

SECONDARY USE OF MY HEALTH RECORD DATA

Response to the Consultation on Development of a Framework for
Secondary Use

November 2017

ABOUT RESEARCH AUSTRALIA

Our vision: Research Australia envisions a world where Australia unlocks the full potential of its world-leading health and medical research sector to deliver the best possible healthcare and global leadership in health innovation.

Our mission: To use our unique convening power to position health and medical research as a significant driver of a healthy population and contributor to a healthy economy.

Our goals:

Engage	Connect	Influence
Australia in a conversation about the health benefits and economic value of its investment in health and medical research.	researchers, funders and consumers to increase investment in health and medical research from all sources.	government policies that support effective health and medical research and its routine translation into evidence-based practices and better health outcomes.

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Summary of recommendations

Purposes	The broadest possible interpretation should be given to the meanings of 'research' and 'public health purposes' and the application of section 15 (ma) of the My Health Records Act.
	To the greatest extent permissible by section 15(ma) of the Act, aggregate data should be 'open by default', and freely and publicly available, in a manner consistent with the negligible risk of re-identification it poses and the provisions of the Data Policy.
	Beyond measures necessary to establish that the release is for research or public health purposes and to mitigate the risk of re-identification, there should not be any restriction on the secondary purposes for which de-identified unit record level data can be used.
	Commercial research should not be automatically excluded from the Framework; to do so is inconsistent with the Australian Government Public Data Policy Statement. De-identified data can and should be available for commercial research purposes and there should not be any access restrictions based on the type or nature of the organisation or individual seeking access.
	When the opportunity arises, section 15(ma) should be amended to remove the current restriction on the purposes for which de-identified data can be provided, to reflect the broader intent of the Commonwealth Data Policy.
	Access to identified My Health Record data should be permitted for any secondary purpose where the healthcare recipient has authorised the disclosure and the authorisation remains current.
	The Framework should not seek to impose any restriction on the types of organisations or individuals that a healthcare recipient can authorise to access their My Health Record data.
	There is no overt reason why access should be restricted to Australian users only. Modern research, by its very nature, is collaborative across national borders.
Principles	To the greatest extent possible, the principles of the Framework for de-identified unit level record data should draw on the Australian Government Public Data Policy Statement.
	To the extent that Principles should be included in the Framework in respect of identified data, it should be to ensure that an individual's instructions in relation to the release of their identified My Health Record data are complied with promptly, effectively and efficiently.

Governance	Research Australia does not support the adoption of any of the governance models outlined in the consultation paper for de-identified My Health Record data. The Data Policy and its overarching principle of 'available by default' should be the starting point for any governance arrangements. While recognising that 'open by default' will not be the end point for de-identified unit level record data, 'as open as possible' should be the objective.
	To the extent that a governance model should be included in the Framework in respect of identified data, it should be to ensure that an individual's instructions in relation to the release of their identified My Health Record are complied with promptly, effectively and efficiently.
	Organisations and individuals granted access to de-identified unit record level data should be required to enter legally binding agreements or licences that clearly outline their obligations in respect of the data, including an obligation to report any breaches/unauthorised use to the System Operator. If the Government adopts the Productivity Commission's recommendations that designated 'trusted researchers' should be allowed access to identified data My Health Records Act should be amended to allow the secondary use of identified data without the individual's consent, and the Framework should be amended accordingly.
Linkage	The linking of My Health Record Data with other datasets requires consideration of the risk that the linkage may enable individuals to be identified. Beyond this largely technical consideration, Research Australia submits that there are no other specific requirements. For consideration in respect of linkage.
	For de-identified unit record level data, the System Operator should specify the processes to be adopted to protect the privacy of individuals in an agreement or licence. This includes using data securely and limitations on how it can be used, including other data to which it can and cannot be linked (if necessary).
Policy changes	The Australian Government Public Data Open Policy Statement takes a 'binary' approach to data (anonymised data should be openly available, access to sensitive data should be restricted) which does not recognise the risk that de-identified data can be subject to re-identification. This risk, and therefore the need to control access to some anonymised data, should be reflected in the Data Policy Statement.
Charges	Publicly available datasets, including aggregated data, should be free to everyone. Cost recovery from organisations should only be considered where a cost is incurred in complying with the request.
Promotion	The Department of Health and the Australian Digital Health Agency should work with the health and medical research sector in its broadest sense to increase understanding of how personal health information can be used for research, and what this means for better health outcomes and improved delivery of healthcare.

SECONDARY USE OF MY HEALTH RECORD DATA

RESPONSE TO THE CONSULTATION ON DEVELOPMENT OF A FRAMEWORK FOR SECONDARY USE

Introduction

Research Australia welcomes the opportunity to make a submission to the consultation on the Development of a Framework for the Secondary Uses of My Health Record Data.

This consultation is occurring in the context of a broader recognition of the value of a range of sources of data and the potential societal and economic benefits of making a greater use of data. Concerns about privacy on the one hand are balanced by the realisation that there are real benefits to be derived, including in better health outcomes and healthcare delivery. Research Australia commissions annual opinion polling to gauge the public's attitude to a range of matters relating to health and medical research. Our 2017 polling revealed 93% support for the use of patients' medical records for research purposes.¹

Technologically, developments are being driven by the greater digitisation of a range of different records and transactions, of which the My Health Record is an exemplar, and by the capacity to read, interpret and analyse large and diverse sources of data.

Research Australia's submission seeks to place the Framework for Secondary Use of My Health Record Data needs within this broader context and the Australian Government Public Data Policy Statement (the Data Policy).² The Data Policy is seeking to shift the focus of the use of public data from risk aversion and avoiding cost to recognising the opportunities that the better use of data provides for our health, welfare and national prosperity. This requires an approach that balances risk with benefits. To the greatest extent possible, all de-identified data held by Government agencies, including de-identified My Health Record data, should be treated uniformly and consistently in accordance with the Data Policy, and in a manner that is commensurate with any risks to privacy, commercial or national interest.

De-identified data from the My Health Record system will be an important national data resource which should be made as widely available as possible. However, while the Data Policy treats all anonymised data as non-sensitive and therefore open by default, Research Australia recognises that even when data released by the System Operator is de-identified, there is a risk that unit record level data, particularly in combination with other datasets, can lead to the identification of individual healthcare recipients or healthcare providers. This risk of re-identification is a legitimate reason for not making de-identified My Health Record unit level data as freely and openly available as the Data Policy proposes. Furthermore, the My Health Records Act

¹ Research Australia, Australia Speaks! Research Australia Opinion Polling 2017

² Australian Government 2015, *Australian Government Data Policy Statement December 2015*

2012 (the Act) only authorises the System Operator to release de-identified data for the purposes of research and public health.

Research Australia submits that in respect of de-identified data, the starting point for the Framework must be the Public Data Policy. While recognising that 'open by default' may be the end point for aggregated data but will not be the end point for de-identified record level data, 'as open as possible' should be the objective.

Any limitations the Framework places on the use of de-identified unit record level data to prevent re-identification, need to be tested against the risk that the Framework inappropriately limits the societal and economic benefits that can be derived from making de-identified unit record level data from the My Health Record system, readily available and usable.

Research Australia submits that the Framework must explicitly recognise and manage the competing requirements to protect privacy and to maximise the availability for research, and the ongoing tension that exists between them.

The Framework also needs to make a clear distinction between the release of aggregated data, de-identified unit record level data for secondary purposes released under section 15(ma) and the release of identified data for secondary purposes with the authorisation of the healthcare recipient.

Response to the Questions

Question 1: What secondary purposes, if any, should My Health Record data be used for?

De-identified data

Section 15(ma) of the Act provides that one of the functions of the System operator is 'to prepare and provide de-identified data for research or public health purposes'. **Research Australia submits that the broadest possible interpretation should be given to this section, and to the meanings of 'research' and 'public health purposes'.**

This position is supported by the Australian Government Public Data Policy Statement, which characterises such data as non-sensitive: *'Non-sensitive data is anonymised data that does not identify an individual or breach privacy or security requirements.'*³ The Data Policy provides that such data should be 'open by default'.⁴

While de-identified data is characterised by the Data Policy as non-sensitive and this is accurate for aggregated data, Research Australia recognises the potential risk for de-identified My Health Record unit record level data to be re-identified, and supports the position taken in the Consultation paper that a Framework is needed to guide the release of this type of de-identified My Health Record Data.

Research Australia submits that to the greatest extent permissible by section 15(ma) of the Act, aggregate data should be 'open by default', and freely and publicly available, in a manner consistent with the negligible risk of re-identification it poses and the provisions of the Data Policy.

Research Australia submits that beyond measures necessary to establish that the release is for research or public health purposes and to mitigate the risk of re-identification, there should not be any restriction on the secondary purposes for which de-identified unit record level data can be used.

The consultation paper states *'The use of data solely for commercial and non-health related purposes is considered out of scope.'*⁵ **Research Australia submits that this position is inconsistent with the Data Policy and the Act in respect of the operation of section 15(ma), and that commercial research should not be automatically excluded.** For example, commercial research is 'research' and should be considered in scope. The Data Policy specifically commits the Australian Government and its agencies to 'collaborate with the private and research sectors to extend the value of public data for the benefit of the Australian public.'

Research Australia submits that when the opportunity arises, section 15(ma) should be amended to remove the current restriction on the purposes for which de-identified data can be provided, to reflect the broader intent of the Commonwealth Data Policy. This will have the additional benefit of removing the obligation on the System Operator to determine whether the release is for research or public health purposes.

³ Ibid, p.1

⁴ Ibid, p.1

⁵ Department of Health, Development of a Framework for the secondary uses of the My Health Record Public Consultation paper, p.1

Identified data

The underlying philosophy of the My Health Record, reflected in its current name and the previous terminology of the Personally Controlled Electronic Health Record, is control of the data by the individual. This includes how the information is used, who the individual chooses to share it with, and the purposes for which they choose to do so.

Section 67 of the Act authorises the healthcare recipient to collect, use and disclose information in his or her My Health record for any purpose. Section 62 authorises a participant in the My Health Record system, including the System Operator, to disclose information to the healthcare recipient's nominated representative.

These two sections appear to be the basis on which information from the My Health Record would be disclosed for a secondary purpose with the healthcare recipient's consent. While the Act authorises, rather than requires, a participant to act in accordance with the healthcare recipient's instruction to release information to a nominated representative, Research Australia submits that the Data Policy creates a positive obligation on the System Operator to facilitate this access, including providing the means for a healthcare participant to nominate a representative and determine the type and level of access the representative will have.

Research Australia submits that access to identified My Health Record data should be permitted for any secondary purpose where the healthcare recipient has authorised the disclosure and the authorisation remains current.

Question 2: What secondary purposes should My Health Record data not be used for?

De-identified data

As is reflected in the response to Question 1, **Research Australia submits that to the greatest extent permissible by section 15(ma) of the Act, aggregate data should be 'open by default', and freely and publicly available, in a manner consistent with the negligible risk of re-identification it poses and the provisions of the Data Policy.**

Research Australia submits that beyond measures necessary to establish that the release is for research or public health purposes and to mitigate the risk of re-identification, there should not be any restriction on the secondary purposes for which de-identified unit record level data can be used.

Identified data

As raised in response to Question 1, the underlying philosophy of the My Health Record, reflected in its current name and the previous terminology of the Personally Controlled Electronic Health Record, is control of the data by the individual. This includes how the information is used, who the individual chooses to share it with, and the purposes for which they choose to do so.

Research Australia submits that access should be permitted to identified My Health Record data for any secondary purpose where the healthcare recipient has authorised the disclosure and the authorisation remains current.

Question 3: What types of organisations/individuals should be able to access My Health Record data for secondary purposes?

De-identified data

Research Australia notes the statement in the Consultation Paper's Introduction that *'The use of data solely for commercial and non-health related purposes is considered out of scope'*.⁶ **Research Australia submits that in regard to de-identified data of both types this position is inconsistent with Government policy and goes beyond the limitations imposed by section 15(ma) of the Act, which does not, for example, exclude de-identified data from being used for commercial research.**

Later in the Consultation Paper there appears to be some recognition that at least some commercial use of secondary data will be permissible.

*'It is envisaged that the Framework will address overlap between commercial and health related uses. For example, use of data for development of pharmaceuticals could be considered both a health related and commercial purpose. Similarly, the data may also be relevant for decision support tools for healthcare provider organisations which could be developed by private industry as a commercial enterprise – but also fulfil an important health purpose which is in the public interest.'*⁷

Research Australia supports the view that de-identified data can and should be available for commercial research purposes and that there should not be any access restrictions based on the type or nature of the organisation or individual seeking access.

Indeed, allowing de-identified data to be used for non-commercial purposes but preventing its use for commercial purposes could be hugely problematic and involve the System Operator in a significant compliance and policing exercise. Australia's universities and other publicly funded and not for profit research organisations (eg. medical research institutes and government agencies like CSIRO) are being encouraged to focus on impact and innovation – on translating research into practical applications. This can involve the commercialisation of what is initially publicly funded research. If the research initially uses de-identified My Health Record data at what point in the commercialisation process does the data cease to be available and existing datasets destroyed? Is there a difference between the research being commercialised 'in house' by a university or CSIRO, being licensed to a commercial entity, or being sold to a commercial entity? Where does access to, and use of, de-identified data cease?

Identified Data

The My Health Records Act currently effectively only permits identified data to be used for secondary purposes with the consent of the healthcare recipient. **Research Australia submits that the Framework should not seek to impose any restriction on the types of organisations or individuals that a healthcare recipient can authorise to access their My Health Record data.**

Research Australia is aware of the recommendations of the Productivity Commission that designated 'trusted researchers' should be allowed access to identified data. Research Australia is supportive of this proposal and would welcome the implementation of this recommendation by the Government in the future in respect of My Health Record data. Research Australia recognises that this is beyond the scope of the current question and is addressed in response to question 8.

⁶ Ibid, p.1

⁷ Ibid,p.3

Question 4: Should access to My Health Record data for secondary uses be restricted to Australian users only or could overseas users be allowed access?

De-identified Data

Research Australia submits there is no overt reason why access should be restricted to Australian users only. Modern research, by its very nature, is collaborative across national borders. As just one example of an undesirable consequence, Australian researchers' ability to collaborate internationally could be severely restricted by such an imposition, at a time when the Australian Government is actively encouraging and supporting international research collaboration.

Identified Data

The My Health Records Act currently effectively only permits identified data to be used for secondary purposes with the consent of the healthcare recipient. **Research Australia submits that the Framework should not seek to impose any restriction on the types of organisations or individuals that a healthcare recipient can authorise to access their My Health Record data.**

Question 5: What principles, if any, should be included in the Framework to guide the release of data for secondary purposes from the My Health Record system?

Research Australia is of the view that a distinction needs to be made between principles that help determine whether data is genuinely de-identified, and principles which help determine where and when de-identified data should be released. The first question is largely a technical one, about how to mitigate the risk (which can never be completely eliminated) that data is not in fact de-identified in all circumstances or can be re-identified. (This includes the risk that the data is held unsecurely, and that an unauthorised third party gains access to the data and undertakes re-identification).

The second is more a question of policy, about the purposes for which data, whether de-identified or not, should be allowed to be used.

De-identified Data

The following extract from the Data Policy Statement could be readily adapted as principles for the Framework for de-identified data:

Australian Government entities will:

- *make non-sensitive data open by default to contribute to greater innovation and productivity improvements across all sectors of the Australian economy;*
- *where possible, make data available with free, easy to use, high quality and reliable Application Programming Interfaces (APIs);*
- *make high-value data available for use by the public, industry and academia, in a manner that is enduring and frequently updated using high quality standards;*
- *where possible, ensure non-sensitive publicly funded research data is made open for use and reuse;*
- *only charge for specialised data services and, where possible, publish the resulting data*

open by default;

- *build partnerships with the public, private and research sectors to build collective expertise and to find new ways to leverage public data for social and economic benefit;*
- *securely share data between Australian Government entities to improve efficiencies, and inform policy development and decision-making;*
- *engage openly with the States and Territories to share and integrate data to inform matters of importance to each jurisdiction and at the national level;*
- *uphold the highest standards of security and privacy for the individual, national security and commercial confidentiality; and*
- *ensure all new systems support discoverability, interoperability, data and information accessibility and cost-effective access to facilitate access to data.*

At a minimum, Australian Government entities will publish appropriately anonymised government data by default:

- *on or linked through data.gov.au for discoverability and availability;*
- *in a machine-readable, spatially-enabled format;*
- *with high quality, easy to use and freely available API access;*
- *with descriptive metadata;*
- *using agreed open standards;*
- *kept up to date in an automated way; and*
- *under a Creative Commons By Attribution licence unless a clear case is made to the Department of the Prime Minister and Cabinet for another open licence.*

Research Australia submits that to the greatest extent permissible by section 15(ma) of the Act, aggregate data should be ‘open by default’, and freely and publicly available, in a manner consistent with the negligible risk of re-identification it poses and the provisions of the Data Policy.

To the greatest extent possible, Research Australia submits the principles of the Framework for de-identified unit level record data should draw on the Australian Government Public Data Policy Statement.

Research Australia recognises that the obligation to ensure data is used for research or public health purposes prevents de-identified data unit record level being made openly available to everyone without an application process. Many of the other measures outlined above, could however be included as Principles.

In respect of the examples referred to on page 9 of the Consultation paper and provided in Appendix B, the following comments are made:

- *The Cross Portfolio Statistical Integration Committee’s Principles 1 and 2 are captured in the above extract from the Data Policy. Principles 3 and 4 are specific to data integration, and Principle 5 seeks to limit the use of the data to statistical and research purposes. This latter Principle is effectively redundant for the My Health Record data because of the restriction imposed by section 15(ma) of the Act. Principle 6 seeks to mitigate the risk of an individual being identified. Principle 7 is captured in the above extract.*
- *The Australian Bureau of Statistics Five Safes Principles largely deal with managing the risk of disclosure, i.e. the ‘risk that a person, group or an organisation is re-identified through a data release or when information can be attributed to them.’⁸ Safe People seeks to establish that the data will be held securely; Safe Projects is about ensuring the data is used in an appropriate manner- i.e. the uses are consistent with the ABS enabling legislation. The remaining three principles deal with*

⁸ Australian Bureau of Statistics, Managing the risk of disclosure: The Five Safes Framework, <http://www.abs.gov.au/ausstats/abs@.nsf/Latestproducts/1160.0Main%20Features4Aug%202017?opendocument&tabname=Summary&prodno=1160.0&issue=Aug%202017&num=&view=>

security of the data and ensuring that the outputs of the statistical analysis also do not identify individuals.

- The Department of Health Principles referred to in the Consultation paper at Table B.2 are relevant where they refer to de-identified data (Principles 1 to 3) and are largely consistent with the Data Policy.
- The NHS Caldicott Principles deal with the use of identifiable information by third parties and are not readily applicable to a consideration of principles for de-identified information.

Identified Data

The My Health Records Act currently effectively only permits identified data to be used for secondary purposes with the consent of the healthcare recipient. **Research Australia submits that to the extent that Principles should be included in the Framework in respect of identified data, it should be to ensure that an individual's instructions in relation to the release of their identified My Health Record data are complied with promptly, effectively and efficiently.**

If in future the My Health Records Act was to be amended to allow the secondary use of identified data for research purposes without individuals' consent, Research Australia would support the recommendations of the Productivity Commission that designated 'trusted researchers' should be allowed access to identified data. Research Australia recognises that this is beyond the scope of Question 5 and has addressed this further in response to Question 8.

Question 6: Which of the governance models described above should be adopted to oversee the secondary use of My Health Record data?

De-identified data

Research Australia does not support the adoption of any of the governance models outlined in the consultation paper for de-identified My Health Record data. All of the governance models assume a degree of discretion about release that goes beyond the provisions of the Act and the Data Policy. Questions of whether the research proposal has 'merit', or has received ethics approval go beyond the role that should be adopted by the My Health Record System Operator. **Research Australia submits that the Data Policy and its overarching principle of 'available by default' should be the starting point for any governance arrangements. While recognising that 'open by default' will not be the end point for de-identified unit level record data, 'as open as possible' should be the objective.**

Research Australia is also opposed to the requirement to destroy the data after 12 months. The Productivity Commission has recognised the ongoing value of these datasets and the cost and inconvenience associated with their re-creation and has recommended that the practice of requiring destruction of datasets cease.⁹ Following publication of a research paper, a criticism of the methodology or findings may lead to a need to review or reanalyse the dataset, which is not possible if it no longer exists. Having the dataset recreated and provided again by the System Operator is likely to lead to additional work and/or expense for all involved.

⁹ Productivity Commission 2017, *Data Availability and Use*, Report No. 82, Canberra, Recommendation 6.17

Identified Data

The Act currently effectively only permits identified data to be used for secondary purposes with the consent of the healthcare recipient. **Research Australia submits that to the extent that a governance model should be included in the Framework in respect of identified data, it should be to ensure that an individual's instructions in relation to the release of their identified My Health Record are complied with promptly, effectively and efficiently.**

Question 7: What principles, if any, should be adopted to enable organisations/ researchers to request and gain approval for de-identified data from the My Health Record system to be provided for secondary purposes?

Research Australia submits that, to the greatest extent possible, the principles of the Framework should draw on the Australian Government Public Data Policy Statement and its overarching principle of 'available by default.'

Limitations on applications for de-identified unit record level data should only be imposed to meet the requirement that the release is for research or public health purposes, and these terms should be clearly defined. Approval of an application should be subject to the capacity of an organisation to comply with re-identification risk mitigation measures, such as the ability to securely store the data and restrict access to authorised personnel.

Research Australia submits that organisations and individuals granted access to de-identified unit record level data should be required to enter legally binding agreements or licences that clearly outline their obligations in respect of the data, including an obligation to report any breaches/unauthorised use to the System Operator.

Question 8: What principles, if any, should be adopted to enable organisations/researchers to request and gain approval for identified data from the My Health Record system to be provided for secondary purposes?

If in future the My Health Records Act is amended to allow the secondary use of identified data without the individual's consent, Research Australia would support the recommendations of the Productivity Commission that designated 'trusted researchers' should be allowed access to identified data. **Research Australia submits that if the Government adopts the Productivity Commission's recommendations in this regard, they should be implemented as uniformly as possible across all applicable Government datasets, including the My Health Record.**

Question 9: Should there be specific requirements if researchers/organisations make a request that needs the My Health Record data to be linked to another dataset? If so, what should these requirements be?

Consideration needs to be given to the risk that linking of data with another dataset may enable individuals to be identified. Beyond this largely technical consideration, Research Australia submits that there are no other specific requirements.

Question 10: What processes should be used to ensure that the data released for secondary purposes protects the privacy of an individual?

Research Australia submits that for de-identified unit record level data, the System Operator should specify the processes to be adopted to protect the privacy of individuals in an agreement or licence. This includes using data securely and limitations on how it can be used, including other data to which it can and cannot be linked (if necessary).

In December 2016 the Australian Government Department of Prime Minister and Cabinet published the *Process for Publishing Sensitive Unit Record Level Public Data as Open Data* (the Process).¹⁰ Figure 1 outlines a process (decision tree) for determining whether a dataset can be released as Open Data. The likely outcome of applying this process to de-identified My Health Record Data is that the release of this 'dataset as open data (would) create unacceptable risk for its value.' In this instance, the Process recommends that 'The agency should consider making this data available under a suitable restricted licence or agreement to relevant experts'.

While the Process does not address the elements of a 'suitable restricted licence or agreement', Figure 2 outlines a process to be followed before a sensitive unit record dataset is released as open data. Elements of this process could be utilised to establish the methodology and conditions that would be applicable to the release of datasets for research or public health purposes by the System Operator. In particular, this process involves a 'data privacy expert' determining the methodology and conditions that should be applied to the release, and its review by a second independent 'data privacy expert'. A key element is a process to periodically review the confidentialisation methodologies and 'to take into account advances in technology' (Step 4 in the Process). The methodology and conditions would be reflected in the 'suitable restricted licence or agreement'. These could be published and subject to a public consultation and review process to test their effectiveness and suitability in mitigating the risks of re-identification.

Research Australia envisages that this process would not need to be undertaken 'de novo' for every application- it is likely that applications for access to data will fall within 'classes' to which a standard licence or agreement will apply. The primary application assessment task for the System Operator will be determining which 'standard' licence or agreement is applicable.

¹⁰ <https://blog.data.gov.au/news-media/blog/publishing-sensitive-unit-record-level-public-data>

Question 11: What precautions should be taken to reduce the risk of de-identified data from the My Health Record system being re-identified after release?

Please refer to Research Australia's response to Question 10.

Question 12: What arrangements should be considered for the preparation and release of My Health Record data and who should be responsible for undertaking and overseeing these arrangements?

The System operator should be responsible for the preparation and release of My Health Record data. The release should be made subject to the terms of the agreement or licence referred to in Question 10.

Question 13: Whose responsibility should it be to make a quality statement about the My Health Record data and to ensure the data are of high quality?

The System Operator should be responsible for making the quality statement and for ensuring the data are of high quality.

Question 14: What monitoring and assurance processes, if any, should be considered to ensure My Health Record data secondary users comply with the Framework?

The specific monitoring and assurance processes will ultimately depend on the Framework. At a minimum, recipients of My Health Record Data should be subject to an agreement or licence which requires the recipient to respond to questions and inquiries from the System operator and to allow inspection/entry to premises and access to computer systems.

Question 15: What risk mitigation strategies should be included in the Framework?

Please refer to Research Australia's response to Question 10.

Question 16: Should there be a public register which shows which organisations/ researchers have requested data, the purpose, the status of their data request, what they have found by using the data; and any publications that have resulted from using the data?

Research Australia supports the creation of a public register which shows which organisations/ researchers have requested data, the purpose, and the status of their data request.

While Research Australia supports in principle the reporting of research outcomes related to the use of public data, we are conscious of the potential administrative burden associated with this and the potential to overlap with recommendations made by the Productivity Commission in relation to the reporting of research outcomes from the use of publicly available data.

Research Australia's preference is that there be one repository/platform for this purpose, and submits that the reporting of outcomes should be considered after the Government has responded to the recommendations of the Productivity Commission in regard to this matter.

Question 17: Are the existing penalties under the My Health Record Act sufficient?

Research Australia has no response to this question.

Question 18: What policy changes, if any, need to be considered to support the release of de-identified data for secondary uses from the My Health Record system

The Australian Government Public Data Open Policy Statement takes a 'binary' approach to data (anonymised data should be openly available, access to sensitive data should be restricted) which does not recognise the risk that de-identified data can be subject to re-identification.

Research Australia submits that this risk, and therefore the need to control access to some anonymised data, should be reflected in the Data Policy Statement.

Section 15(ma) of the Act unnecessarily restricts the purposes for which My Health Record Data can be used, and in a manner that is inconsistent with the Data Policy. **Research Australia submits that when the opportunity arises, section 15(ma) should be amended to remove the current restriction on the purposes for which de-identified data can be provided, to reflect the broader intent of the Commonwealth Data Policy.** This will have the additional benefit of removing the obligation on the System Operator to determine whether the release is for research or public health purposes.

Q.19: Is there anything else you think should be considered in the development of the Framework for secondary uses of My Health Record Data?

The Consultation paper does not address the question of cost recovery for providing access. **Research Australia submits that publicly available datasets, including aggregated data, should be free to everyone. Cost recovery from private organisations should only be considered where a cost is incurred in complying with the request. In the case of publicly funded research organisations, cost recovery or charging fees for access is essentially an exercise in cost shifting from one element of government to another and incurs the overheads associated with the transaction costs. Cost recovery and the charging of fees should not be applied to publicly funded and/or not for profit research organisations.**

The potential benefits of better using individuals' health information for research purposes are enormous, as is evident in countries the world over. However, these benefits are sometimes poorly understood by the general public, while the risks of using the information in this way can be easily exaggerated. **Research Australia submits there is a clear role for the Department of Health and the Australian Digital Health Agency to work with the health and medical research sector in its broadest sense to increase understanding of how personal health information can be used for research, and what this means for better health outcomes and improved delivery of healthcare.**

Conclusion

Data has the potential to transform our wellbeing, our health system and our economy.

Our health system collects millions of pieces of information about us every day. While currently fragmented, these data have the potential to provide valuable insights into the Australian population and our healthcare if made more readily available for research. The need to protect the identity of individuals is acknowledged, but needs to be balanced against the opportunities and benefits that can accrue to the broader community from utilising personal health data for research and public health purposes, as articulated in several papers and reports of the Australian Productivity Commission.¹¹

The Australian Government Public Data Policy Statement articulates a clear strategy and rationale for making data available for research purposes, with an overarching principle of 'available by default.' Research Australia proposes the Framework be drafted with this new vision of the future in mind, rather than looking backward to existing governance frameworks that were drafted for a different time.

Research Australia recognises that 'available by default' is not the mindset that prevailed when the My Health Record was enacted in 2012, and that legislative amendments will be required to give full effect to the changes embodied in the Data Policy. The Framework is also being prepared in advance of the Government's response to the Productivity Commission Inquiry into Public Data Availability, which is likely to further support the greater use of data, including health record data for research purposes. While these initiatives lie ahead in a hypothetical future, the Framework should be drafted in a manner that anticipates these changes and sets the scene for a new approach to the secondary use of data that optimises the value of health data to our community and economy while protecting individuals' privacy.

¹¹ Productivity Commission 2015, *Efficiency in Health*, Commission Research Paper, Canberra; Productivity Commission 2017, *Data Availability and Use*, Report No. 82, Canberra; Productivity Commission 2017, *Shifting the Dial: 5 Year Productivity Review*, Report No. 84, Canberra

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