DEVELOPMENT OF A FRAMEWORK FOR SECONDARY USE OF MY HEALTH RECORD DATA

Submission to the Department of Health from the Population Health Research Network

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PHRN
Population Health Research Network

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National Research Infrastructure for Australia
An Australian Government Initiative
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About the Population Health Research Network

The Population Health Research Network (PHRN) is a national data linkage infrastructure network. The PHRN commenced in 2009 and is funded by the Australian Government’s National Collaborative Research Infrastructure Strategy (NCRIS), with support from state and territory government agencies and academic partners. The University of Western Australia is lead agent for the PHRN. The PHRN’s primary purpose is to build and support the operation of collaborative, nationwide data linkage infrastructure capable of securely and safely linking data collections from a wide range of sources including within and between jurisdictions and across sectors and providing access to linked data.

Through the support of the PHRN, Australia now has the facilities and capabilities to link and provide access to linked data in all jurisdictions. This infrastructure is of international significance. PHRN achievements include:

- Establishment of new data linkage units in Queensland, Victoria, Tasmania and South Australia
- Establishment of an accredited Commonwealth Integrating Authority at the Australian Institute of Health and Welfare (AIHW)
- New online application and secure data delivery systems which facilitate access to data
- Establishment of a remote access data laboratory (SURE) that enables researchers to access linked datasets in a secure environment from anywhere in Australia

The PHRN infrastructure supports the linkage of data collections from both the public and private sectors across a range of disciplines including health, education and social services e.g. hospital admitted patients, cancer registries and the Australian Early Development Census.

The PHRN and its participants have decades of experience in operating safe and secure, national data linkage infrastructure. More than 80% of research using linked data in Australia uses the PHRN infrastructure.

The PHRN is continuing to improve Australia’s data linkage infrastructure, increase access to linked data and expand the use of linked data. Current PHRN projects include:

- Enduring/routine linkage of Commonwealth to Commonwealth data collections e.g. MBS and PBS and Commonwealth to state/territory data collections e.g. hospital to PBS
- Expansion of the number and type of data collections that are routinely linked at both the Commonwealth and state/territory levels
- Streamlining of application and approval processes required to access linked data
- Content data repositories such as the equivalent of the Custodian Administered Research Extract Server in each jurisdiction to reduce the burden on data custodians and minimise the time to extract data for research and analysis

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DEVELOPMENT OF A FRAMEWORK FOR SECONDARY USE OF MY HEALTH RECORD DATA

Submission to the Department of Health

Recommendations

The PHRN supports the secondary use of My Health Records data and would like to see mechanisms established to link My Health Records data to other data collections using the Australian Government funded national research infrastructure. The following recommendations are made:

1. The Framework for Secondary Use of My Health Record Data (the Framework) should be developed in a manner that is flexible and able to adapt to a changing data policy and ethics environment.
2. The Framework should incorporate a more informed understanding of identifiability and privacy protection than demonstrated in the consultation paper. Categories of identifiability should not be included as they are difficult to define and sometimes contradictory.
3. A one size fits all or simple de-identify and forget approach should not be implemented to address privacy risks. Techniques to minimise and manage risks should be proportionate to the risk level and potential benefits.
4. There should be continued consultation with those who have expertise in the specialised areas related to the secondary use of health and medical data as the Framework is developed. There should also be public consultation on a draft Framework.
5. The disclosure and use of identifiable data, where ethically acceptable, for public benefit e.g. high quality linkage of data, should be allowed. Legislative change may be required to support this.

1. Introduction

This submission has been prepared in response to the Department of Health’s public consultation paper – “Development of a Framework for Secondary Use of My Health Record Data”. The PHRN welcomes the opportunity to comment on the matters raised in the consultation paper. The focus of this submission is on the linkage of My Health Record data to other data collections for research.

It is noted that the consultation paper acknowledges a number of Australian Government activities around the use of government data particularly the Data Integration Partnership for Australia and the Government response to the Productivity Commission’s Report on Data Availability and Use. It is possible that there will be significant changes in Australia’s data policy environment in the short to medium term. It is therefore important that the Framework is developed in a manner that is flexible and able to adapt to a changing environment.

Recommendation 1: The Framework should be developed in a manner that is flexible and able to adapt to a changing data policy and ethics environment.

The PHRN submission proposes a framework (section 2) for the secondary use of My Health Record data. The framework is based on the PHRN’s extensive experience in building and operating national data linkage infrastructure and facilitating the secondary use of health data in the Australian context. The PHRN’s approach to data linkage and secondary use of health data has been built on extensive consultation and discussions with data custodians,
researchers and the community over many years. The PHRN approach uses a privacy-preserving separation model where identifiable linkage variables (e.g. name, address, date of birth) are used to create a dynamic, enduring index showing where health records are held. Linkable content data is then provided to researchers for approved projects. Conditions apply, including use of a secure remote-access data laboratory when required.

The My Health Records Act 2012 restricts access to My Health Records data for research to de-identified data only. We note that the term ‘de-identified’ is not defined in the Act. The PHRN recommends that the legislation is changed to enable the release of identifiable data for research in certain circumstances for a number of reasons:

- Probabilistic linkage using identifiable variables (e.g. name, address, date of birth) results in the highest quality linkage between data collections.
- Some very important research cannot be conducted without identifiable data e.g. use of full date of birth in perinatal research.
- It is very difficult to define de-identified data (see section below).

Identifiability of data
The identifiability of My Health Record data is central to assessing, minimising and managing the risks associated with secondary use of this data. The consultation paper describes a range of categories of identifiability (anonymised, de-identified, non-identified, and re-identifiable). Some of these terms are defined in the Privacy Act 1988 and the National Statement on Ethical Conduct in Human Research (The National Statement) and some are not. The PHRN does not recommend the use of categories of identifiability. However, if they must be used it is recommended that the definitions of terms used in the Framework should be consistent with those in the Privacy Act 1988 and/or the National Statement. Additional terms/definitions which may lead to confusion should not be included. It is noted that the National Statement, sections 3 and 5 are currently under review by the National Health and Medical Research Council (NHMRC). A new version is expected to be released in 2018 and it is essential that the Framework should be consistent with the revised version.

The use of these categories suggests that identifiability is an intrinsic quality of the data and that one can simply determine the relevant category. Identifiability is better understood as a spectrum. The following factors must be taken into consideration when assessing where on the identifiability spectrum data falls and the risks of identification:

- The type of information (e.g. unit record level, name, date of birth)
- The quantity of information
- The other information held by the person who receives it
- The skills and technology available to the person who receives it

It is recommended that the Framework should acknowledge this.

The consultation paper also relies heavily on the concept of de-identification and the assumption that unit record level data can be rendered non-identifiable. There has been recent criticism of reliance on the idea of de-identification to protect privacy and eliminate ethical concerns. Even when identifiers are removed or other de-identification techniques are applied the data provided to researchers may still be identifiable. The Framework’s focus should be on minimising and managing risks in the context of the great benefits that can be
realised from the secondary use of My Health Record data. This approach would be consistent with the approach taken under privacy legislation in every jurisdiction in Australia that has such legislation including the \textit{Privacy Act 1988}.

A proportionate approach should be taken to the management of privacy risks to ensure that the benefits of sharing My Health Records data are realised.

**Recommendation 2:** The Framework for Secondary Use of My Health Record Data should incorporate a more informed understanding of identifiability and privacy protection than demonstrated in the consultation paper. Categories of identifiability should not be included as they are difficult to define and sometimes contradictory.

**Recommendation 3:** A one size fits all or simple de-identify and forget approach should not be implemented to address privacy risks. Techniques to minimise and manage risks should be proportionate to the risk level and potential benefits.

### 2. Proposed Framework for the Secondary Use of My Health Record Data

The PHRN proposes an approach to the Framework below which is based on PHRN policy and practice and the work by Adams and Allen on access to government databases.\textsuperscript{7} Further detailed discussion and consultation with those who have expertise in the specialised areas related to the secondary use of health and medical data will be required before the Framework is finalised.

**Recommendation 4:** There should be continued consultation with those who have expertise in the specialised areas related to the secondary use of health and medical data as the Framework is developed. There should also be public consultation on a draft Framework.

Current governance arrangements for secondary use of other government data collections have been criticised because they are complex, overlapping and not transparent. This leads to inefficiency, unjustified delay and stakeholder dissatisfaction. It is not in the public interest for the secondary use of My Health Records data to be managed inefficiently. In the development of the Framework existing governance mechanisms and arrangements should not be further complicated or duplicated.

#### 1.1. Metadata and Data Quality (Question 13)

High quality metadata which describes the My Health Record data and how it was collected will be important to ensure reliable and accurate conclusions are drawn from analysis of this data. A consultation\textsuperscript{8} conducted by the PHRN showed that the following types of metadata would facilitate high quality research:

- Quality of the data (including reliability, accuracy, completeness)
- Detailed descriptions of the variables in the data collections (including mode and method of collection, changes over time)
- Links to any validation studies of the data available

The Data Custodian (System Operator) should maintain and publish appropriate metadata. This should include quality statements which advise on the quality of data in the My Health Record, including on the quality of individual identification.


1.2. **Secondary uses of My Health Record Data (Questions 1 & 2)**

The PHRN is very supportive of the secondary use of My Health Record data to:

- Facilitate research which may contribute to the promotion, protection and maintenance of the health and wellbeing of the public
- Facilitate the planning, evaluation and delivery of health services
- Contribute to knowledge regarding the health and welfare of the community

All secondary use of the My Health Record data should be in the public interest.

The PHRN would not support My Health Record data being used for purposes without a likely public benefit e.g. where the sole beneficiary is a private sector entity.

1.3. **Eligible Users of My Health Records Data (Questions 3 & 4)**

Eligible My Health Record data users should include data users with the appropriate experience, qualifications, facilities and funding to conduct the proposed research or evaluation. This includes students who are part of a research team with appropriate experience and qualifications.

Data users should not be restricted based on the type of organisation as long as all access criteria are met and required approvals received.

Foreign data users who meet all criteria for access should not be excluded subject to the requirements of Australian Privacy Principle 8 and any other relevant legislation being met.

1.4. **Applications to use My Health Records Data**

An application process including any required forms should be published on the My Health Record website.

The following information should also be published on the website:

- The criteria for access to My Health Records data
- Timeframes for decision making on requests for access
- Terms and conditions for access to My Health Records data including information security requirements
- The process to seek independent, external review of a decision to refuse access to My Health Records data
- Charges, if any

1.5. **Approval to use My Health Records Data (Question 6)**

**Ethics Approval**

All requests to use My Health Records data for research must be reviewed by a Human Research Ethics Committee (HREC) registered with the National Health and Medical Research Council.
The HREC will consider whether the proposal has sufficient merit (including research design and qualifications of the research team) to justify the involvement of human participants. The ethical values of justice, beneficence and respect will also be considered.

It is not recommended that My Health Record establish their own HREC. There is currently a working party of the National Mutual Acceptance Scheme considering how linked data could be included in this scheme in a way that minimised duplication of ethics review. My Health Record should consider participating in this scheme.

*Data Custodian Approval*

The Data Custodian (the System Operator) makes the decision whether to release data or not for secondary purposes. The System Operator may consider establishing an advisory committee to assist in decision making.

The decision whether to release the data or not should be based on published criteria.

Criteria could include:

- HREC approval
- The release of the data is lawful
- Compliance with a set of high level principles. The Caldicott Principles⁹ could be considered as a model.

The System Operator will provide reasons in writing for a decision to refuse to release data.

1.6. **Costs**

The consultation paper is silent on the issue of the cost to access My Health Records for secondary purposes. Ideally access to publically funded data, like My Health Record data, for publically funded purposes e.g. NHMRC funded research should be provided free of charge. Charges for access by commercial entities would be reasonable. However, it is recognised that there are costs involved in preparing and providing data for secondary uses and it may be necessary to recover some of these costs. Any charges should be kept to a minimum to ensure equity of access to this national resource. The Framework should include details on the pricing structure and the basis on which prices are set.

1.7. **Terms and Conditions (Question 11)**

All approved users/user organisations of My Health Records data should be required to enter into a data transfer/use agreement. The agreement should cover the following:

- Details of the data to be supplied/accessed
- Authorised use and disclosure
- Restrictions on use and disclosure
- Information security requirements
- The term and termination

An example agreement for the transfer of data to a data linkage unit can be found at [http://www.phrn.org.au/media/31745/PHRN%20Data%20Transfer%20Agreement%20v1.0.pdf](http://www.phrn.org.au/media/31745/PHRN%20Data%20Transfer%20Agreement%20v1.0.pdf).

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It will be very important to build and maintain the support of the Australian community for the secondary use of My Health Records data. No single approach will achieve this. A range of processes/activities should be implemented including:

- The requirement for all publications arising from the use of My Health Record data to acknowledge the use of the data.
- The requirement for any publications arising from the use of My Health Record data to be deposited into an open access institutional repository and/or made available in another open access format within a twelve month period from the date of publication. This is consistent with ARC and NHMRC policy.
- The establishment of a public register on the My Health Record website of all approved data applications, a lay summary of the results and links to any publications.
- A mechanism to encourage active consumer involvement in research using My Health Record data consistent with the NHMRC Statement on Consumer and Community Involvement in Health and Medical Research.\(^\text{10}\)

1.8. Monitoring (Question 14)

According to the National Statement the responsibility for monitoring research lies with the institution conducting the research (Chapter 5.5). At least annually researchers are also required to provide reports to the relevant review bodies and institutions e.g. HREC and My Heath Record. These reports should include compliance with any conditions of approval e.g. the terms and conditions and maintenance and security of records.

My Health Record could also audit compliance with use agreements either on an ad hoc or routine basis.

3. Linkage of My Health Record Data (Questions 9 & 10)

The availability of linked population-based data is important because:

- No single data collection is sufficient to allow an understanding of the complex pathways that result in health or disease and whether Australia’s health and social service systems work in optimal ways.
- Australia is a federation and different jurisdictions collect different data. For example, the states/territories collect hospital admissions data and the Commonwealth collects MBS and PBS data. In order to understand individual patient pathways and the health system as a whole these data collections must be linked.
- Collecting data once and using many times for different purposes e.g. service provision and research is more cost effective than collecting data multiple times.

The My Health Records data, particularly when the opt-out approach is implemented will be a nationally significant population level data collection. The PHRN currently links a range of Commonwealth, state, territory and researcher data collections including hospital admissions, MBS, PBS, births, deaths, cancer registries and researcher cohorts such as the 45 & Up Study. The inclusion of My Health Records into the national linkage system would add a range of data such as general practice and imaging data that is currently missing from the national linkage system. The addition of My Health Records data to the national linkage system would

result in an enhancement to Australia’s internationally recognised research infrastructure that would enable important additional innovation and research.

Australia has world leading data linkage infrastructure through the PHRN which has been safely and securely linking data for many years. The My Health Record data should be linked to other data collections through this existing system. There is no need and it would be inefficient and wasteful for new infrastructure to be built and operated.

The major impediment to linkage of My Health Record Data is that the My Health Records Act 2012 does not allow for the release of identifiable data. To achieve high quality linkage the legislation will need to be changed so that linkage variables (name, address, date of birth) can be released to authorised data linkage units. At a minimum linkage variables should be able to be released to the AIHW for inclusion in the National Master Linkage Key.

**Recommendation 5:** The disclosure and use of identifiable data, where ethically acceptable, for public benefit e.g. high quality linkage of data, should be allowed. Legislative change may be required to support this.

The My Health Records content data should remain with the System Operator. It should not be copied and stored elsewhere e.g. within an Integrating Authority. This is consistent with the role articulated for the System Operator in the My Health Records Act 2012 – “to prepare and provide de-identified data for research or public health purposes”.

Please note that there is a significant problem with the suggestion that Statistical Linkage Keys maintain confidentiality (see section 4.4.1 (3) of the Consultation Paper). They generally represent partially identified data and hash algorithms are not necessarily applied. Note also that use of hash algorithms results in poorer quality linkage, whether applied to fully or to partially identified data.

4. **My Health Records Act 2012 (Question 18)**

One of the issues that the PHRN has experienced and has been well recognised in a number of reviews\(^{11,12}\) is that the legislative environment for the linkage of data collections is extremely complex and confusing. In part this is due to the fact that the legislation that authorises the collection of data often is not sufficiently clear or consistent on the use and disclosure of data for secondary purposes. In response to this issue the PHRN commissioned an experienced privacy consultant, Ms Judy Allen, to write a set of guidelines for Legislation Supporting Data Linkage Research. The guidelines are attached to this submission (Attachment 1). They should be considered in any review of the My Health Records Act 2012 to enable the maximum benefits to be achieved from the secondary use of My Health Records data.


Legislation Supporting Research Using Linked Data

Guidelines

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# Summary Guidelines

1. Legislation should be uniform for all data and all agencies and decision making should be centralised.

2. Legislation should provide clear authority for the approval of both the use and disclosure of all personal information held by an agency in specified circumstances.

3. The legislation should provide clear immunity from liability under any other statute, the common law and equity for the use or disclosure of personal information, or other information, authorised by the provisions.

4. The authorised purposes of the use and disclosure should include;
   - all kinds of research;
   - the creation of research infrastructure;
   - funding, monitoring and evaluation; and
   - compilation or analysis of statistics.

5. The legislation should not limit the recipients of the information to particular persons or institutions.

6. The legislation should deal separately and explicitly with the use and disclosure of information for data linkage.

7. The legislation should permit data linkage facilities to collect, store and use the information for the maintenance of linkages and creation of approved new linkages.

8. The legislation should;
   - specify the person/position who can authorise the release of information;
   - specify the criteria for approval;
   - provide for the imposition of conditions related to security of the information and the beneficial use of the information;
   - impose confidentiality obligations on recipients; and
   - provide for processes that ensure transparency and accountability.
Background

In February 2017 the PHRN Participant Council (The Council) met for a workshop on access to linked data. The meeting agreed that the definition of access was:

“The ability to make use of a linked dataset for the purpose of research, monitoring, evaluation or policy development.”

The meeting also identified a target/endpoint for access:

“Appropriate and relevant linked data available in a timely manner at a reasonable price in compliance with ethical and privacy values.”

Barriers to achieving this endpoint were discussed as well as ways to overcome the barriers. One of the barriers identified was the legal environment for data linkage in Australia, particularly the multiple pieces of legislation that apply to collection, use and disclosure of data. The Council agreed that a list of requirements needed in legislation or regulations to enable linkage with identifiable variables would assist them when legislation was being reviewed or new legislation drafted. These guidelines were commissioned in response to that request.

The guidelines are intended to provide practical guidance to those responsible for reviewing legislation or instructing on the drafting of new statutory provisions.

Introduction

Legislation supporting research using linked data should achieve the following aims;

- ensure that the necessary collection, use and disclosure of information is lawful;
- establish transparent, accountable and efficient decision making;
- provide for robust risk-based security and confidentiality obligations; and
- support community trust in the use of personal information for research.

The landscape of research using linked data is changing so rapidly that legislation needs to be very flexible. Legislation that is too detailed and prescriptive will rapidly become outdated and either too restrictive or irrelevant. In this context the role of legislation should be to provide general authority and to empower good decision making that is transparent and accountable. Security and confidentiality obligations need to be robust but must also be adaptable to different contexts, different levels of risk and changing technology. This flexibility can be achieved by building these considerations into criteria for approval. Decision making that is transparent and that includes community involvement will help support public trust.

The following guidelines are directed to the reform of legislation governing information held by government agencies. The research use of information held by private organisations such
as private health care providers raises different issues. These are not dealt with in full here but some brief comments are included at the end of this document.

Clear and consistent legislation is only one component of good governance of data for research and data linkage. These guidelines address only this component. The legislative framework provides the essential foundation for policies and decision making practices that support the beneficial use of information and protect individual interests.

Guideline 1

**Legislation should be uniform for all data and all agencies and decision making should be centralised.**

**Uniformity**
The complexity of the current law is due in part to the multiplicity of statutes. Separate data collections are governed by different statutes, even those held in one agency. There are often several statutes dealing with confidentiality that apply to one data collection - including statutes specifically governing that collection and more general statutes that apply to all data collections. Similarly, the use and release provisions are embedded in a variety of statutes. The order of precedence of these statutes is often not clear. This complexity and uncertainty contributes to inefficiency in the approval processes for linking and releasing data. Legislative review should aim to achieve simplicity and clarity in the relevant law and to adopt one set of rules for all government held data.

Ideally, each jurisdiction would have one statute dealing exclusively with the use and disclosure of personal information for data linkage and research. The provisions should apply to all data collection in all agencies in a jurisdiction.

**Centralisation**
Distributed decision making leads to inconsistent and risk-adverse decision making and the need for multiple approvals. Authority to release data for all data collections should be centralised as much as possible. This would not exclude the role of data custodians who can continue to provide advice on the release of data.

There are three alternative models for achieving greater uniformity and centralisation in a jurisdiction that are workable.

1. One set of use and disclosure rules for all data collections in an agency. The agency makes its own decision about release of data.
2. One set of use and disclosure rules for all agencies. A single statute that applies to all agencies and authorises each agency to use and disclose data held by it. Each agency would continue to make its own decision about release of data.

3. A one-stop shop. A statute that empowers a single specialist agency to make decisions about use and disclosure of data from any agency. This model is proposed by the Productivity Commission Inquiry Report, Data Availability and Use (No. 82, 31 March 2017). This approach would centralise decision making in one agency and would be most efficient in reducing the need for multiple approvals.

The Productivity Commission has recommended the establishment of Accredited Release Authorities which would operate at a national level and “would be responsible for:

- deciding (in consultation with original data custodians) whether a dataset is available for public release or limited sharing with trusted users;
- collating, curating, linking and ensuring the timely updating of National Interest Datasets and other datasets;
- offering advice, services and assistance on matters such as dataset curation, de-identification and linking; and
- providing risk-based access to trusted users.”

Guideline 2

**Legislation should provide clear authority for the approval of both the use and disclosure of all personal information held by an agency in specified circumstances.**

The use and disclosure of personal information (reasonably identifiable information) is restricted by common law, equity and a range of statutes in all jurisdictions. Government agencies are empowered by statute to collect information and may only use and disclose that information lawfully if they are authorised by statute to do so. Clear statutory authority is required to ensure that data holders can lawfully use and disclose information for data linkage and research using linked data.

**Use and Disclosure**

The provisions must permit both the use and the disclosure of data for the authorised purposes. Some existing provisions authorising the use of data for research have been interpreted as only permitting research that is conducted by the agency itself. The legislation should make it clear that personal information can be lawfully used for linkage and research within the agency and can be lawfully disclosed to others for the purpose of linkage, for the

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1 Productivity Commission Inquiry Report, *Data Availability and Use* (No. 82, 31 March 2017), at 255
creation of research infrastructure such as a data warehouse, for particular research, and for quality assurance projects.

What kinds of data should be covered?
The provisions should apply to all data held by the agency, including personal information (reasonably identifiable information). Personal information should be available for data linkage and should also be available for research projects in limited circumstances.

The degree of identifiability of information always needs to be assessed in a particular context and in the hands of the particular holder of the information. While information can no longer ever be considered to be completely de-identified, the concept of reasonable identifiability still has utility. Many of the statutory and common law restrictions on the use and disclosure of information apply specifically to personal/identifiable information. Therefore, it is important that provisions providing statutory authority for use and disclosure of information apply explicitly to personal information.

To promote uniformity and clarity the definition of personal information in the Privacy Act 1988 (Cth) should be adopted by all jurisdictions. There is some variation in the definitions currently used in different jurisdictions but they all adopt a test of reasonableness. A number of jurisdictions use the wording of the old definition of personal information from the Commonwealth Privacy Act 1988 (a definition that has since been amended).

It is recognised that information will have different levels of sensitivity for a variety of reasons. This variation can be accommodated in the decision making process and in the conditions imposed.

Guideline 3

The legislation should provide clear immunity from liability under any other statute, the common law and equity for the use or disclosure of personal information, or other information, authorised by the provisions.

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2 Information or an opinion about an identified individual, or an individual who is reasonably identifiable, whether the information or opinion is true or not, and whether the information or opinion is recorded in a material form or not.

3 Eg Health Records and Information Privacy Act 2002 (NSW), s5 - ‘Information or an opinion .... about an individual whose identity is apparent or can reasonably be ascertained ...’. Note that this wording has been complicated by a decision of the Federal Court in Telstra Corporation Limited [2017] FCAFC 4 (19 January 2017). In that case this wording was interpreted to require a two pronged enquiry:

- Is the information about an individual?
- Is the individual’s identity apparent or can it reasonably be ascertained.
The statutory authorisation must take precedence over all other law, including all other statutes, the common law and equity, and provide immunity from liability under all civil or criminal law. If this is not explicitly stated then data holders may remain subject to other duties of confidentiality and secrecy provisions.

The common law or equitable duty of confidentiality will apply where the information is originally collected in a confidential relationship - such as health care. The defences to a breach of this duty are ill-defined in the context of research. It is unlikely that the public interest defence to a breach of a common law or equitable duty of confidentiality will apply in the context of research in Australia, so reliance must be placed on a defence of statutory authority. It is, therefore, essential that the provisions apply expressly to liability under the common law and equity.

Guideline 4

The authorised purposes of the use and disclosure should include:
- all kinds of research;
- the creation of research infrastructure;
- funding, monitoring and evaluation; and
- compilation or analysis of statistics.

What kind of research?
The statutory authority for the use and disclosure of the information for the purpose of research should be kept broad. It should not be confined to medical research or health research. These limitations raise difficult questions of definition and do not have any defensible ethical basis. Linked data enables research addressing complex questions that cannot be confined to particular disciplinary categories. The beneficial use of government-held data should not be confined to particular areas of research.

Research Infrastructure
Statutory authority should explicitly extend to the use and disclosure of personal information for the creation of research infrastructure such as a data repository. Authority to use data for research may be interpreted as applying only to the conduct of a particular research project and may not include the creation of research resources such as a biobank or ongoing data repository that will be used for future research projects. Under this interpretation data custodians would then be unable to provide data for research infrastructure. This should be dealt with explicitly in legislation.
Funding, monitoring and evaluation
The statutory authority should extend to funding, monitoring and evaluation activities (QI) as well as research. Linked data is increasingly being used for these activities both internally by government agencies and by external users. The distinction between research, and funding, monitoring and evaluation activities is notoriously difficult and they all raise the same ethical issues in relation to confidentiality.

Guideline 5

The legislation should not limit the recipients of the information to particular persons or institutions.

The statutory authority should not limit the recipients who are permitted to receive data. Some current statutes restrict disclosure of data for research to particular institutions. This limits the beneficial use of the data and is too inflexible to accommodate changes over time. The suitability of the recipients should be assessed as part of the approval process.

Guideline 6

The legislation should deal separately and explicitly with the use and disclosure of information for data linkage.

The statutory authority to collect, use and disclose personal information for data linkage should be dealt with explicitly. Although the creation of research infrastructure may well cover data linkage this may be complicated where linkage systems are being used for business purposes as well as research. To put the matter beyond doubt it would be preferable to have separate provisions for data linkage.

The authority to disclose personal information for data linkage should not be confined to particular data linkage units. It may be appropriate to have a process of approving and prescribing data linkage units that meet appropriate standards of quality and security.

A clear definition of data linkage is needed. The definition must be able to accommodate developing methods of linkage. A suggested definition is as follows:

A process of locating and connecting information that relates to the same person, place or family.
Guideline 7

The legislation should permit data linkage facilities to collect, store and use the information for the maintenance of linkages and creation of approved new linkages.

The ability to collect and store linkage variables and use them for the ongoing maintenance of linkages and the creation of new linkages is essential for the efficient and beneficial use of linked data. This should be explicitly authorised.

Guideline 8

The legislation should:
- specify the person/position who can authorise the release of information
- specify the criteria for approval
- provide for the imposition of conditions related to security of the information and the beneficial use of the information
- impose confidentiality obligations on recipients
- provide for processes that ensure transparency and accountability

Who should authorise release of information?
Responsibility for approving the release of information should be centralised at a high level in an agency. Distributed decision making at a lower level in an agency leads to inconsistent and risk adverse decision making and the need for multiple approvals. Accordingly any permitted delegation of decision-making should be very limited.

Criteria for approval
Decision makers should be guided by express, but general, criteria which must be taken in to account when making a decision. Transparency requires that these criteria are publically available, either in the statute, regulations or otherwise. Decision makers must be able to provide reasons for their decisions in terms of these criteria.

Appropriate criteria include;
- the use and disclosure is in the public interest;
- approval of an HREC;
• consent of the individual or a waiver of consent approved by an HREC (using specified guidelines such as the Section 95A Guidelines);
• satisfaction that the information will be kept securely; and
• satisfaction that confidentiality will be protected and privacy maximised.

Decision makers should take advice from appropriate sources when applying these criteria. It should be noted that approval of an HREC indicates that it is satisfied that the research methodology will produce sound outcomes, that the research is in the public interest and that there is adequate protection of individual interests. This includes consideration of the security of the data and protection of confidentiality. HREC approval is a source of independent expert advice on these matters. Importantly it includes input from general ‘lay’ members of the community. Decision makers should also take internal advice on governance issues such as risk assessment, insurance and intellectual property matters.

Conditions of approval
Decision makers should be empowered to impose conditions on the release of data to ensure;

• that agencies benefit from knowledge gained and that research is translated into beneficial outcomes;
• the security of information (for example through compliance with specified guidelines and approved security plans); and
• the confidentiality of the information (see below)

Confidentiality
Recipients of personal information should be bound by explicit obligations of confidentiality. This can be achieved by including a provision in legislation imposing a duty of confidentiality on all recipients. Additionally, the conditions of release can include a requirement that every person who will have access to the information must sign a confidentiality contract or an acknowledgement of an existing duty of confidentiality

Good decision making
The legislation should provide a framework for timely, transparent and accountable decision making. This should include;

• the publication of criteria for decisions;
• reasons to be given where applications are refused;
• decisions to be made in a timely fashion;
• an appropriate appeal process; and
• the publication of information about approved projects.
Private Organisations

Private organisation that hold personal information that is valuable for research, such as private health care providers, are also bound by common law and equitable duties of confidentiality and various privacy statutes. In some jurisdictions reliance is placed on the research exception in the various privacy statutes to authorise the release of personal information. The research exception provisions in the privacy statutes do clearly provide an exception to the duties created by the particular privacy act. However, it is not always clear that these provisions provide immunity to liability under the common law and equity or under other statutes. To put this beyond doubt it is necessary to have an explicit statutory provision granting immunity to liability under any other law, including common law and equity and specifying when that immunity applies. For example, such immunity could apply when there is compliance with the research exception in the relevant privacy statute.