



Australian Government

National Health and Medical Research Council

## NHMRC Public Consultation: Offline Submission Form

### Targeted Consultation on the Draft Principles for Accessing and Using Publicly Funded Data for Health Research

Please complete this form and include it with your mail or fax submission.

**Submissions that do not have this form attached will not be accepted.**

**Does this submission reflect the views of the organisation or an individual?**

An individual

An organisation

#### Contact Details

Name:	
Organisation:	Population Health Research Network
Background:	<p>The Population Health Research Network (PHRN) is responsible for the creation of a research infrastructure that enables research using linked data from health data collections across all jurisdictions in Australia. The data linkage infrastructure supports the beneficial use of information held by governments for population based research to improve the health and wellbeing of Australians and enhance the effectiveness and efficiency of health services</p> <p>The PHRN was established in 2009 with collaboration between Australian state and territory governments and their academic partners to develop national data linkage infrastructure. It has received \$38 million from the Australian Government Department of Education through several research infrastructure programmes including the National Collaborative Research Infrastructure Strategy and the Education Investment Fund. State and</p>

	<p>territory governments and their academic partners have contributed a further \$51 million in cash and in-kind.</p> <p>The PHRN works with all Australian jurisdictions to develop and operate safe and secure infrastructure for the linkage of health and related data contained in statutory and administrative data collections, and for the provision of this data to researchers for approved projects. This includes the capacity to link data across state and territory boundaries.</p> <p>The purpose of the PHRN is to support the conduct and quality of population level research which can be conducted without researchers having access to personal information. The protection of privacy is, therefore, central to the rationale and activities of the PHRN.</p> <p>All PHRN Participants were invited to contribute to this submission. Not all Participants made a contribution. This submission is a summary of the responses received and should not be taken as individual endorsement by each individual PHRN Participant Organisation.</p>
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**\*\*Please only include the name of the organisation here if your views reflect those of the organisation.**

**Permission to publish on the NHMRC website**

Yes, NHMRC may publish my submission on the NHMRC website

No, I do not consent to my submission being published on the NHMRC website

My submission contains some information which I do not want published on the NHMRC website. I have clearly marked the information I'd like redacted before NHMRC may publish my submission.

*\*Note: Any submission made to the NHMRC may be subject to the requirements of the Commonwealth Freedom of Information Act 1982. NHMRC retains the right to determine which submissions it will publish. All personal information should be removed from your submission if permission to publish has been granted. Submissions may not be made public if personal information is included in the submission*

**Agreement**

I am aware that if I agree to have my submission published on the NHMRC website, it will be widely available, e.g. it may be placed on the NHMRC website and made available in hard copy. I am also aware that the information

may be further referenced in later publications. If I have named an organisation, I agree that my comments are representing the views of the organisation.

Any direct contact details, e.g. phone numbers and addresses, will be redacted from the submission. Such information will not be used or disclosed for any other purpose, without prior written consent. Submissions may not be made public if personal information, including health information, about the submitter or a third party is included in the submission.

*Please note material submitted to the NHMRC will not be returned. We recommend that you keep a copy of all submitted materials for your personal records.*

Name (please print):	
Signature:	
Date:	

*Note: It is acceptable to type your name in the signature box of this form as your electronic signature.*

# Questions

## 1. Would you describe you or your organisation as a:

- a. researcher who uses publicly funded health and health related datasets (please go to question 2); or
- b. another user of publicly funded health and health related datasets (please go to question 2); or
- c. custodian who has responsibilities regarding release of publicly funded health and health related datasets (please go to question 3); or
- d. other- please specify (please go to question 2)

The PHRN is a collaboration between Australian state and territory governments and their academic partners to develop national data linkage infrastructure. It is one of the National Collaborative Infrastructure Strategy capabilities funded by the Australian Government Department of Education.

## 2. How could the principles in the draft Guide add value when making a request to access existing health and health related datasets for the purposes of health research and for your use of the data?

The principles should provide a useful and easy reference framework for researchers and data custodians to consider when accessing or providing access to publically funded data for health research.

These principles provide a good starting point to facilitate communication between researchers and data custodians which will foster a better understanding of respective roles and responsibilities.

The principles highlight the need for consistent processes and protocols which cover access use, management, storage and legal responsibilities.

The principles should help promote consistency of decision making and also to foster a degree of trust in the high levels of protection and transparency the system delivers.

## 3. How could the principles in the draft Guide add value (to you or your organisation) when considering an application to access existing health and health related datasets for the purposes of health research?

## 4. What barriers exist in adhering to or achieving the principles in the draft Guide? How could these be overcome?

### The legal framework for access to publically funded data for research

Australia has an extremely complex legal framework governing the collection, use and disclosure of data for research which incorporates three different bodies of law (statutory duties of confidentiality, equitable duties of confidentiality, privacy legislation). There is also variation between jurisdictions and in the clarity and terms of individual legislation. Whilst in most cases the empowering legislation permits the use and disclosure of data collections for research, each research project must be considered on a case by case basis.

Data custodians' primary responsibility is to ensure that they comply with the law when considering requests for access to data for research. Understandably they may not always feel confident about decision making in such a complicated legal environment and may act cautiously.

There are a number of approaches that could overcome the barriers that the legal framework causes. In the short term the provision of guidance materials and training for data custodians to assist them to understand the legal framework better. In the medium term changes to legislation to clarify the use of specific data collections for research may be required and in the longer term Australia should consider a more uniform national approach.

## The National Statement on Ethical Conduct in Human Research

Human research ethics committees (HREC) will also have responsibilities in ensuring that the principles are implemented. The most challenging ethical question around the use of publically funded data for research is when a waiver of consent is requested. The NHRMC is encouraged to review the whole of Chapter 2.3 of the National Statement on Ethical Conduct in Human Research to assist HRECs to consider waivers of consent. This would assist in the implementation of the principles. There are a number of issues that should be considered including:

- An amendment to Chapter 5.1.6 is required to add research where HREC review is required by privacy legislation to the types of research that require review by an HREC. In our experience many HRECs find the fact that this is not listed as one of the types of research which require review by an HREC to be confusing.
- The relationship between 2.3.6(a); 2.3.10(a) and 5.1.6 - 5.1.7
- 2.3.6(c) and 2.3.10(c) - reconsider the word "impracticable" and include consideration of
  - the impact on people of seeking consent and
  - whether the outcomes of the research will be compromised
- The difficulty of applying 2.3.10(d)
- Should legality be a question for the HREC - 2.3.6(i) and 2.3.10(i)? This is more appropriately a question for research governance or data governance. It appears to require that HRECs obtain legal advice on each occasion.
- Clarify the responsibility in 2.3.12. Is this the responsibility of the institution conducting the research or the institution providing ethical review? Either way there does not appear to be compliance so it does need reconsideration. Why is it here and not in chapter on institutional responsibilities?

### Data Custodian Resources

A data custodian's ability to comply with these principles will depend on the agency's policies, priorities and available resources. These are likely to vary significantly from custodian to custodian and result in inconsistent adherence to the principles.

### 5. Is there other relevant legislation, regulations and/or policies that could be added to Appendix A in the draft Guide? Please specify, including their relevance.

The list of legislation, regulations and policies in Appendix A is incomplete. It does not include documents like the Information Policy – Principles on open public sector information from the Office of the Australian Government Information Commissioner. The value of including a list of relevant legislation is questioned as given the complexity of the legal framework (mentioned in question 4) without significant guidance about how to interpret it would be unhelpful and difficult to keep up to date. The list of documents was helpful in the consultation process but it is recommended that unless there is explicit guidance about how each document is to be used in relation to the principles then Appendix A should be deleted. This level of detail is more appropriately provided in practical guidance and training materials.

### 6. If the Guide was co-badged by other Australian Government Departments would you or your organisation be more likely to implement it? Why? Why not?

Access to linked data for research requires the agreement and cooperation of government data custodians both State and Commonwealth, academic institutions and the community. The principles will be easier to implement if they are co-badged by organisations representing all three groups e.g. the Department of Health, Department of Human Services, all state and territory health departments, Universities Australia and the Consumers' Health Forum of Australia. In particular state and territory governments have significant data resources that can be used for health research and their active support for the principles would make implementation much more likely. Co-badging by the State and Commonwealth Privacy Commissioners would also assist with implementation.

### 7. What could be done to publicise and disseminate the Guide, and to encourage its adoption and implementation by researchers and data custodians?

## 8. Do you have any other comments or concerns on particular sections of the document?

If so, please identify the section you wish to comment on:

### • Purpose

The “Background” does not adequately capture the breadth and quality of Australia’s publically funded data resources. Australia is one of the few countries in the world with a relatively stable but diverse population which has near-universal access to comprehensive healthcare services, which in turn generate data in nationally standardised formats, permitting the creation of high quality population-based health data collections. These data collections cover a wide range of areas, including all hospitalisations (both public- and private-sector), emergency department attendances, all births (including obstetric details), all deaths, all cases of cancer and notifiable communicable diseases, health screening services (including Pap tests and mammographies) as well as Medicare and Pharmaceutical Benefits data. These core population-based data collections are being supplemented by a rapidly growing range of more special purpose clinical data collections, covering areas such as cancer chemotherapy and radiotherapy, intensive care, renal disease and trauma.

In addition this section does not explain the benefits of sharing publically funded data to all of the stakeholders including researchers, data custodians, government and the Australian community. The obvious benefits of using publicly held health and health related data are substantial, particularly in relation to:

- Cost reduction: Maximise the potential of existing statistical systems and avoid duplication i.e. using existing data is cheaper and more effective than undertaking new data collections.
- Making better use of available data: Enhance the value of information gained from a single source i.e. data and information used and reused to inform significant decisions in government and the wider community.
- Collaboration and communication: Data sharing and exchange raises the level of communication between researchers, clinicians, administrators, consumer groups and the media.

### • Scope and target audience

The two stated aims of the draft Principles are:

- “to facilitate communication between researchers and data custodians to foster a better understanding of respective roles and responsibilities”
- “To optimize the appropriate use of publicly-funded data for health-related research”

Whilst both aims are strongly supported and a set of principles is likely to contribute significantly towards meeting the first aim it seems optimistic that on their own a set of principles could achieve the second aim.

*“The need for the principles”*

The recognition that “...priorities for data custodians include adherence to legislation, privacy protection, ensuring that the suitability and limitations of the data for specific research applications are understood and the need to meet internal work demands” is welcomed. However, adherence to legislation and privacy protection are substantively more than “priorities”. These are legislated obligations which have consequences if not adhered to.

### • Principle 1a

Add the following phrase “Have processes (e.g. data management plan) in place that not only cover use of the data for the purpose for which they were collected, but also any future research purposes including data linkage for which they may be used. They should also include agency resource allocation for data provision.

- **Principle 1c**

This principle may be better placed in a separate principle on “Discoverable and useable information” or “Effective information governance”.

The use of “Researchers should expect ...” creates an “us” and “them” approach to the principles. It is suggested that this phrase is deleted.

- **Principle 1e**

Regarding the statement, “...”key priority areas for research should be identified by researchers in collaboration with data custodians, policy makers, practitioners and the community”. A collaborative approach to the identification of research priority areas is strongly supported. However, this principle places the emphasis on researchers identifying the priorities. A change of wording in order to place the focus on collaborative identification of priorities is recommended.

- **Principle 1f**

Consumer and community participation is strongly supported. It is suggested that this warrants its own principle.

- **Appendix B**

Perhaps include research institutes as an example of research organisations as they are key research organisations.