



Policy on Data Access and Use for Research

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Summary:	This policy sets out the process and criteria for authorising access to, and the use of, Council documents and data for research purposes.		
Applies to:	The Medical Council of NSW and potential researchers.		
Author:	Corporate Governance Committee, Medical Council of NSW		
Owner:	Executive Officer, Medical Council of NSW		
Related legislation, Awards, Policy and Agreements:	<p>NSW Health - PD 2010_055: Research – Ethical and Scientific Review of Human Research in NSW Public Health Organisations</p> <p>NSW Health - PD 2010_056: Research – Authorisation to Commence Human Research in NSW Public Health Organisations</p> <p>NSW Health - PD 2010_057: Research – Human and Animal research and the National Health & Medical Research Council Act 1992</p> <p>NSW Health - GL 2011_001: Research Governance in NSW Public Health Organisations</p> <p>NSW Health – PD2012_018: Code of Conduct</p> <p>Office of the Privacy Commissioner, NSW. Statutory Guidelines on Research.</p> <p>Public Interest Direction Relating to the Disclosure of Information by NSW Public Sector Agencies for Research Purposes</p>		

National Registration and Accreditation Scheme Data Access and Research Policy, approved 30 August 2013

National Health and Medical Research Council: National Statement on Ethical Conduct in Human Research (2007)

National Health and Medical Research Council, Guidelines Under Section 95 of the *Privacy Act 1988*

National Health and Medical Research Council, Guidelines Approved Under Section 95A of the *Privacy Act 1988*

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)

Privacy Act 1988 (Cth)

Freedom of Information Act 1982 (Cth)

Review date: April 2017

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PURPOSE

The Medical Council of NSW (the Council) recognises that review of and reflection upon its processes and the outcomes of its various pathways for handling of complaints about medical practitioners can play an important role in maintaining standards and in improving regulatory processes and outcomes.

The Council supports appropriate quality assurance processes and research projects. This policy outlines the processes for handling requests to access Council information, such as statistical or other data and documents produced by the Council. It includes the application requirements for researchers.

This policy applies to all research to which access to Council information is being sought. Research can be conducted by Council Members, staff or external researchers. It applies to research projects to which the Council may provide funding, either whole or in part, and to projects that are funded by external bodies.

Note to applicants:

In August 2013, AHPRA (the Australian Health Practitioner Regulation Agency) published its *National Registration and Accreditation Scheme Data Access and Research Policy*.

Applicants need to carefully consider which policy applies to the information they seek to access, noting that the Medical Council of NSW operates under a different legislative regime to the Medical Board of Australia and other national health practitioner boards.

BACKGROUND

What is Research and when is approval required?

At times Council Members, staff and/or external researchers may seek access to information to review Council processes and/or outcomes of pathways used for handling complaints about medical practitioners.

Any research undertaken using information that is not publicly available or that requires commitment of staff time or resources is governed by this policy and requires approval prior to commencement, except where the work is undertaken for internal Council quality assurance purposes or in the course of management of the Council's activities.

Use of publicly available data by staff or Council 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 as these are part of the ordinary course of business for the Council, and are covered by normal internal approval processes and the Code of Conduct in relation to public comment.

APPLICATION REQUIREMENTS

An application for access to Council information for use in research must be submitted in writing and contain:

- a) the aims, objectives and outcomes of the project
- b) a description of the methodology
- c) the time frame for the project, 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, that is, 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) 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* (2007)
- 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.

Applicants may contact the Council to discuss a proposed research project 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's Executive Committee.

The researchers must provide the Council with a copy of any final report or publication arising from the research project.

STATUTORY REQUIREMENTS TO BE CONSIDERED BY THE EXECUTIVE COMMITTEE

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

When considering a proposal to access data held by the Council, the Executive Committee must first consider the statutory requirements in NSW that are relevant to the release of personal and/or health information.

Health Practitioner Regulation National Law (NSW)

The Executive must consider the Council's obligations with respect to information and privacy under Part 10 of the *Health Practitioner Regulation National Law (NSW)*.

Privacy and Personal Information Protection Act 1998 (NSW)

Under the *Privacy and Personal Information Protection Act 1998 (NSW)* (PIIP Act), disclosure of personal information by the Council is limited as provided in sections 18 and 19.

The Public Interest Direction Relating to Disclosures of Information by NSW Public Sector Agencies for Research Purposes provides that:

an agency may reasonably depart from sections 18 and 19 of the PIIP Act, provided that it follows guidelines or policies of the agency covering the disclosure of personal information for research purposes which were established at 1 July 2000, or the proposed research has been approved by a committee established for the purpose of giving ethical approval to research projects after such a committee has considered the privacy implications of the collection and subsequent use of such information by the researcher in the absence of express consent.

Where a research proposal involves a request for access to personal information, the Executive Committee must consider whether the Public Interest Direction permits the disclosure of personal information.

Health Records and Information Privacy Act 2002 (NSW)

Health Privacy Principle 11 (HPP 11) in the *Health Records and Information Privacy Act 2002 (NSW)* (HRIP Act) is relevant to the use and disclosure of health information. Where a research proposal involves a request for access to health information held by the Council, the Executive Committee must consider whether disclosure for research is permitted under HPP11(1)(f).

The Executive Committee must have reference to the *Statutory Guidelines on Research* issued by the Office of the Privacy Commissioner NSW. These Statutory Guidelines require, inter alia, that a research proposal be submitted to a Human Research Ethics Committee for approval, that the application contains specified information, and that the Human Research Ethics Committee weighs the public interest in considering the application. The Committee will have reference to the checklist on *Using and Disclosing Personal Information for Research* contained in the *Statutory Guidelines on Research* (Appendix 2).

The *Statutory Guidelines on Research* issued by the Office of the Privacy Commissioner, NSW note that Guidelines exist which regulate the use and disclosure of information for research under the Commonwealth *Privacy Act 1988*. The *Guidelines under section 95* apply to Commonwealth agencies and the *Guidelines under section 95A* apply to private sector organisations. These guidelines may be relevant for researchers seeking access to information held by agencies or organisations covered by the *Privacy Act 1988*.

Approval in accordance with the *Guidelines under section 95A* is deemed to be sufficient to ensure compliance with NSW Privacy Commissioner's statutory guidelines.

ADDITIONAL REQUIREMENTS TO BE CONSIDERED BY THE EXECUTIVE COMMITTEE

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

1. Whether the proposed research is consistent with the Council's aims and objectives.
2. Whether the proposed research will assist the Council to achieve its goals or maintain or promote its standards.
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 medical practitioners, 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 Privacy NSW.
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 Executive Committee may make reference to the NSW Health Guideline, *Research Governance in NSW Public Health Organisations* (GL2011_001).

Approval of the application

The Executive Committee will document its decision regarding approval of the application. This advice will include any obligations, restrictions or other requirements the Committee may wish to impose on the research project. The Executive Committee may require researchers to enter into an agreement to ensure confidentiality of information.

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. The researcher will be required to meet any obligations or conditions the Council may impose, and provide the Council with a copy of any final report or publication arising from the research project, including acknowledging the Council's support for the project.

RESPONSIBILITIES

The Executive Officer of the Council is responsible for:

- Ensuring that applications submitted for Executive Committee consideration are complete and include all the required information as outlined in points a) to l) above. The Executive Officer must return incomplete applications to the sender for revision prior to submission to the Executive Committee.
- Advising the applicant in writing of the Executive Committee decision regarding approval 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 any timeframes, obligations and other contractual agreements throughout the research period, and reporting to the Executive Committee as required.
- Ensuring that researchers provide the Council with a copy of their research report, or other outcomes/results at the conclusion of the project, or at other time/s as requested by the Executive Committee.
- Making this policy available to all potential researchers.

STATUTORY PROVISIONS IN NSW

Privacy and Personal Information Protection Act 1998 (NSW)

[Section 18 Limits on disclosure of personal information](#)

[Section 19 Special restrictions on disclosure of personal information](#)

Health Records and Information Privacy Act 2002 (NSW)

[Schedule 1 Health Privacy Principles](#)

[Clause 11 Limits on disclosure of health information](#)

PART 1: USING AND DISCLOSING HEALTH INFORMATION FOR RESEARCH

1.1 When can I use or disclose health information for research or statistics?

This checklist will tell you when you can use and disclose health information for research or statistics, and whether you need to comply with the statutory guidelines on research (which require the research activity to be referred to a Human Research Ethics Committee for consideration). The checklist assumes that:

- the information you are proposing to use or disclose is 'personal information' – that is, information about an individual whose identity can reasonably be ascertained from the information
- the information you are proposing to use or disclose is 'health information'
- you are covered by the HRIP Act

1. Could the purpose of the research or statistics be served by using or disclosing de-identified information?

Yes	<input type="checkbox"/>	You should use or disclose de-identified information only. If you de-identify the information then you do not need to read any further, and you do not need to comply with the statutory guidelines on research [Note: although the process of de-identifying health information is a use by the organisation for the purposes of research, it does not need to be conducted in accordance with the statutory guidelines on research]
No	<input type="checkbox"/>	Go to question 2.

2. Are you proposing to use or disclose the health information with the consent of the individual(s) concerned?

Yes	<input type="checkbox"/>	You can use or disclose the health information relying on the 'consent exemption' in HPP 10(1)(a) or 11(1)(a). If you de-identify the information then you do not need to read any further, and do not need to comply with the statutory guidelines on research.
No	<input type="checkbox"/>	Go to question 3.

Best practice tip: Wherever possible, you should seek the consent of the person. Use or disclosure authorised by the person is almost always to be preferred to relying on one of the other exemptions, provided the consent is freely given and informed. It is important that the person does not feel pressured to participate.

3. Was the health information collected for the primary purpose of the research or statistics?

Yes	<input type="checkbox"/>	You can use or disclose the health information for the research or statistics relying on HPP 10(1) or 11(1). You do not need to read any further, and do not need to comply with the statutory guidelines on research.
No	<input type="checkbox"/>	Go to question 4.

4. Is the research, or the compilation or analysis of statistics activity directly related to the primary purpose for which the health information was collected and would the person reasonably expect you to use or disclose their health information for the activity?

Yes	<input type="checkbox"/>	You can use or disclose the health information for the research or the compilation or analysis of statistics activity relying on the 'direct relation exemption' in HPP 10(1)(b) or 11(1)(b). You do not need to read any further, and do not need to comply with the statutory guidelines on research.
No	<input type="checkbox"/>	Go to question 5.

For example: It is unlikely that many research activities will come within this exemption, however some compilation or analysis of statistics activities might come within it. Using health information to compile statistics about the number of patients treated for a particular disease within a hospital, for example, would arguably come within this exemption.

5. Is the use or disclosure for the research or statistics authorised, required, permitted or reasonably contemplated under another law?

Yes	<input type="checkbox"/>	You can use or disclose health information relying on the exemption in HPP 10(2) or 11(2). You do not need to read any further, and do not need to comply with the statutory guidelines on research.
No	<input type="checkbox"/>	Go to question 6.

For example: You may be required to disclose health information involving notifiable diseases pursuant to the Public Health Act 1991 (NSW), or in accordance with another statutory direction under Commonwealth law or court order or other subpoena.

6. Can you rely on the 'research exemption' to use or disclose the health information?

Yes	<input type="checkbox"/>	You can use or disclose health information relying on the 'research exemption' in HPP 10(1)(f) or 11(1)(f) if you: <ul style="list-style-type: none"> • meet the four exemption criteria in Part 1.2 of this publication and • comply with the statutory guidelines on research in Part 2 of this publication (which require the activity to be referred to a Human Research Ethics Committee for consideration) Go to question 7.
No	<input type="checkbox"/>	You cannot use or disclose the health information for the research or statistics. (Unless you have identified another exemption in the HRIP Act that permits you to do so)

7. Are you a private sector organisation that is already covered by the NHMRC Guidelines under section 95A of the Privacy Act 1988 (Cth)?

Yes	<input type="checkbox"/>	You may use or disclose health information for research or statistics in accordance with the NHMRC Guidelines under section 95A of the Privacy Act 1988 (Cth). If you are bound by the Federal Privacy Act 1988 and operate under the section 95A Guidelines you will be taken to have complied with the statutory guidelines on research. You do not need to read any further, and do not need to comply with the statutory guidelines on research.
No	<input type="checkbox"/>	Any use or disclosure for research or statistics must be in accordance with the statutory guidelines on research in Part 2 of this publication.