Other:  |

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| **References:**  |  |

Ethical Considerations Checklist

This checklist is based on the [*HREC: Human Research Ethics Committees – Quality Improvement & Ethical Review: A Practice Guide for NSW* (GL2007\_020)](https://www1.health.nsw.gov.au/PDS/pages/doc.aspx?dn=GL2007_020)

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| Section 1: Issues that may require consent |
| 1. | The data to be collected is of a sensitive nature or application |
|  | Sensitive health information could lead to a breach of confidentiality if such communication were to be read by another person that is not authorised to view the information.  | Choose an item. |
| 2. | The data will be used or available in such a way that may identify individuals |
|  | Data that allows for identification of a specific individual are referred to as ‘identified data’. Examples of identifiers are the individual’s name, date of birth, address, or diagnosis where the condition is rare. In very small data sets, even information such as a postcode may be an identifier. | Choose an item. |

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| Section 2: Privacy and Confidentiality |
| 3. | There is no process for de-identification of data. |
|  | Data should be de-identified before being given to third parties who would not normally have access to them.  | Choose an item. |
| 4. | The project involves rare conditions or a small community. |
|  | Where patient numbers are limited or the diagnosis is rare, this may inadvertently result in the patient being identified, even where the data have been de-identified in the usual manner. Quality Activities that combine groups of similar patients from small units may assist in maintaining confidentiality, where this is feasible. See further information on [case study/series](https://nnswlhd.health.nsw.gov.au/human-research-ethics-and-governance/what-is-research-governance/). | Choose an item. |
| 5. | Data will be selected or identified by: Aboriginal or Torres Strait Islander status; or Ethnic, religious or minority group. |
|  | Quality Activities amongst religious, ethnic, or minority groups should be undertaken following appropriate consideration of cultural difference, as relevant to the activity. Some ethical issues associated with a Quality Activity may need to be considered in a broader context than the individual patient context, for example the notion of ‘community privacy’ often applies in Aboriginal communities. | Choose an item. |
| 6. | Data will be collected beyond that which is normally collected in routine care. |
|  | No additional comment.  | Choose an item. |

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| Section 3: Other Implications |
| 7. | The project will involve the analysis of results of genetic tests/testing. |
|  | Genetic testing may have an impact on not only the individual being tested, but also other family members. Quality Activities involving genetic information need informed consent, given the sensitive nature of the information and its potential implication. | Choose an item. |

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| 8. | The project may potentially infringe the rights, privacy or professional reputation of carers, health professionals or institutions. |
|  | There is increasing interest in the comparison of patient outcomes or other performance indicators within or across units, departments or individual clinicians. However, these comparisons must be against agreed benchmark standards, and with appropriate consideration of the variables impacting on outcomes and performance, such as patient acuity. Where use of comparative data between individual clinicians or institutions occurs, this should be clearly grounded within the institution’s clinical governance system. There is a general obligation to feedback results of Quality Activities to health professionals who have been directly involved in a Quality Activities or affected locally by its results. There should also be consideration given to providing results of Quality Activities to other participant groups. | Choose an item. |
| If the response to any of the above statements is “**true**”, you will need to provide more information and it is highly likely you will need full Ethics Committee approval for your project. Consult the NNSW LHD Research Office for further guidance by email: NNSWLHD-Ethics@health.nsw.gov.au or telephone: (02) 6672 0269  |

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| 9. | The project is likely to generate data that may lead to publication. |
|  | Many professional journals require evidence of ethical review[[1]](#footnote-1) before Quality Activity results will be published, especially where identifiable or sensitive data are audited, or potential harms or burdens exist. This also applies where the results of the Quality Activities are for publication as a conference abstract. Some, in particular international, journals may apply different standards for ethical review. Intending authors should explore this on an individual basis.  | Choose an item. |

1. Ethical review: Review of research by an HREC or other body (see: [The National Statement](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#toc__1931)). [↑](#footnote-ref-1)