

DATA SHARING AND RELEASE LEGISLATION

Response to the Issues Paper

August 2018

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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 role:

Engage

Australia in a conversation about the health benefits and economic value of its investment in health and medical research.

Connect

researchers, funders and consumers to increase investment in health and medical research from all sources.

Influence

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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TABLE OF CONTENTS

SUMMARY OF RECOMMENDATIONS.....4

 THE PURPOSE TEST FOR DATA SHARING AND RELEASE..... 4

 ROLE OF THE NATIONAL DATA COMMISSIONER 4

 TRUSTED USER ACCREDITATION 4

INTRODUCTION.....5

THE PURPOSE TEST FOR DATA SHARING AND RELEASE.....6

THE ROLE OF THE NATIONAL DATA COMMISSIONER8

ACCREDITATION OF TRUSTED USERS.....9

CONCLUSION..... 11

Summary of recommendations

<p>The Purpose Test for Data Sharing and Release</p>	<p>Careful consideration needs to be given to the purpose test, including allowing for the prospect (rather than certainty) of benefits and refinement/clarification of ‘direct public benefits’. It must not preclude the use of data in circumstances where there is only the prospect, rather than the certainty, of a public benefit.</p>
	<p>The legislation needs to make it clear that the prospect of a private benefit to a company, organisation or individual does not preclude the consideration of the prospect of a public benefit.</p>
	<p>The legislation should not preclude private companies from making data sharing applications. Applications from private companies should be assessed against the same criteria as other applications, including the prospect of a public benefit.</p>
	<p>The Purpose Test should be the subject of further consultation, including to better understand different scenarios, uses of data and types of benefit.</p>
<p>Role of the National Data Commissioner</p>	<p>The National Data Commissioner’s role should extend beyond guidance to include assisting and supporting applicants for shared data in respect of their application and with decisions to refuse an application. This assistance could extend to reviewing applications, suggesting alternative methodologies and controls; and facilitate resolution between the data custodian and the applicant. In this role, the NDC could draw on its knowledge of other approaches within Government and of what is standard/normal practice to educate and inform both applicants and data custodians.</p>
<p>Trusted User accreditation</p>	<p>Further information needs to be collected about the potential number of organisations and individuals that will be eligible for accreditation before an appropriate accreditation model for trusted users can be developed. Consultation on this model will be critical because of the significant resource implications it will have for applicant organisations and individuals undertaking accreditation and ongoing compliance with accreditation requirements.</p>

DATA SHARING AND RELEASE LEGISLATION

RESPONSE TO THE ISSUES PAPER

Introduction

Research Australia welcomes the opportunity to make this submission, which is informed by the Issues paper and the roundtable meeting attended in Melbourne on 23 July.

Research Australia is supportive of the broad objects of the Data Sharing and Release Legislation to improve access to access to data the Government holds while ensuring appropriate safeguard are in place, particularly to protect data integrity and individuals' privacy.

Our members are involved in the conduct of health and medical research and development in Australia. Data about our health systems and the health of Australians is crucial to improving health outcomes for Australians and the safer, higher quality, more effective and efficient delivery of health services. This data comes directly from patients, and from third parties such as Commonwealth, state and territory government agencies, public and private hospitals and health insurers. We recognise and acknowledge the sensitive nature of much of this information and the obligation this creates to deal with data responsibly.

Our capacity to respond to the Issues paper is restricted by the short consultation period. Research Australia only become aware of the Issues Paper on 18 July and while we have alerted our members to the existence of the Issue Paper we have had insufficient time to canvass their view on particular questions the Issues Paper raises.

We welcome the advice provided in the roundtable on 23 July that the consultation will continue beyond 1 August.

The views provided in this submission are limited for this reason; in many cases they seek to raise issues that need to be considered and addressed further before the Data Sharing and Release (DS&R) Bill is drafted.

The purpose test for data sharing and release

Research Australia notes the Issues paper states the following could be included as a purpose test in the Bill relating to the release and sharing of data:

- *informing government policy making*
- *supporting the efficient delivery of government services or government operations*
- *assisting in the implementation and assessment of government policy, and*
- *research and development with clear and direct public benefits.*¹

While supportive of these purposes and noting that it is not necessarily an exclusive list, we question whether this list of purposes is sufficient to realise the benefits of greater sharing of data that are identified on the same page in the Issues paper:

- *more efficient and effective government services for citizens*
- *better informed government programs and policies*
- *greater transparency around government activities and spending*
- *economic growth from innovative data use, and*
- *cross-sectoral research solutions to current and emerging social, environmental and economic issues.*²

Whether the last three of these benefits can be achieved (transparency, economic growth, solutions to social, environmental and economic conditions) will depend heavily on the purpose of ‘research and development with clear and direct public benefits.’ Research Australia makes the following observations in relation to this purpose.

Firstly, the public benefits of research and development are often not ‘clear and direct’ at the outset. Whether there is any benefit at all will be dependent on the outcome of the research and development. If research and/or development seeking to establish the cause of a medical condition or develop a cure is unsuccessful in doing so, then there was arguably not a clear and direct public benefit from the research. This is despite the fact that other information may have been gathered which may prove useful in a different research setting; and importantly, so that the research conducted does not go to waste, but could rather be used to avoid future duplication of similar research. If a data custodian or the National Data Commissioner is required to be satisfied that a public benefit will arise before the release can be made, this is a test that is too strict.

In a similar vein, ‘economic growth from innovative data use’ will only ever be a prospect at the point that a decision about the release of data is made; there can be no certainty. And is economic growth from innovative data use a ‘direct’ benefit or would it be considered an indirect benefit? In most cases the innovative use of data will only be one of the inputs that leads to the economic growth, and arguably is not a direct public benefit from the sharing of the data.

Research Australia submits that careful consideration needs to be given to the purpose test, including allowing for the prospect (rather than certainty) of benefits and refinement/clarification of ‘direct public benefits’. It must not preclude the use of data in circumstances where there is only the prospect, rather than the certainty, of a public benefit, including economic growth.

¹ Issues Paper, page 6

² Issues Paper, page 6

Clinical trials are undertaken as part of the research, development and commercialisation of new medicines and medical devices. They involve testing potential new drugs and devices on healthy volunteers and patients with particular conditions to determine their safety and efficacy.

Successive Australian governments have identified the economic and other benefits that derive from encouraging the conduct of both commercial and non-commercial clinical trials in Australia and has provided a range of different policies and programs in support.

There are many different types of Australian government data which can support decisions by overseas companies about whether to conduct clinical trials in Australia and subsequently support the conduct of those trials. This includes information about the prevalence of disease, treatments currently available in Australia, characteristics of the health system, and information about patients who could potentially be recruited as trial participants.

The enrolment of Australian patients in commercial clinical trials can lead to foreign investment and expenditure in our economy. If the trial is successful, it can lead to new cures and /or improved quality of life for Australian trial participants as well as future patients. Would clinical trials like this meet the definition of 'clear and direct public benefit'? While Research Australia would argue that it does, it is also possible to mount the counter argument- the economic benefit is indirect, and the direct benefit to the patients in the clinical trial is a private benefit to those individuals. On such an assessment, access to data to support a clinical trial would not be supported.

Successful clinical trials lead to private benefits for the companies that profit from the subsequent sale of the new medicine. Does this private benefit, which may be to an overseas company, provide a reason to prevent the use of data, notwithstanding that there may be a public benefit? Is the existence of a private benefit grounds for a data custodian or the National Data Commissioner to refuse an application, even if there is a potential public benefit?

Research Australia submits that the legislation needs to make it clear that the prospect of a private benefit to a company, organisation or individual does not preclude the consideration of the prospect of a public benefit.

On page 14, the Issues Paper expands on the purposes. In relation to 'research and development with clear and direct public benefits', it includes 'work by research institutions and academics'. Is the intention to specifically exclude 'commercial' bodies? Are partnerships between public/academic researchers and commercial entities to be excluded? How will 'commercial' arms of research institutions and academic institutions be treated?

Research Australia submits that the legislation should not preclude private companies from making data sharing applications. Applications from private companies should be assessed against the same criteria as other applications, including the prospect of a public benefit.

As currently framed, it is not clear that the purpose test will be sufficient to deliver the benefits of greater data sharing that are identified in the Issues Paper. **Research Australia submits that the Purpose Test should be the subject of further consultation, including to better understand different scenarios, uses of data and types of benefit as well as unintended outcomes resulting from overly narrow definitions.**

The role of the National Data Commissioner

The DS&R Bill aims to provide data custodians with an alternative process (the Data Sharing and Release Framework) to use when considering whether to share and release data. The role of the National Data Commissioner (NDC) is to ‘provide oversight and guidance on implementing the (Framework)’.

It is clear that this role will extend to issuing (general) guidance, and ‘monitoring and oversight of the integrity of the system’. It is not clear that there is any role envisaged for the NDC to provide guidance or assistance to data custodians when making decisions on individual data sharing applications/proposals.

It also appears that it is not envisaged that the NDC would play any role in advising or supporting applicants for shared data in relation to their application or in responding to a decision by a data custodian to refuse an application, provide only part of the data sought, or place other restrictions as a condition of the application.

Given the Productivity Commission’s finding that ‘a risk averse culture and complex and inconsistent requirement among Australian Government agencies was a barrier to release’,³ such a role for the NDC would be potentially very useful to both data custodians and data applicants alike.

It would also be consistent with the NDC’s role to provide oversight and regulation of the new data sharing and release framework. Involvement at this level will give the NDC a detailed understanding of how the Framework is operating (and where there are problems) that will be difficult to acquire otherwise. It will support efforts to address inconsistencies in the application of the Framework between different Data Custodians and inform the NDC’s guidance. It will also inform the NDC’s guidance, audit, inquiry, and monitoring functions, as disputed decisions can be a good indication of where problems in the application of the Framework are arising.

Research Australia submits that the NDC’s role should extend beyond guidance to include assisting and supporting applicants for shared data in respect of their application and with decisions to refuse an application. This assistance could extend to reviewing applications, suggesting alternative methodologies and controls; and facilitate resolution between the data custodian and the applicant. In this role, the NDC could draw on its knowledge of other approaches within Government and of what is standard/normal practice to educate and inform both applicants and data custodians.

³ Issues paper, page 8

Accreditation of Trusted Users

Research Australia is supportive of the concept of the trusted user if it will help to streamline the process of applying for and receiving access to sensitive data. While the Issues Paper identifies the NDC as being responsible for establishing accreditation criteria and processes, it does not address:

- who will be able to accredit trusted users
- how long accreditation will be provided for,
- whether accreditation will be 'multi use' or application specific
- whether accreditation will be specific to a particular data custodian and/or data set
- the process for monitoring and assurance.

The accreditation process is most useful if the prior accreditation is recognised and relied on by multiple data custodians; otherwise the accreditation process will need to be repeated unnecessarily. It also seems clear that accreditation will at some level need to apply to organisations and at another level to individuals. For example, much of the accreditation will be based on the existence of appropriate IT infrastructure, security measures, data standards and protocols. These will typically exist at an organisational level and will be beyond the control of the individual data user. For this reason, assurance that these exist and will be maintained will need to be provided by the organisation. Other components, such as undertakings not to engage in unauthorised use or release of the data, will apply at the individual level.

There are several different possible models for this accreditation, including:

- self-accreditation by organisations in accordance with guidance issued by the NDC;
- accreditation by Data Custodians in accordance with guidance issued by the NDC; and
- accreditation by the NDC.

It is also possible for accreditation of the organisations to be undertaken by the data custodian or NDC, with the organisation then responsible for accrediting individuals within their own organisations. Each of these models has different implications and repercussions, including for resourcing.

A key difficulty now in estimating the impact is that it is difficult to know the numbers involved. For example, if accreditation is undertaken at the organisational level, there are 43 universities and a similar number of independent medical research institutes. At the next level down (School, Faculty, Centre, research team) there are several hundred potential different bodies/groups to be accredited. There are also several organisations that provide data management capability and expertise to universities and which employ staff that will have access to the data.

Beyond universities, medical research institutes and government agencies like the CSIRO, there is an unquantifiable number of other companies and organisations that could potentially be applying to share data. And if the legislation is successful in increasing access to government data and promoting its use, it is reasonable to expect that this number will be greater than it is under current arrangements.

Within all these organisations there will be individuals who have access to data at varying levels of granularity and sensitivity (identified data, potentially reidentifiable data, aggregated data) and these individuals will need to be identified and be subject to an appropriate level accreditation in some form.

These individuals include not only researchers and research staff but administrative assistants, data scientists, IT support and technicians. Some will be employees, others will be contractors and collaborator from other institutions and organisations. If trusted user accreditation requires all of these individuals to be identified, assessed, accredited and registered/tracked (people change jobs and employers) the accreditation task is potentially very significant. In turn, the resource implications have consequences for the kind of accreditation model to be implemented.

Currently, no-one really knows how many organisations and individuals will need to be subject to accreditation. It is possible to obtain the information needed to estimate these numbers, but this will take time. It will also require the development of some parameters, such as: the types of organisations who will be able to be accredited (does it include businesses?); the types of data for which accreditation will be required (business and personal data, identified/potentially reidentifiable); and the roles of individuals requiring accreditation.

Research Australia submits that further information needs to be collected about the potential number of organisations and individuals that will be eligible for accreditation before an appropriate accreditation model for trusted users can be developed. Consultation on this model, including the ongoing monitoring an assurance processes, will be critical because of the significant resource implications it will have for applicant organisations and individuals undertaking accreditation and ongoing compliance with accreditation requirements.

While not a requirement for the legislation, consideration should also be given to establishing a process for reviewing the effectiveness of the trusted user accreditation process. This review should include evaluation of the nature and severity of breaches by trusted users and an assessment of the resources required from the NDC and the trusted user community to ensure the process is, and remains fit for purpose, and that the resource commitment is commensurate with the risks it is addressing.

Conclusion

Research Australia is broadly supportive of the Data Sharing and Release legislation proposed in the Issues Paper and believes that this legislation, including the creation of a National Data Commissioner is essential if Australia is to unlock the immense value of data for health and medical research and innovation, leading to better health outcomes and the stronger economy as the Issues paper envisages. We also believe the legislation strikes an appropriate balance between making better use of data and protecting the privacy of individuals.

This can only be achieved, however, by taking a broad view of the public benefit that can be derived and by not being overly prescriptive about the types of research that can be supported by data sharing. We also believe that an expanded and more proactive role for the NDC is required.

Lastly, while we support the concept of trusted user, the design of the accreditation process requires careful consideration if it is to succeed without imposing an unnecessary regulatory and compliance burden on researchers, research organisations and government alike.

Equally, the appropriate checks and balances need to be in place to ensure not only compliance, but that the data is used for the purposes described and the integrity of the data is maintained. This includes ensuring that any privacy concerns or potential privacy issues are adequately assessed and addressed.

We look forward to participating further in the consultation process over coming months as the DS&R Bill is drafted. When the DS&R Bill is available we anticipate being able to provide more detailed and specific comments in relation to how it will operate and its implications for the work of the health and medical research community we represent. We would be pleased to support this process by convening our membership to provide specific feedback.

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