

# DATA SHARING AND RELEASE LEGISLATIVE REFORMS DISCUSSION PAPER

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Response to the Discussion Paper

Population Health Research Network

15 October 2019



# ABOUT THE PHRN

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.

## Our Roles

- We are a respected, independent and trusted broker, valued for bringing governments, organisations, individuals and data together securely.
- We collaborate to enhance and maintain significant, innovative research infrastructure to improve the nation's data linkage capability.
- We facilitate and grow the use of linked data in the areas of health and human services.
- We advocate for an improved authorising environment for better access, use and sharing of data.
- We support the whole of government focus on accessing, sharing and using data for the national good.

## Our Vision

Linking life data to improve the wellbeing of all Australians

## Our Mission

To lead and enable the linking of data for world class, action-oriented research

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# PHRN RESPONSE TO THE DISCUSSION PAPER

## Scope of the data sharing and release legislation

The Discussion Paper clarified that, at least initially, state and territory data will not be in the scope of the new legislation. Additional clarification would be helpful about whether state and territory government data e.g. hospital admissions data, held by a Commonwealth Government agency e.g. AIHW, would fall under the data sharing legislation or whether it would remain under the auspices of relevant state government legislation and any data sharing agreement between the state and the Commonwealth.

We note that without more streamlined and consistent processes for cross-jurisdictional data sharing much important research in Australia will remain difficult and cumbersome.

### 1. Do you think the distinction between data sharing and data release is clear? How could this distinction be clearer?

We think the distinction between data sharing and data release is clear.

### 2. What are the challenges for open release of public sector data?

No comment.

### 3. Do you think the Data Sharing and Release legislative framework will achieve more streamlined and safer data sharing?

In the case of health and human services research using Commonwealth data the Data Sharing and Release legislative framework seems unlikely to achieve more streamlined and safer sharing. In most cases there is already clear legislative authority to share this data for research. The most significant impact of the Framework will be to embed the existing practices in legislation.

We have demonstrated this point by mapping the existing processes against the likely processes for a research project involving linked MBS and PBS data based on the information in the Discussion Paper. (Attachment 1).

The Discussion Paper indicates that the Data Sharing and Release legislation will “*provide authority to share data where it is currently prohibited or complex to do so*”. The Discussion Paper provides no information about how to determine when it is too complex to share data under existing legal authority. Data custodians’ ability to answer this question may have an impact on whether more streamlined data sharing is achieved.

Whilst there will likely be benefits in providing legal authority where it is currently prohibited we remain concerned as articulated in our 2018 submission in circumstances where there is existing legal authority.

*“This approach runs the risk of increasing rather than simplifying the legislative complexity by just adding another piece of legislation for data custodians to consider. If data custodians are able to choose which legislation they wish to apply then there is a risk that they may treat applicants for data inconsistently, that is, they may choose to apply the more permissive framework for some applicants and the more restrictive framework for others. This has the potential to lead to actual*

*or perceived bias in decision-making, which are both inconsistent with the principles of good administrative decision-making. Bias, or the perception of bias, will undermine trust among applicants and the community.”*

Without a significant increase in funding for data custodians and accredited data service providers it seems unlikely they will be able to respond in a timely way to the anticipated increase in requests for data and also apply the requirements of the new legislation.

#### **4. What do you think about the name, Data Sharing and Release Act?**

No comment.

#### **5. Do the purposes for sharing data meet your expectations? What about precluded purposes?**

In the original issues paper the purpose test included *“research and development with clear and direct public interest”*. Our original criticism was not that the use must be in the public interest but that the public interest must be *“clear and direct”*. This seemed a very high bar for most potential uses particularly in the research context.

The PHRN is pleased that the words clear and direct have now been removed from the purpose test. However, the removal of any reference to the public interest from the purpose test seems to imply either that each of the three categories in the purpose test are always in the public interest or that the public interest is not an important part of the test. It was also noted that the words *“public benefit”* which were included in the Project Principle *“Data is shared for an appropriate purpose that delivers a public benefit”* in the Best Practice Guide for Applying Data Sharing Principles (March 2019) has been removed from the Project Principle in the Discussion Paper.

Despite this shift away from the concept of public interest/benefit in the purpose test and data sharing principles it remained throughout the Discussion Paper. For example, the discussion of commercial uses of public data had a focus on the public interest and the need to shift the public service culture to one where data is used for public benefit. Therefore it is assumed that the public interest remains an important concept in data sharing and release. If the public interest remains an important component of the purpose test and project principle then all stakeholders will need more guidance on how to determine the public interest.

What is not so clearly discussed in the Discussion Paper is the importance of weighing the public interest in privacy versus the public interest in data being shared or released. This concept should be incorporated into the purpose test and the data sharing principles more explicitly.

#### **6. What are your expectations for commercial uses? Do we need to preclude a purpose, or do the Data Sharing Principles and existing legislative protections work?**

Private industry is an integral part of the Australian health system and has an important role in health care delivery as well as the development of new therapeutic interventions. If all commercial purposes for data sharing were precluded this may negatively impact on Australia’s ability to improve health services and treatments. However, the community clearly has concerns about commercial uses of publically funded data.

We recently commissioned The Australian Centre for Health Engagement Evidence and Values at the University of Wollongong to examine community attitudes towards governments sharing linked administrative health data sets with private companies for research and development of treatments

for disease and disability. This research suggests that sharing public sector health data with private industry will require concerted and nuanced public engagement. Where the intent is to share public sector health data with private companies, even greater engagement will be needed. This is because people are more worried about sharing health data than they are about many other types of public sector data.

The research indicates:

- There has been very little research conducted in Australia about public attitudes to sharing publicly-held health data with commercial companies.
- Community understanding of how the health sector works is poor. Community members do not understand the nature and extent of data collection and research, how data is owned and shared, the roles of different organisations and individuals within health research and the existing safeguards.
- The public do not understand that pharmaceutical companies and device manufacturers are an integral part of new drug and device development in Australia.
- International research, particularly in the UK in the wake of the introduction of the Care.data patient data sharing scheme, suggests that public willingness to share public sector health data will be dependent on a range of interconnected conditions as follows:
  - the purpose of the research using the data should be of public benefit
  - access to the data should be tightly controlled
  - the data should be held securely
  - comprehensive safeguards be in place to deter misuse
  - particular care should be taken with very sensitive data such as genetic data
  - the potential for harm to individuals, vulnerable groups and society be considered.

We would be happy to share the final research report with the Office of the National Data Commissioner when it is finalised.

The purpose test as described in the Discussion Paper and the Best Practice Guide to Applying Data Sharing Principles are insufficiently developed to assist a data custodian to decide whether data sharing with a commercial entity will result in public benefit. There is also not enough information about the purposes for which the community supports data sharing with commercial entities. Significant ongoing investment will be required to involve the community in this area.

## **7. Do you think the Data Sharing Principles acknowledge and treat risks appropriately? When could they fall short?**

We note the proposed development of a Sensitive Data Code and would be keen to be involved in the consultation to ensure that it will meet the needs of the research and linkage communities. In particular we would want to ensure that high quality linkage conducted by specialist data linkage units (e.g. PHRN supported DLUs) using identifiable data such as name, address, and date of birth was allowed under the code. In the Commonwealth case this often relates to datasets that represent near-universal characteristics such as having a Medicare card or having a tax file number. The release of this information, without the added context of the associated service data is relatively benign in the context of data linkage activities.

The new legislation should strive to enable sharing of Commonwealth identifiable data with jurisdictions for the purposes of linkage and integration, to protect privacy while maximising jurisdictional capabilities.

See the answer to “Do the safeguards address key privacy risks?” below.

### **8. Is the Best Practice Guide to Applying Data Sharing Principles helpful? Are there areas where the guidance could be improved?**

As a principles based approach has been chosen for the new data sharing and release legislation the Office of the Data Commissioner will need to provide considerable support and guidance to ensure consistent application of the data sharing and release legislation. The Best Practice Guide is a good start. Data custodians will likely need much more detailed guidance on how to set up appropriate, proportionate and efficient governance processes to implement the data sharing principles. Without additional guidance there is a high risk of the implementation of inconsistent and cumbersome processes. Areas of governance in which data custodians may require very specific guidance include how to determine:

- what is in the public interest
- whether a proposed data use is ethical
- whether there is legal authority to share the data without requesting legal opinion in every case

Whilst the National Statement on Ethical Conduct in Human Research provides detailed assistance for sharing of data for human research there is little guidance available to data custodians on how to determine the public interest in and ethical data sharing for non-research purposes. Further work will be required in this area to assist data custodians and ensure that consistent approaches are applied to all data sharing activities covered by the legislation.

### **9. Do the safeguards address key privacy risks?**

The safeguards will likely be adequate to address the risks associated with re-identification of individuals or organisations. However, the data sharing principles do not explicitly acknowledge risks other than re-identification. For example, the application of the data sharing principles may be necessary but not sufficient to address the risk of undermining community trust or loss of social licence for some data sharing or release. There are a number of well-known examples e.g. care.data where potentially beneficial data sharing activities have been stopped not because of the risk of re-identification but because of insufficient community involvement in and support for the activity.

Once published, the analysis of data where all the data sharing principles were diligently implemented may still result in risks to groups or communities even if there is no individual re-identification. This is sometimes referred to as group privacy. Inherent bias in an original data collection can result in particular cultural or ethnic groups being negatively impacted by published results. In addition sometimes data analysis creates groups that were previously unknown and actions taken based on these new groupings can have both positive and negative impacts on these groups.

### **10. Are the core principles guiding the development of accreditation criteria comprehensive? How else could we improve and make them fit for the future?**

The core principles appear reasonable. The most important issue for the PHRN is that the right balance is achieved between giving data custodians the confidence and trust to share data and not adding an additional layer of bureaucracy to an already burdensome approval system.

It can be extremely onerous for organisations to achieve accreditation in some existing accreditation systems such as the Accredited Integrating Authorities. Once accreditation is achieved there is no guarantee that data custodians will agree to share data with the accredited Integrating Authority.

Careful consideration will be needed to build an accreditation system that promotes data sharing. The wrong approach could result in reduced data sharing particularly if accreditation is too burdensome, costly or difficult.

We would be happy to comment further when more information is available about the proposed accreditation system.

**11. Are there adequate transparency and accountability mechanisms built into the framework, including Data Sharing Agreements, public registers and National Data Commissioner review and reporting requirements?**

The proposed transparency and accountability mechanisms seem reasonable.

**12. Have we achieved the right balance between complaints, redress options and review rights?**

No comment

**13. Have we got our approach to enforcement and penalties right for when things go wrong? Will it deter non-compliance while encouraging greater data sharing?**

No comment

**14. What types of guidance and ongoing support from the National Data Commissioner will provide assurance and enable safe sharing of data?**

Please see our response to question 8. In addition, guidance on community involvement in data sharing activities and decisions will also be required.

## Will the new data sharing and release legislation streamline the application and approval processes for access to linked Commonwealth data for research?

Access to data for research in Australia, particularly for population level research without consent can be a long and complex process. The difficulties and consequences of these long processes have been highlighted over many years in a range of government reports and research publications<sup>1</sup>. These issues were addressed in the Productivity Commission Report on Data Availability and Use<sup>2</sup>. The recommendations from the report were accepted by the Australian Government and part of the response was the establishment of the Office of the Data Commissioner and the drafting of Commonwealth data sharing and release legislation<sup>3</sup>.

The research community in Australia has high expectations that the new Commonwealth data sharing legislation will significantly improve their access to data. They are seeking simpler and faster application and approval processes. The complex and lengthy approval processes for access to linked cross-jurisdictional data are of particular concern.

The Office of the Data Commissioner released a discussion paper on 3 September 2019 which indicates the Office's current thinking on how the legislation will be framed<sup>4</sup>.

We reviewed the discussion paper and the Best Practice Guide for Applying Safe Data Sharing Principles to better understand whether the proposed data sharing framework would address the complaints of the research community<sup>5</sup>.

The discussion paper is clear that although the calls for a national system have been heard, initially the scope of the new legislation will only be Commonwealth data.

*"We are working towards building a national system. Our scheme will begin with a focus on Commonwealth data and enable participation by all levels of government. Commonwealth, State, Territory and local government authorities may be accredited and access shared data under the legislation, but State and Territory data will not initially be in scope".*

Therefore the research community should temper its expectations of short term improvements in the complex processes required to access cross-jurisdictional data.

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<sup>1</sup> Mitchell RJ, Cameron CM, Bambach MR. Data linkage for injury surveillance and research in Australia: perils, pitfalls and potential. *Aust N Z J Public Health*. 2014;38(3):275-80. Moore HC, Guiver T, Woollacott A, de Klerk N, Gidding HF. Establishing a Process for Conducting Cross-Jurisdictional Record Linkage in Australia. *Australian & New Zealand Journal of Public Health*. 2016;40(2):159-64. Andrew NE, Sundararajan V, Thrift AG, Kilkenny MF, Katzenellenbogen J, Flack F, et al. Addressing the challenges of cross-jurisdictional data linkage between a national clinical quality registry and government-held health data. *Aust N Z J Public Health*. 2016;40(5):436-42.

<sup>2</sup> Australian Government Productivity Commission. Productivity Commission Inquiry Report; Data availability and use: Overview and Recommendations. Canberra: Productivity Commission; 2017.

<sup>3</sup> The Australian Government's response to the Productivity Commission Data Availability and Use Inquiry. In: Cabinet DotP Ma, editor.: Commonwealth of Australia; 2018.

<sup>4</sup> Commonwealth of Australia, Department of the Prime Minister and Cabinet, Data Sharing and Release Legislative Reforms Discussion Paper. 2019.

<sup>5</sup> Commonwealth of Australia, Department of the Prime Minister and Cabinet, Best Practice Guide for Applying Safe Data Sharing Principles. 15 March 2019.

To investigate whether application and approval processes for linked Commonwealth data collections might be more streamlined we used a previously published case study. The case study involves the use of linked MBS and PBS data for a research project without consent. Our original paper described the existing legal authority to share the data with researchers and the decision making criteria applied by the data custodian (Department of Health) and the human research ethics committee (HREC)<sup>6</sup>. In this article we mapped the current application and approval process which relies on the existing legal authority to release the data (see figure 1).

The proposed new data sharing framework will allow the new data sharing legislation to be the legal authority for data sharing if *“the data cannot be shared easily under existing authority”*. There is no assistance in the discussion paper on how to determine whether data can currently be shared easily or not. For the purposes of this exercise we assumed that the current lengthy processes were not easy and it would be reasonable to use the data sharing legislation pathway. We mapped the likely application and approval process for access to linked MBS and PBS data for research without consent (Figure 2).

The basic steps required in both pathways are very similar. The issues that emerge from the comparison are discussed below.

The purpose test replaces the public interest test required by the Public Interest Certificate. The discussion paper indicates that there will be further guidance developed on the purpose test required under the data sharing legislation. From the information available any research and development activity *“to advance knowledge, contribute to society and create better public policy”* would meet the requirements of this test and on the face of it no evaluation of the public interest is required. However, there is a brief reference to *“how to design the purpose test to maximise public benefits while meeting community expectations”*. It is possible that HREC review may be sufficient to meet this requirement but further clarity is necessary.

From the information available it seems that, unlike the current situation, relying on data sharing and release legislation may not require approval by a HREC. This is based on the assumption that, as the data sharing and release legislation was being relied upon for legal authority, the AIHW Act s29(2)(c) which requires approval by the AIHW HREC would not need to be complied with. However, researchers would still be required to have HREC approval to meet the requirements of the National Statement on Ethical Conduct in Human Research. The data custodian may require HREC review even if the legislation does not.

It was also not clear whether a data custodian, in this case the Department of Health, could delegate their decision-making responsibilities to an accredited data service provider (AIHW). If they can, then some streamlining may be achieved by only one organisation being involved in the decision making process. However, the discussion paper does state that

*“Data Custodians and Accredited Data Service Providers will have joint legal responsibility for managing the data sharing, with the Data Custodian retaining responsibility for overseeing the Data Sharing Agreement and ensuring the terms are met”.*

It may not be appealing to a data custodian to delegate the final decision about data sharing whilst retaining legal responsibility for the data sharing.

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<sup>6</sup> Flack F, Adams C, Allen J. Authorising the release of data without consent for health research: The role of data custodians and HRECs in Australia. *Journal of Law & Medicine*. 2019;26(3):655-72.

Currently the final decision to share data is made by the Secretary of the Department of Health by the issuing of a Public Interest Certificate. A Public Interest Certificate would not need to be issued if the data sharing and release legislation was used. However, even if this step is not required there will still need to be a step where the final decision about whether or not to share the data is made.

In this example if the Department of Health retains their decision making responsibilities then the steps in the application and approval process are likely to be very similar or the same as the current situation i.e. there would be no clear benefit in relying on one or other of the available legal authorities to share.

It is proposed in the discussion paper that:

*"Under the Data Sharing and Release legislation, a Data Custodian will only be able to enter into a Data Sharing Agreement with an Accredited User organisation and will only be able to share data with accredited individuals within that organisation".*

For access to linked MBS and PBS data using the existing legal authority, the researcher must complete a training course for access to the data within the SURE. This can be considered equivalent to being an "accredited user" under the new data sharing and release legislation. The SURE is also accredited as part of the AIHW's Integrating Authority accreditation. This is equivalent to being an "accredited data service provider" as described in the discussion paper. If the new data sharing and release legislation was relied on as the legal authority to share linked MBS and PBS data for research the researcher's organisation would also have to be accredited as an "accredited user organisation". This is an additional step in the approval pathway. The discussion paper seems to suggest that even if the data will be shared in a secure analysis environment hosted outside the researcher's organisation e.g. SURE, both the individual and the organisation will still need to be accredited for the Department of Health to enter into a data sharing agreement with the researcher's organisation.

Based on the information currently available it seems that the current application and approval processes for access to linked MBS and PBS data without consent for research are consistent with the proposed data sharing framework i.e. safe projects, safe people, safe settings, safe data, safe outputs. Apart from the requirement for the researcher's organisation to be accredited there will be little change from the current process.

**Figure 1: Current Legal Authority and Application Process for Access to Linked MBS and PBS Data for Research Without Consent**

**Five Safes Framework**

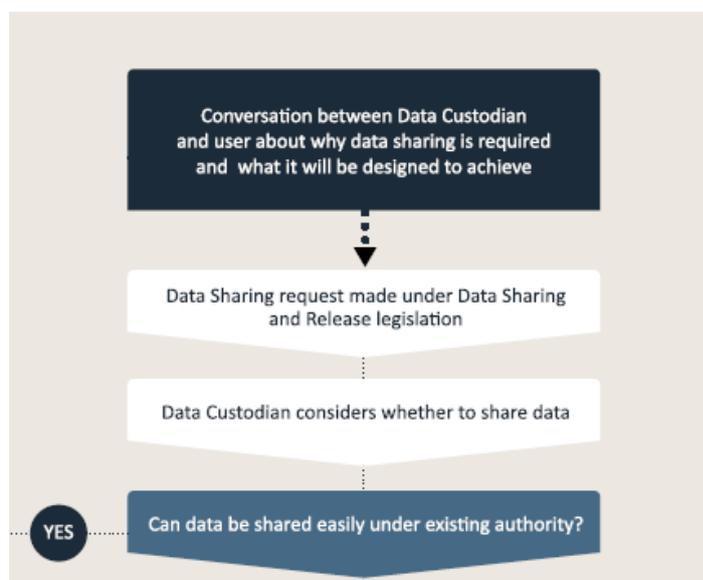
**Safe project  
Safe data**

**Safe project  
Safe people  
Safe setting  
Safe data**

**Safe people**

**Safe setting**

**Safe output**



**Legal Authority**

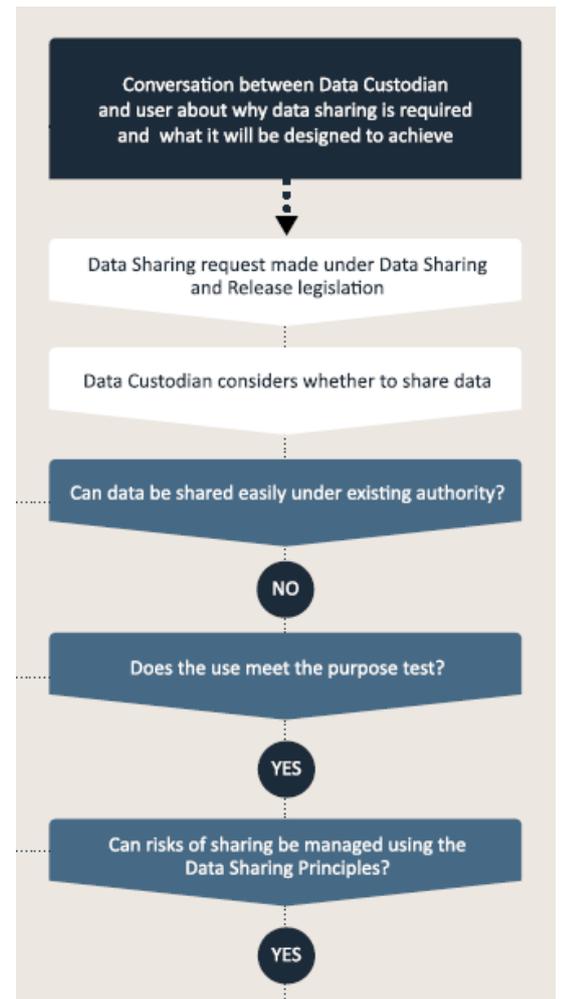
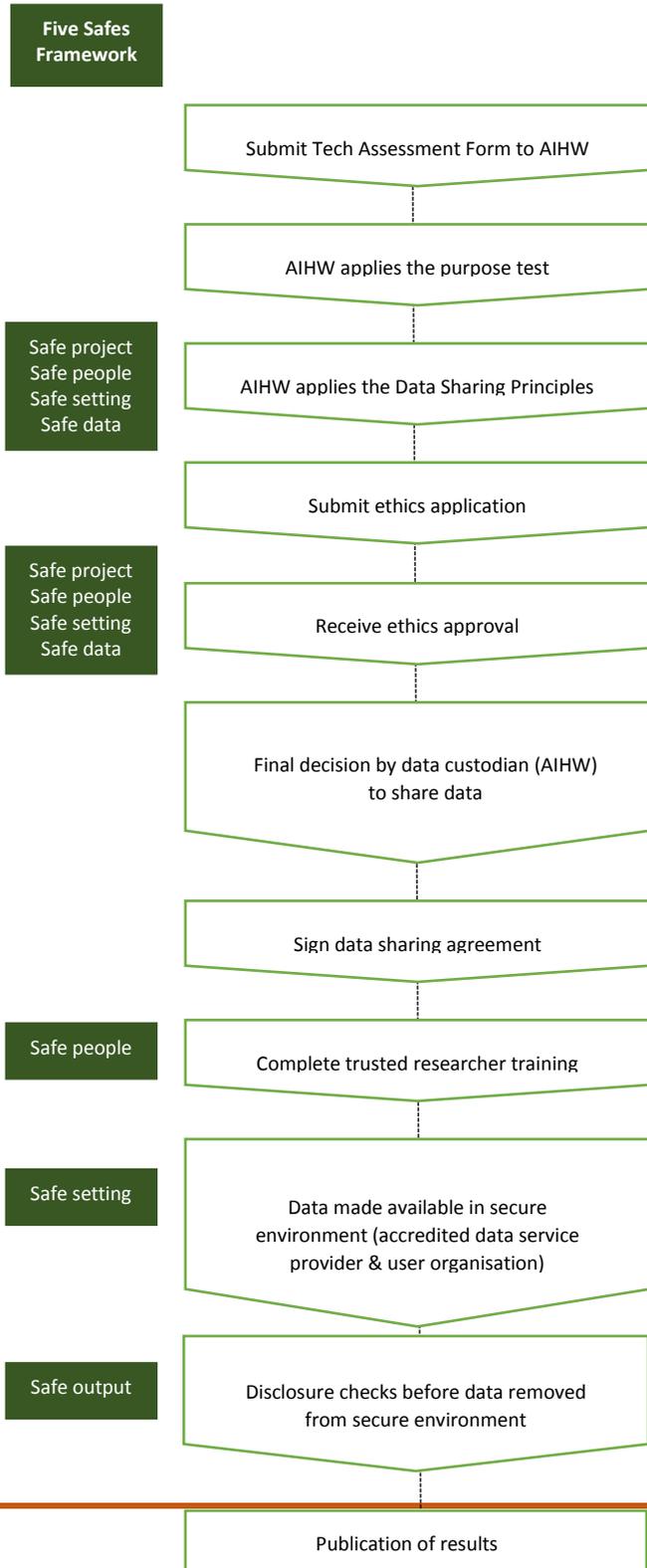
*“The Health Insurance Act 1973 and the National Health Act 1953 provide the legal authority to release MBS and PBS data, respectively, to researchers. The data custodians may release the data if the Minister for Health certifies that the release is necessary in the public interest. It should be noted, therefore, that in this case study the disclosure of information for research is permitted under Australian Privacy Principle (APP) 6.2(b) of the Privacy Act 1988 – “the use or disclosure of the information is required or authorised by or under an Australian law”. It is therefore unnecessary to rely on the research exception in the Privacy Act 1988 – “the act is done in the course of medical research and in accordance with [the section 95] guidelines”.*

Flack F et al 2019

**NOTES**

The AIHW is an accredited Integrating Authority and has an agreement with the Department of Health (data custodian) to link, securely manage the MBS & PBS data and run the application process. The final decision to share the data remains with the Minister for Health or delegate. Therefore the AIHW currently acts as an *Accredited Data Service Provider* as described in the consultation paper.

**Figure 2: Legal Authority and Application Process for Access to Linked MBS and PBS Data for Research Without Consent Relying on Data Sharing Legislation**



**Legal Authority**

In this example the Dept of Health could decide that although there is existing legal authority the data cannot be shared easily. Therefore it would rely on the Data Sharing legislation.

**NOTES**

In this example the following assumptions were made:

- DOH would use AIHW as an accredited data service provider rather than become one themselves.
- All research projects involving unit record MBS and PBS data would be categorised as high risk and the data would be required to be handled by an accredited data service provider.
- The Best Practice Guide for Applying Data Sharing Principles would be followed.
- The data sharing legislation would allow DOH to give AIHW the authority to make the decision to share the data. DOH would share legal liability.

Although the existing legal authority would require ethics approval, the best practice guide indicates this will not be required to be taken into consideration by the data custodian or delegate decision maker. However, human research of any kind requires ethics review.

