

## NMC RESEARCH POLICY FRAMEWORK

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**Summary:** The framework sets out the policy issues for research activities that the Council may commission or undertake. It includes the range and scope of research activities, processes for, seeking and approval of, research projects, and the process and criteria for authorising access to, and the use of, Council information for research purposes.

It includes templates and model documents for research activities.

**Applies to:** The Nursing and Midwifery Council, HPCA staff and researchers

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**Related legislation, policies, awards, agreements**

- Health Practitioner Regulation National Law (NSW)
- Health Records and Information Privacy Act 2002 (NSW)
- Privacy and Personal Information Protection Act 1998 (NSW)
- Government Information (Public Access) Act 2009 (NSW)
- NSW Health, Research governance in NSW Public Health Organisations (GL 2011\_001)
- NSW Health, Human Research Ethics Committees – Quality improvement & ethical review: A practice guide for NSW (GL2007\_020)
- NSW Health, Research – Ethical and scientific review of human research in NSW Public Health Organisations (PD 2010\_055)
- NSW Health, Research – Authorisation to commence human research in NSW Public Health Organisations (PD 2010\_056)
- NSW Health, Research – Human and animal research and the National Health & Medical Research Council Act 1992 (PD 2010\_057)
- National Health and Medical Research Council, Australian Research Council, Australian Vice Chancellor's Committee, National Statement on ethical conduct and human research (2014)
- Office of the Information and Privacy Commissioner, Statutory Guidelines on Research
- Office of the Information and Privacy Commissioner, Public interest direction relating to the disclosure of information by NSW public sector agencies for research purposes

**Review date:** October 2018

# Research Policy Framework

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## INTRODUCTION

The review of Council processes and analysis of the outcomes of the complaint handling pathways can play an important role in maintaining standards, informing process improvements and ultimately supporting public protection.

Section 41S of *the Health Practitioner Regulation National Law (NSW)* (the Law) provides that the Council may establish an Education and Research Account for research purposes relating to the health, performance and conduct of registered health practitioners or students.

This document:

- sets the policy framework to ensure that research activities meet ethical, regulatory, policy and professional standards
- outlines the range and scope of research that the Council undertakes
- the processes for handling requests and
- the processes for providing access to information, such as statistical or other data and unpublished documents
- and applies to the provision of, and access to, information for research purposes to other stakeholders and partners.

Information that may be provided includes personal and other information that Councils have collected in the conduct of their regulatory activities, that is not publicly available and/or that requires commitment of staff time or resources to identify and collate.

Publicly available data used by staff or members in the course of giving presentations, seminars or written papers about the work of the Council and its programs does not require formal approval under this policy. These activities are part of the ordinary course of business for the Council and HPCA, and are covered by normal internal approval processes and the Code of Conduct in relation to public comment.

## DEFINITIONS

**Research** is generally defined as “original investigation undertaken to gain knowledge, understanding and insight.”<sup>1</sup>

**Quality assurance** includes a range of methods for monitoring and evaluating health care with the aim of improving its delivery. These quality improvement (QI) activities include incident monitoring, root cause analysis, sentinel event monitoring, peer review, morbidity and mortality review and other forms of audit.<sup>2</sup>

### **Research or quality assurance?**

The term “research” is used in this document and in the Law in relation to Education and Research Accounts, however the primary purpose of most such activities and projects relate to quality assurance. This is an important distinction when determining the need for ethics committee approval of a project, particularly when the information can be de-identified.

The NSW Health Guideline, *Human Research Ethics Committees – Quality improvement and ethical review: a practice guide for NSW*, (GL2007\_020) includes a checklist to assist in identifying when a proposed quality assurance activity entails ethical risks.

**Human research** is research conducted with or about people, or their data or tissue as described in the *National Statement on Ethical Conduct in Human Research* (2007).

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<sup>1</sup> National Health and Medical Research Council (2007), *Australian code for the responsible conduct of research*, p1

<sup>2</sup> NSW Health (2007), *Human Research Ethics Committees – Quality improvement and ethical review: a practice guide for NSW*, p1

**Human Research Ethics Committee** reviews research proposals involving human participants to ensure that they are ethically acceptable and in accordance with relevant standards and guidelines.

**The Law** means the *Health Practitioner Regulation National Law (NSW)*.

## BACKGROUND

### Legislation

Section 41S of the Law provides that each Council may establish an Education and Research Account. The amount of funds transferred into the account is determined by the Minister, in consultation with the Council.

Section 41S (4) sets out the purposes for or towards which funds in an Education and Research Account may be expended, that is for:

- any purpose relating to education and research about the health, performance and conduct of registered health practitioners or students registered in the health profession for which the Council is established; and
- meeting administrative expenditure incurred with respect to the Education and Research Account and the purposes for which it is used.

### Access to and provision of personal information

Personal information, including health information, held by a Council can only be disclosed in limited circumstances, which are governed by legislation and guidelines. Personal information will only be released for research purposes in accordance with these provisions.

Data collection and use is subject to privacy legislation and the requirements of the NSW Health *Privacy Management Plan* and the NSW Health *Privacy Manual for Health Information*.

When considering a proposal to access data the statutory requirements in NSW that are relevant to the release of personal and/or health information must be taken into account.

Relevant NSW legislation includes:

- *Health Records and Information Privacy Act 2002*
- *Privacy and Personal Information Protection Act 1998*
- *Government Information (Public Access) Act 2009*

The Commonwealth *Privacy Act 1988* binds the private sector in NSW including non-government organisations and private health sector providers (such as individual nurse practitioners and private hospitals).

### NMC Strategic Plan 2015 – 2018

The Council's plan includes the strategy: to develop and implement the NMC Research Plan with priorities for research that address current and emerging NMC issues and problems and takes account of HPCA and AHPRA research priorities.

The HPCA *Strategic Framework 2014-2016* includes the key strategic theme, to "Demonstrate Value" with the objective to "undertake research, measure performance and build and communicate evidence of the effectiveness and impact of the Councils' and HPCA's role". The HPCA will provide a coordinated approach to research to enable the

shared interests of Councils to be identified and investigated, provide value for money and facilitate a comparative analysis across professions.

The agreed research priorities over the next three years are outlined in the Councils' *Research Program Plan* (HP14/8161). The Plan will focus on objectives in the Strategic Framework and areas of common interest and shared funding.

## RESEARCH PROGRAM

Research can be conducted by Council members, staff or external researchers, including from academic institutions and stakeholder organisations such as the Australian Health Practitioner Regulation Agency (AHPRA) or the Health Care Complaints Commission (HCCC).

Research may comprise:

- Projects commissioned by the Council, the HPCA, and/or other Councils for a specified strategic or regulatory purpose
- Joint or shared projects in partnership with external agencies, such as AHPRA/ National Boards, the HCCC, or other agencies seeking Council participation or support, such as universities
- Grants provided to researchers for specific projects through a competitive process.

The majority of research aims to improve processes and understanding of the outcomes of Councils' regulatory activities and their impact on practitioners and public safety. It is therefore primarily focused on quality assurance and continuous improvement.

### Commissioned research

The Council identifies research questions that relate to priorities in the Council's strategic plan. A request for quotation or tender is approved by the Council or its Education and Quality Committee. It is then forwarded to targeted researchers or more widely advertised. The request will include details of the project deliverables, eligibility criteria, cost and duration. Applications are reviewed by the Education and Quality Committee or an evaluation panel established for the purpose, using agreed evaluation criteria.

### Partnership projects

The Nursing and Midwifery Council supports collaborative research with other councils, with stakeholders and other external agencies, both nationally and internationally. Where research collaboration exists, an agreement will be put in place covering access to information, ownership of intellectual property, confidentiality and copyright, responsibility for ethics and research safety, ownership and location of research data and materials, and the future purpose and use of research findings.

Financial and/or in-kind support from the Council for a research project may be sought by external bodies, and includes applications for an Australian Research Council grant. All such requests must be made in writing to the Council. Applications must include:

- a project description, including aims, objectives and expected outcomes;
- identity of chief and collaborating researchers
- project approach or methodology, including data collection and outcomes measures
- timeline
- budget and resource implications, and
- the benefits to be realised from the project.

### **Grants and other supported research**

Applications for grants may be advertised to research a proposed topic within funding guidelines. Applicants are typically academics and other experienced researchers. Applications are made on a Council approved form according to specified guidelines and selection criteria. (Application form for Research Grants HP15/12050-01 and Research Grant Guidelines 2015-2016 HP15/12050-02)

### **Ethics committee approval**

The Nursing and Midwifery Council may seek advice from a relevant Ethics Committee and require submission of research proposals for ethics committee approval or review.

In considering research applications and proposals the Council will err on the side of caution in requiring ethics committee approval prior to a project being approved or commenced. Initially, to help establish precedents for future research, HPCA staff will contact the Ethics Committee delegate to seek advice on the Council's proposed research to establish parameters for the review of applications and the requirements for ethics committee approval or review.

The Council notes that research involving humans will usually require Ethics Committee approval. HPCA staff will review the Ethics Review Checklist (HP15/3958) to assist the Council to determine the need for future ethics committee involvement. The Council will carefully consider any research proposal to determine whether the risk for harm (including the likelihood that the harm will occur and the severity of the harm and its consequences) requires Ethics Committee consideration or approval. Low risk<sup>3</sup> or negligible risk<sup>4</sup> research does not require Ethics Committee review or approval.

In order to minimise the ethical risks arising from proposed research, the Council will only release data or information that is de-identified and not capable of identification even if de-identified.

The Council will also consider whether the work that they wish to commission or undertake meets the definition of a quality assurance review. Ethics committee approval may not be required for such projects. The NSW Health Guideline *Human Research Ethics Committees – Quality improvement and ethical review: a practice guide for NSW*, (GL2007\_020) provides advice on the differences between research and quality assurance and includes a checklist to help determine when ethics committee approval is required.

Research involving Aboriginal and Torres Strait Islander peoples is conducted in accordance with *Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research* and the *Guidelines for Ethical Research in Indigenous Studies*.

Community participation in research should be conducted in accordance with the *Statement on Consumer and Community Participation in Health and Medical Research*.

### **Adherence to relevant codes and standards**

All research undertaken by, in partnership with, or on behalf of the Nursing and Midwifery Council must adhere to applicable national and state codes, standards, guidelines and directives to ensure the highest ethical, scientific, regulatory and professional standards.

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<sup>3</sup>Low risk is research in which the only foreseeable risk is one of discomfort. Research in which the risk for participants is more serious than discomfort is not low risk - National Statement on Ethical Conduct in Human Research, 2007 (updated March 2014) p15

<sup>4</sup>Negligible risk is research in which there is no foreseeable risk of harm or discomfort; and any foreseeable risk is no more than inconvenience – *ibid* p15

### **Data collection and use**

The Council collects a wide range of personal and other information for the primary purpose of managing complaints. Data is recorded in the case management system (MaCS) and collated for reporting to AHPRA and inclusion in annual reports and other publications.

This information provides the basis for quantitative and qualitative research which may help the Council to better understand and manage its regulatory activities, and provide insight into trends and issues for quality assurance and risk control.

Researchers may seek access to information to research complaints activity or profiles, to review Council processes or pathways used for handling complaints, and the outcomes of complaints management activities. This information may include de-identified statistical data, personal information or the processes and outcomes of Council activities or decisions. All such requests must be made in writing with a project description, including aims, objectives and expected outcomes; chief and collaborating researchers; project approach including methodology, including data collection and outcomes measures; timeline, budget and resource implications, and the benefits to be realised from the project.

## **RESEARCH MANAGEMENT**

### **Governance**

The Council has an Education and Quality Committees that oversees expenditure from the Education and Research Account. The Committee reviews and recommends to Council the allocation of research funds for commissioned research or grants as a result of calls for expressions of interest. The Committee has a terms of reference (HP14/3280).

The Council will collaborate with other health professional councils on their research priorities and interests, share the findings and outcomes of their research and be alert to opportunities to partner in research activities with external parties and stakeholders. The Presidents' Forum will oversee the Research Program Plan and agree on shared research priorities, in collaboration with the HPCA Executive and the Council's Education and Quality Committee.

### **Staffing and resourcing**

The Council's works with two Policy and Project advisors who provide oversight of the Council's research activities. The Council will consider the time and resources required when commissioning or approving a research project, particularly research by third parties. The effective resourcing and monitoring of research projects for accountability and sign off can be time consuming and at times resource intensive. The Council may consider cost recovery from researchers arising from any expenses incurred by the research which should be set out in the research contract or agreement.

### **Funding**

The expenditure of funds from the Education and Research Account must be consistent with the purposes set out in section 41S (4) of the Law, that is for any purpose relating to education and research about the health, performance and conduct of registered health practitioners or students.

Each year the Council may determine the amount to be allocated for research. Amounts to be allocated for individual research projects or grants may be fixed at a maximum rate advised to applicants.

### **Risk management**

Mechanisms to manage, record and monitor risks to participants, the research team, the organisation and others involved in research will be documented and included in the project

brief, proposal and the contract or deed of agreement. The risks should be assessed in line with the Council's Risk Register.

### **Receiving and managing research applications**

Research applications may be received as a result of a targeted or general call for proposals or expressions of interest. The Council, the Education and Quality Committee on behalf of the Council, other nominated or specially convened committee will review the applications.

In managing the research process the Council's Policy and Project Advisors are responsible for:

- Ensuring that applications submitted for consideration are complete and include all the required information as outlined in the application form or project proposal. Incomplete applications may be returned to the sender for revision prior to submission to the Council, as long as the closing date for applications has not passed.
- Advising the applicant in writing of the Council's decision regarding the outcome of their proposal and ensuring that any contractual agreements or obligations are provided to the researcher and agreed in writing, prior to commencement.
- Confirming any resource implications, including staff time and access to resources and facilitating access to data, documents or other Council resources as required.
- Monitoring timeframes, obligations and other contractual agreements throughout the research period, and reporting to the Council as required, including a financial acquittal and non-financial progress report.
- Ensuring that researchers provide the Council with a copy of their financial acquittal report, final research report, or other outcomes/results at the conclusion of the project, and at other time/s as requested by the Council and/or as prescribed in the funding agreement.
- Negotiating publication or other research output and publicising the findings with stakeholders and other interested parties.

### **Selection criteria**

The Council has the authority to approve or reject an application. If disclosure of personal or health information is permitted in accordance with statutory requirements, the Council will apply the following criteria to assess an application and inform its decision making:

1. Whether the proposed research is consistent with the Council's legislative responsibilities, aims, objectives and priorities in the strategic plan or other enabling document.
2. Whether the proposed research will assist the Council to achieve its strategic goals, maintain or promote its standards, or enable the Council to demonstrate value.
3. The scientific validity of the proposed project and methodology.
4. The proposed outcomes from the project.
5. The resource implications for the Council, including a cost benefit analysis.
6. The sensitivity of the information, including any personal and/or health information of health practitioners, complainants or others to be accessed for the research.
7. The steps taken in order to ensure compliance with privacy legislation and the statutory guidelines on research issued by the Office of the Information and Privacy Commissioner.
8. Whether a reasonable person would expect the information that will be accessed for the project to be used in the manner and for the purposes proposed.



9. Whether the information to be accessed will be used and/or published in an aggregated and de-identified form.
10. Whether approval for the research project has been granted by a Human Research Ethics Committee (HREC) constituted in accordance with the requirements of the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research* (2007).

In considering any matter relating to a research project, the Council, its Education and Quality Committee or other delegate may make reference to the NSW Health Guideline, *Research Governance in NSW Public Health Organisations* (GL2011\_001).

### **Conflicts of interest**

Council members must comply with the Council Code of Conduct and the Conflict of Interest Policy and be careful to disclose any conflict or potential conflict of interest, whether real or perceived, that may arise in considering a research proposal.

Council members who are employed by, or otherwise associated with, an organisation that has applied for a grant of funds are mindful of declaring that relationship and where practicable will remove themselves from any discussion or vote on the application.

There may be instances in which it is not practicable for all members to be removed from voting on a matter who have or may be perceived to have potential conflicts of interest. This is likely to occur where the rigorous disqualification of all members with any possible conflict may leave the Council unable to form the necessary 2/3rds majority required to approve a proposal. In these cases the advice of the Council's legal member and/or HPCA legal officers will be sought.

### **Approval of the application**

The Council will document its decision regarding approval of the application. This advice will include any obligations, restrictions or other requirements imposed on the research project.

The Council reserves the right to withdraw at any time, its approval for a research project to commence or continue, including any approval to access documents or data held by the Council.

## **RESEARCH APPLICATIONS**

Approval of a research proposal and/or access to information is required prior to commencement, except where the work is undertaken for internal Council quality assurance purposes or in the course of management of a Council's activities.

Researchers seeking access to Council information should discuss a proposed research project with the Executive Officer or a Policy and Project Advisor at a preliminary stage before proceeding to a full application. However a project will not be considered or approved until a full application addressing the matters outlined above has been formally submitted to the Council.

Applicants must read the relevant Grant Guidelines prior to submitting their application. Applications must be submitted on the application form and include a written submission that contains:

- a) the aims, objectives and outcomes of the project
- b) a description of the methodology
- c) the project timeframe, including key milestones if applicable

- d) the material or data to which access is sought or that will be collected in the course of the project
- e) details of any personnel, in addition to the chief investigators, who will be involved in the project
- f) CVs of all personnel involved in the project
- g) the source and amount of funding that will be used to support the project. If financial resources are sought from the Council, a full budget with a justification for each budget line must be provided
- h) the resource implications for the Council, including demands upon staff time in accessing the material or data, financial impact, access to consumables or other Council resources
- i) the proposed method, location and time period for storage of any personal information collected as part of the project. Personal information must be kept in secure storage in a secure location, and only accessed by approved parties
- j) whether it is proposed to publish the outcomes of the project. If so, the application must specify where and in what format the research findings will be disseminated (eg. peer reviewed publications), and the measures that will be taken to protect the privacy of personal information accessed or used in the project
- k) if required, proof of approval from a Human Research Ethics Committee constituted in accordance with the requirements of the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research* (2014)
- l) a declaration of any conflicts of interest that may be relevant to the proposed research and information as to how any conflicts identified will be managed.

## RESEARCHER RESPONSIBILITIES

### Contracts and Agreements

The researcher will be required to enter into a formal Funding Agreement with the Council that outlines the parties' rights and the obligations or conditions the Council may impose and a Schedule of timeframes and milestones. It should include:

- the purpose and scope of the project
- how and when the funds are to be transferred to the project
- clear reporting and accountability clauses to ensure the Council is informed and satisfied with the progress of the project
- rights regarding termination of the agreement or contract
- arrangements for the return of any unexpended funds, or the return of funds for non-performance or termination of the agreement
- rights to use, and ownership of, any intellectual property and publication arising from the project
- identification and management of risks to participants, the research team, the organisation and others involved in the project.

A model Research Grant Funding Agreement is attached (HP15/4392).

### Research ethics

Researchers must conduct their activities in an ethical and professional manner, ensuring validity and accuracy in the collection and reporting. Researchers must comply with all ethical requirements in conducting research using Council data or in partnership with a Council or the HPCA.

If required the researcher must obtain ethics committee approval or review prior to submitting their research proposal or application. The Executive Officer/Policy and project Advisor and the applicant should discuss the requirements prior to the application being submitted, or at least prior to the applications being reviewed by the Council or its delegated committee.

#### **Disclosure of conflicts of interest**

Researchers have an obligation to disclose, at the time of reporting or proposing research (for example, in a grant application), any conflict of interest which has the potential to influence research and investigations, publication and media reports, grant applications, applications for appointment and promotion, or research commercialisation.

#### **Privacy and confidentiality**

Researchers are responsible for ensuring that personal information is only used for the purposes for which consent to its access and use was given and that appropriate security for any confidential material is maintained in accordance with the *NSW Health Privacy Management Plan* which complies with the *NSW Privacy and Personal Protection Act 1998*.

Confidential information must only be used for the purpose for which it was made available. Researchers must maintain the confidentiality of any information to which they have been given access to on a confidential basis. This includes ensuring secure storage for confidential information.

All reports and publications resulting from research must be presented in a way that does not enable an individual's identity to be determined.

#### **Intellectual property and publication of results or findings**

Intellectual property should be identified and recorded. Intellectual property and copyright ownership and rights to subsequent use should be agreed through the project contract.

#### **Publication and research outputs**

Researchers and Councils should be committed to publishing results and disseminating research findings in an accurate and timely manner, whenever appropriate. The Council's ownership, or otherwise, of the intellectual property generated by the research will be made clear in the project contract.

#### **Accountability**

Researchers must commit to regular reporting on progress and achievements, along with a financial report for acquittal of the funds granted, to the Policy and Project Advisor as required by the project contract or other agreement.

## **RESOURCES**

1. Research Program Plan (HP14/8161)
2. Research Grant Guidelines (HP15/12050-01)
3. Research Grant Application Form and Referee Report Form (HP15/12050-02)
4. Ethics Review Checklist (HP15/3958)
5. Model Funding Agreement (HP15/4392).

## REFERENCES

1. National Health and Medical Research Council, the Australian Research Council and Universities Australia (2007), *Australian code for the responsible conduct of research*. Canberra: Australian Government, 2007.
2. NSW Health, Research – Ethical and Scientific Review of Human Research in NSW Public Health Organisations, PD20010\_055.
3. NSW Health, Research – Authorisation to Commence Human Research in NSW Public Health Organisations, PD2010\_056.
4. NSW Health, Research – Human and Animal research and the National Health & Medical Research Council Act 1992, PD 2010\_057.
5. NSW Health (2015), Privacy Manual for Health Information, 3rd ed.
6. NSW Health, Privacy Management Plan, PD2005\_554.
7. National Statement on ethical conduct and human research 2007 (updated March 2014), National Health and Medical Research Council, Australian Research Council, Australian Vice Chancellor's Committee.
8. Office of the Information and Privacy Commissioner, Statutory Guidelines on Research.
9. Office of the Information and Privacy Commissioner, Public Interest Direction Relating to the Disclosure of Information by NSW Public Sector Agencies for Research Purposes.