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Principles for accessing and using publicly funded data for health research

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PRINCIPLES FOR ACCESSING AND USING PUBLICLY FUNDED DATA FOR HEALTH RESEARCH

Purpose

Background:

Australia has many publicly funded data holdings, including registries, administrative databases, clinical datasets and survey data. Access to these for research into population health, health services and clinical care provides our greatest opportunity to unlock the value in these records and benefit the public by leading to improvements in prevention, screening and treatment. It is particularly important that the use of Aboriginal and Torres Strait Islander data maximises opportunities to improve health outcomes for this population group.

It is essential that accessing these datasets and determining their fit-for-purpose to address a research question occurs within the appropriate legislative and governance structure, and with due respect for the individuals whose information may be contained in the data.

These *Principles for Accessing and Using Publicly Funded Data for Health Research* (the Principles) provide a framework for researchers and data custodians to consider when requests or applications are made for access to existing publicly funded datasets for the purposes of research. The Principles should be read in conjunction with the *National Statement on Ethical Conduct in Human Research (2007)*[1], the *Australian Code for the Responsible Conduct of Research*[2] and other policies and legislations such as those outlined in Appendix A.

The Principles are a guide for researchers who are requesting access to wholly or partially publicly funded datasets, and for organisations that hold them. These Principles augment existing ethics and grant review practices as well as internal custodian processes. They do not dictate a particular process that must be followed, nor restrict an organisation from using its own data access policies. The Principles acknowledge that requests for data are made in the context of custodian's core business requirements, the primary aim of which may not include support of research. Organisations holding relevant data that are not publicly funded, such as those conducting clinical trials, are also encouraged to consider and use the Principles.

The need for the Principles:

Researchers and data custodians often have different perspectives and priorities in data sharing. It is important to recognise that, whilst the data has value in its potential to improve health outcomes, it may comprise information of individuals who expect that their privacy will be protected. Priorities for custodians include adherence to legislation, privacy protection, ensuring that the suitability and limitations of the data for specific research applications are understood as well as the need to meet internal work demands and resource constraints. Researcher priorities overlap with custodian priorities, but also include expeditious study implementation, often determined by the time frames specified by research funding agencies.

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[1] http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/e72_national_statement_130207.pdf

[2] http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/r39.pdf

The Principles aim to ensure that all parties have a common set of priorities that govern the use of this data, to facilitate communication between researchers and data custodians to foster a better understanding of respective roles and responsibilities, and to optimise the appropriate use of publicly funded data for health-related research.

Scope and target audience

The Principles are for custodians and researchers using publicly funded health and health-related datasets, including linked datasets, whether held at national, state/territory or local level. This may include both aggregate and unit record data held in registries, administrative, survey-based and clinical datasets/databases, existing health research datasets/databases, and datasets held by universities. Researchers should understand that many datasets are not primarily designed to suit potential research.

Health-related data can include non-health-specific data sets, for example urban planning data. These data are not always publicly funded, but in some situations, this privately collected data may be provided to government stakeholders. Agreements covering this data use should not rule out using the datasets for research. Appendix B includes a map of health data key stakeholders and a list of examples of health-related data.

Principles

1. Maximise the use of publicly funded health and health-related data for research

a. Research is an important use of publicly funded health and health-related data and is vital to unlocking their value to benefit Australians by driving improvements in disease prevention and clinical care.

b. The value of data lies in its use. Use of datasets for research should be promoted, encouraged and maximised for public benefit, while also protecting privacy and confidentiality.

c. To maximise public benefit, health and medical research should develop processes and systems to incorporate and support sustainable consumer and community involvement.

d. Public trust in the use of personal data for research should not be compromised.

2. Data custodians should recognise their responsibilities and accountabilities when providing access to data for research

Custodians of publicly funded health and health-related datasets should:

a. Encourage, support and facilitate access to data, including for data linkage, to promote high quality and sustainable research outcomes.

b. Ensure that data releases for research purposes protect the privacy of individuals and maintain confidentiality of their data in accordance with relevant legislation, policies and ethics guidelines.

c. Specify the conditions of data access and licensing, and provide a description of their data holdings to assist researchers to determine whether the data are fit-for-purpose.

d. Provide researchers, whose applications for access have met the required criteria and have been approved, with timely access to data for research on a ‘best endeavours’ basis.

e. Seek wherever possible to harmonise access, approval and data supply processes with other data custodians responsible for similar or related data sets.

f. Be transparent and proactive about:

- requirements for ethics approval (if applicable)
- how requests or applications for data access are made, assessed, and approved, and how long assessing applications may take
- timelines for provision of data
- any charges associated with data provision
- processes to follow up on outstanding data access requests
- processes to follow when seeking review of decisions to deny data access
- how data will be made available, and
- requirements for researchers to sign confidentiality, data use and/or other agreements.

3. Researchers should recognise their responsibilities and accountabilities when accessing and using publicly funded health and health related datasets

Researchers using publicly funded health and health-related datasets should:

a. Consult with data custodians early in the research project development: be clear about their research intent, and check that the data are appropriate for the intended research purpose.

b. Comply with the *National Statement on Ethical Conduct in Human Research* (2007)[3]; and be aware of relevant state, territory and Commonwealth legislation relating to privacy and use of data.

c. Ensure that the identity of individuals is not disclosed to unauthorised persons, that data are kept secure and only used for the purpose for which their use is approved.

d. Meet obligations under legislation and in signed agreements with data custodians for the use of data; including restrictions[4] imposed on the use, sharing and destruction of data; and any requirements for review of research findings and reports.

e. Publicly acknowledge in their publications, reports and presentations the data source, and support given by data custodians.

f. Be transparent and proactive about:

- declaring conflicts of interest
- source/s of funding
- measures taken to protect and prevent misuse of data
- the quality of datasets, including identifying any limitations
- objective reporting of research findings
- consultation with stakeholders including relevant consumer representatives
- timeframes for research and publication of findings
- considerations for research translation
- compliance with the terms and conditions of data provision and usage, and
- compliance with all relevant legislation, including the Privacy Act 1988.

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[3] http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/e72_national_statement_130207.pdf

[4] NHMRC *National Statement on Ethical Conduct in Human Research (2007); Australian Code for the Responsible Conduct of Research; Section 95 and 95A of the Privacy Act*

APPENDIX A

Alignment with existing data policies and guidance

The legislative environment covering data collection and access is complex and layered, with Commonwealth, State and Territory legislation having to be adhered to. The Guide complements existing data principles, policies and guidance documents including but not limited to the following high level legislation:

Name	Link to website	Relevance to Principles
Australian Government Information Management Office *Australian Public Service Big Data Strategy*	http://www.finance.gov.au/sites/default/files/Big-Data-Strategy_0.pdf	Details the whole-of-government-approach to the use of big data. This approach can be used to provide better access to Australian government data for research.
Australian Public Service *Better Practice Guide for Big Data*	http://www.finance.gov.au/sites/default/files/APS-Better-Practice-Guide-for-Big-Data.pdf	Aims to address the key considerations for government agencies when growing their capability in big data and big data analytics. It is intended initially as an introductory and educative resource for agencies looking to introduce a capability and the specific challenges and opportunities that accompany such an implementation. It is also relevant to those in industry, research and academia who can work as partners with government. It states that further work is required to provide specific guidance and approaches for managing the responsible use of the data and data analytics to address vulnerabilities in relation to privacy, security, acquisition of data and the application of insights obtained from data.
National Statistical Service (NSS) *A Good Practice Guide to Sharing Your Data with Others*	http://www.nss.gov.au/nss/home.nsf/NSS/E6C05AE57C80D737CA25761D002FD676?opendocument	Provides a basic framework for data sharing agreements, including key factors to consider when developing data sharing agreements. Designed to assist government data custodians, data providers and data users as well as assisting staff working on, or contributing to, data sharing projects.
NSS: *High Level Principles for Data Integration Involving Commonwealth Data for Statistical and Research Purposes*	http://www.nss.gov.au/nss/home.NSF/pages/High+Level+Principles+for+Data+Integration+-+Content?OpenDocument	Outlines seven principles that facilitate linkage of social, economic and environmental data for statistical and research purposes.
NSS: *Statistical Data Integration using Commonwealth data collections*	http://www.nss.gov.au/nss/home.NSF/pages/Data+Integration+Landing%20Page?OpenDocument	Outlines the Australian Government's position regarding statistical data integration of health administrative data collections.

Alignment with existing data policies and guidance

Name	Link to website	Relevance to Principles
Office of the Australian Government Information Commissioner: *Principles on open public sector information*	http://www.oaic.gov.au/information-policy/information-policy-resources/information-policy-agency-resources/principles-on-open-public-sector-information.	These principles rest on the democratic premise that public sector information is a national resource that should be available for community access and use
National Aboriginal and Torres Strait Islander Health Data Principles	www.aihw.gov.au/WorkArea/DownloadAsset.aspx?id=6442472790	Organisations with significant responsibilities in Aboriginal and Torres Strait Islander health data should apply these principles and establish meaningful partnerships with Aboriginal and Torres Strait Islander Australians. The principles set out a culturally respectful foundation for the collection, storage and use of Indigenous Australian's health and health-related information.
The NHMRC open access policy for dissemination of research findings	http://www.nhmrc.gov.au/grants/policy/dissemination-research-findings	To maximise the benefits from research, the open access policy requires that any publication arising from NHMRC supported research must be deposited into an open access institutional repository within a twelve month period from the data of publication.
The NHMRC *Statement on Data Sharing* (2015)	http://www.nhmrc.gov.au/grants-funding/policy/nhmrc-statement-data-sharing	Provides advice from NHMRC regarding researchers sharing research data, in line with open access requirements.
The Australian Research Council *Open Access Policy*	http://www.arc.gov.au/applicants/open_access.htm	To maximise the benefits from research, publications resulting from research activities must be disseminated as broadly as possible to allow access by other researchers and the wider community and must be deposited into an open access institutional repository within a twelve month period from the date of publication, taking into account any restrictions relating to intellectual property or culturally sensitive data.
NHMRC's *Ethical Considerations in Quality Assurance and Evaluation Activities* (2014)	http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/e111_ethical_considerations_in_quality_assurance_140326.pdf	This advice is designed to assist organisations in deciding the appropriate level of oversight for quality assurance and evaluation. Organisations should consider this guidance when developing policies/advice on quality assurance activities, particularly as related to the triggers for ethical review.

Alignment with broader legislation, regulations and policies

The Guide also complements a range of broader Commonwealth, State and Territory legislation, regulations and policies, including but not limited to:

Name	Link to website	Relevance to Principles
The Australian Institute of Health and Welfare Act 1987 (AIHW Act)	http://www.aihw.gov.au/privacy-of-data/	The AIHW's main functions relate to the collection and production of health-related and welfare-related information and statistics, and are specified in s.5 of the Act. The Act stipulates that the AIHW operates under a strict privacy regime which has its basis in s.29 of the Act. From the perspective of both subjects and providers of information held by AIHW, a major strength of s.29 is that it specifically imposes on recipients of data released by AIHW the same confidentiality obligations applying to AIHW staff. These include a specific restriction on being required to divulge or communicate any of that information to a court [(s.29(1)(e)].
Government Data Toolkit	http://toolkit.data.gov.au http://data.gov.au	Various policies and papers available including the eGovernment and Digital Economy Policy and economic papers about the value of public sector data.
The *Census and Statistics Act* 1905	http://www.comlaw.gov.au/Details/C2006C00178	Provides the Australian Statistician with authority to conduct statistical collections. The Act requires the Australian Bureau of Statistics to maintain the confidentiality of information collected under the Act
The National Health Information Agreement	http://meteor.aihw.gov.au/content/index.phtml/itemId/182135	An agreement between the Australian Government and state/territory government health authorities to coordinate the development, collection and dissemination of health information in Australia, including the development, endorsement and maintenance of national data standards.
The *National Statement on Ethical Conduct in Human Research* (2007)	http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/e72_national_statement_130207.pdf	Specifies a requirement for consent of participants of human research projects including use of a person's data for research purposes.
The *Australian Code for the Responsible Conduct of Research*	http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/r39.pdf	Discusses the responsibilities of institutions and researchers in management of research data and primary materials.
Ethical Considerations in Quality Assurance and Evaluation Activities	http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/e111_ethical_considerations_in_quality_assurance_140326.pdf	Assist organisations in deciding the appropriate level of oversight for quality assurance and evaluation. Chapter 2.3 of the National Statement on Ethical Conduct in Human Research, 2007 refers to this document.

Alignment with broader legislation, regulations and policies

Legislation and links regarding privacy: *The Privacy Act 1988* (note Section 95) NHMRC guidelines Office of the Australian Government Information Commissioner	http://www.comlaw.gov.au/series/c2004a03712 http://www.nhmrc.gov.au/guidelines-publications/pr2 http://www.oaic.gov.au/privacy/privacy-resources/privacy-fact-sheets/other/privacy-fact-sheet-17-australian-privacy-principles http://www.oaic.gov.au/privacy/privacy-act/health-and-medical-research	Privacy Act gives permission for guidelines to be approved regarding the protection of privacy by agencies in the conduct of medical research. The public interest in the promotion of research of the kind to which the guidelines relate should outweigh to a substantial degree the public interest in maintaining adherence to the Australian Privacy Principles. NHMRC guidelines provide a framework to ensure privacy protection of health information that is collected, used or disclosed in the conduct of research and the compilation or analysis of statistics, relevant to public health or public safety, and in the conduct of health service management activities.
The *Privacy Guidelines for the Medicare Benefits and Pharmaceutical Benefits Programs*	http://www.oaic.gov.au/privacy/applying-privacy-law/legally-binding-privacy-guidelines-and-rules/privacy-guidelines-for-the-medicare-benefits-and-pharmaceutical-benefits-programs-issued-march-2008-effective-from-1-july-2008	Applies a further set of privacy obligations on Commonwealth agencies in relation to the information collected under the Medical Benefits Scheme and the Pharmaceutical Benefits Scheme.
The *Freedom of Information Act 1982*	http://www.comlaw.gov.au/Details/C2012C00231	Allows members of the public rights of access to official documents of the Government of the Commonwealth and of its agencies. Functions and powers given by this Act are to be performed and exercised, as far as possible, to facilitate and promote public access to information, promptly and at the lowest reasonable cost. The Parliament also intends to increase recognition that information held by the Government is to be managed for public purposes, and is a national resource.
The *National Health Act 1953*	http://www.comlaw.gov.au/Details/C2013C00083	An Act relating to the provision of pharmaceutical, sickness and hospital benefits, and of medical and dental services. Section 135A Officers to Observe Secrecy prescribes the conditions under which information collected under this Act may be communicated to any person about the affairs of a third person. Subsection 3 of this section describes the limited situations when information can be communicated. Subsection 4 deems that an authority or person receiving information under subsection 3 is subject to the same obligations and liabilities as if they were an Officer under the Act and cannot communicate the information to any other authority or person. Section 135AA Privacy Guidelines requires the establishment of privacy guidelines that apply a further set of privacy obligations on Commonwealth agencies in relation to the information collected under the Medical Benefits Scheme and the Pharmaceutical Benefits Scheme.

Alignment with broader legislation, regulations and policies		
The *Health Insurance Act 1973*	http://www.comlaw.gov.au/Details/C2014C00550	An Act providing for payments by way of medical benefits and payments for hospital services and for other purposes. Section 130 Officers to Observe Secrecy prescribes the conditions under which information collected under this Act may be communicated to any person about the affairs of a third person. Subsection 3 of this section describes the limited situations when information can be communicated. Subsection 4 deems that an authority or person receiving information under subsection 3 is subject to the same obligations and liabilities as if they were an Officer under the Act and cannot communicate the information to any other authority or person.
The *Social Security (Administration) Act 1999*	http://www.comlaw.gov.au/Details/C2013C00127	An Act to provide for the administration of the social security law, and for related purposes.

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5 Reviews of data access policies should be undertaken at regular intervals to ensure continued compliance with relevant legislation, regulations and policies.

APPENDIX B

Publicly Funded Health Datasets Stakeholder Map

DATA USERS AND/OR PROVIDERS

GOVERNMENT DEPARTMENTS

Includes but is not limited to federal, state/territory and local departments and policy makers in the areas of:

- Ageing
- Defence
- Communication
- Education
- Environment
- Health and human services
- Industry
- Prime Minister and Cabinet
- Social Services
- Treasury
- Veterans' Affairs

University faculties, schools of health and/or medicine (or equivalent), other researchers or research organisations

Public and private hospitals, private health service providers, clinical registries

Council of Australian Governments and relevant subcommittees, other state and territory governments and agencies, state government births, deaths and marriage registries

General public, NGOs

GOVERNMENT AGENCIES

Includes but is not limited to agencies and policy makers in the areas of:

- Aboriginal and Torres Strait Islander Health
- Cancer
- Defence Science and Technology
- Health and welfare
- Nutrition research funding
- Productivity
- Safety and quality in health care
- Sports
- Statistics
- Scientific and industrial Research
- Antarctic Research Expeditions

ADDITIONAL SOURCES OF DATA

- Ambulance data
- Australian Electoral Commission
- Crime data
- Demographic data
- Education data
- Environmental data
- Geographic data
- Immigration data
- Police data
- Road safety data
- Sales data
- Social Security data
- Sporting performance data

APPENDIX C

Glossary

Term	Definition
Confidentiality	The treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be used or divulged to others in ways that are inconsistent with the understanding of the original disclosure, without permission[6].
Data custodian[7]	Agencies responsible for managing the use, disclosure and protection of source data used in a statistical data integration project. Data custodians collect and hold information on behalf of a data provider (defined as an individual, household, business or other organisation which supplies data either for statistical or administrative purposes). The role of data custodians may also extend to producing source data, in addition to their role as a holder of datasets.
Data quality[8]	The seven dimensions of quality are: Institutional Environment, Relevance, Timeliness, Accuracy, Coherence, Interpretability and Accessibility. All seven dimensions should be included for the purpose of quality assessment and reporting. However, the seven dimensions are not necessarily equally weighted, as the importance of each dimension may vary depending on the data source and context.
Fit-for-purpose	The quality of the dataset is sufficient to be able to address the research question(s).
Health and Health related data	Includes any data required to inform health research/health status. This includes data sets with health specific and non-health specific data, as well as data sets linked to data where the primary issue is health (e.g. socio economic status, education, occupational health and safety). It includes data sets from bio specimens and tissue banks.
Privacy	The individual's right or expectation that personal and other identifying information will not be disclosed.
Public benefit	Advantage gained for parts or the whole of society from accessing and using data for research purposes. Provision of data that will contribute to the generation of knowledge that will benefit the general community or lead to the formation of policies and practices to benefit the Australian population.
Publicly funded data	Data whose collection and maintenance rely on funding from the government at relevant jurisdictional levels. These include those collected for statistical, research, or administrative purposes.
Research[9]	The original investigation undertaken to gain knowledge, understanding and insight. It is a broad concept and there is no simple, single way to define research for all disciplines.

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[6] Population Health Research Network Glossary - http://www.phrn.org.au/media/27174/phrn%20glossary.pdf

[7] The National Statistics Service: http://www.nss.gov.au/nss/home.nsf/pages/Data+Integration+-+Roles+and+responsibilities+of+data+custodians?opendocument

[8] Australian Bureau of Statistics ABS Data Quality Framework at http://www.abs.gov.au/ausstats/abs@.nsf/mf/1520.0

[9] Australian Code for the responsible conduct of research http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/r39_australian_code_responsible_conduct_research_150107.pdf