DATA AVAILABILITY AND TRANSPARENCY BILL

Submission to the Senate Finance and Public Administration Legislation Committee

March 2021

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We are the national peak body representing the whole of the health and medical research pipeline.

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
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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Matters raised in the report of the Scrutiny of Bills Committee	**What constitutes 'public interest' will vary depending on the nature of the data sharing request and the purpose for which the data will be used, but the assessment of public interest should not be necessarily burdensome or need detailed guidance.** **'Public interest' should not be defined in the Bill in the first instance. The application of the public interest test should be a subject of the periodic reviews of the operation of the Act required under clause 142 of the Bill.**
	The Bill as currently drafted strikes a reasonable balance between the primary legislation and the use of delegated legislation, and is an appropriate use of a delegated legislative power.
	There should not be an expectation that all Data Sharing proposals under the Research and Development purpose require the approval of a Human Research Ethics Committee.
	The assessment of ethical considerations by the Data Custodian and the role of the National Statement for Research Ethics should be addressed in guidance by the National Data Commissioner rather than in the Bill.

DATA AVAILABILITY AND TRANSPARENCY BILL

SUBMISSION TO THE SENATE FINANCE AND PUBLIC ADMINISTRATION LEGISLATION COMMITTEE

Introduction

Research Australia welcomes the opportunity to make this submission to the Senate Finance and Public Administration Legislation Committee.

Research Australia supports the Data Availability and Transparency Bill (the Bill) that is currently before the Senate. We participated in the Productivity Commission Inquiry into Data Availability and Use in 2016 and 2017. We welcomed their proposal for greater use of data for research purposes by trusted users, and the risk-based approach they adopted, recognising that while there are risks associated with greater use of data held by the Australian Government, the benefits of doing so in a controlled way outweigh the risks.

We have consulted closely with the taskforce established by the Department of Prime Minister and Cabinet and led by the Interim National Data Commissioner on the design of the legislation and the framework for the release of data. We believe the Bill and the framework for data availability it establishes is a robust and effective mechanism for utilising data for research purposes while mitigating the risk of privacy and/or data breaches.

Research Australia submits that the Senate Finance and Public Administration Legislation Committee should recommend the passage of the Bill to the Senate.

Risk and Reward

Research Australia acknowledges that the use of any data comes with risk. The risks include data being misinterpreted, used for a purpose for which it was not intended and/or being disclosed to unauthorised people. These risks, and the circumstances in which they arise, exist now. Government held data is already being used for all the purposes proposed by the Bill- for the delivery of government services; informing government policy and programs; and research and development.

Rather than creating these risks, the Bill proposes a framework within which these risks can be better managed. By providing data custodians with a process for considering the use and release of data, and guidance on how to evaluate the risks and benefits of doing so, Research Australia expects the Bill will reduce the risks associated with the use of data, even as it increases the use of this data.

The risks associated with any action cannot be considered in isolation- they must be weighed against the benefits. Research Australia represents Australia's health and medical research sector. Health and medical research delivers new and better ways of treating and preventing illness and disease, of improving health and the health system. It provides us with longer healthier lives. And to do so it relies on data. Not all of this data is information about individuals, but much of it is. Even where it is information about individuals, it is typically not necessary to know who the individual is (their name and address); just information that is relevant to the research. This might be information, for example, about how old they are, their medical history (have they ever smoked, what illnesses they have suffered), their occupation.

Research Australia believes the Bill will improve the access of researchers to information held by the Australian Government, leading to improvements in the health of Australians which would otherwise not be possible. This benefit is the opportunity the Bill provides; it is not risk free, but the risks are worth it.

Casestudy: IHOPE understanding disparities in health

While there have been improvements in the health and wellbeing of Aboriginal and Torres Strait Islander Australians in recent years, some long-standing challenges remain.

Through the Indigenous Health Outcomes Patient Evaluation (IHOPE) project, Professor Louisa Jorm and her team set out to investigate factors influencing health outcomes for Indigenous Australians.[1]

"Every time you visit a GP, hospital or emergency department, valuable data is generated. Yet, these data are underutilised to inform improvements in health care.

"There is so much crucial health information in data banks that can analysed to understand the best way to deal with major diseases and health issues," Professor Jorm explained.

The team applied advanced statistical modelling techniques to understand how individual, geographic and hospital factors may contribute to disparities in health outcomes for Indigenous people in New South Wales.

By comparing hospital data for Indigenous and non-Indigenous people, the team sought to determine whether these health disparities could be targeted with specific interventions. Factors

[1] Australian Government, 2016, The National Health and Medical Research Council, 10 of the Best NHMRC Research Projects 2015, page 18 https://www.nhmrc.gov.au/sites/default/files/documents/reports/ten-best-2015.pdf

investigated throughout this research included socioeconomic status, remoteness, access to hospital and specialist services, and hospital characteristics.

"Our research found that crucial issues driving poor outcomes for Aboriginal people included high rates of comorbidities, low levels of private health insurance, use of smaller hospitals with fewer specialist services, and limited access to publicly-funded services," Professor Jorm remarked.

The research showed that rates of cataract surgery in Aboriginal people were 30 per cent lower than in non-Indigenous people, despite higher rates of cataract. This disparity relates to limited access to publicly funded eye health services for Indigenous Australians.

"IHOPE research has already helped in planning cardiac, ear and eye health services for Aboriginal people in New South Wales.

"The research has also been used to inform five national and state policy documents."

This will play a vital role in closing the gap and ensuring all Aboriginal and Torres Strait Islander people enjoy the same opportunities as non-indigenous Australians to live a long, healthy and happy life.

Public benefits and private risk

Research Australia recognise that while the benefits to human health and wellbeing that arise from the better use of data are generalised, the consequences of a data breach are typically borne by individuals. We acknowledge that this makes it more difficult to weigh the risks and the benefits; but the benefits are nonetheless real, and it is individuals as well as the community that benefit. It is also true that these risks exist now, but that the current lack of a coherent and consistently applied risk based framework for making decisions about the use of data is preventing us form realising many of the benefits of using data.

Throughout this submission we have provided cases studies provided to us from our membership. These are case studies that demonstrate the benefits to the community from the use of personal data for research purposes. These include examples of the use of deidentified data, as well as cases where personal identified helath data is being used with a person's consent.

There are also examples of where the current system has failed; where the potential benefits of research were lost because of risk aversion and poor decision making by data custodians and unnecessarily bureaucratic processes.

Case Study: Identifying unecessary testing

Pathology tests are used as a standard part of care for many patients in hospital. They are often ordered initially as part of diagnosis and then reordered at regular intervals to monitor a patient's condition. Pathology tests come at a cost and involve both a physical and psychological risk of harm to people who are tested, so are pathology tests only ordered where they are necessary?

Research undertaken by the Hunter Medical Research Institute at the John Hunter Hospital in Newcastle and the smaller Tamworth Referral Hospital analysed the ordering of pathology tests at both hospitals for a range of conditions over 2014 and 2015.[2]

Focusing on the two most common pathology tests it found that after a patient had been in hospital for 2 or three days, tests were often ordered on a regular daily basis, even if the results

[2] Hure, A et al, Identifying low value pathology test ordering in hospitalised patients: a retrospective cohort study across two hospitals*, Pathology* October 2019 https://doi.org/10.1016/j.pathol.2019.06.003

from previous tests had been normal. This suggested that the tests were being ordered without proper clinical consideration of whether a further test was warranted. The research suggests that prompts or nudges to cause a clinician's active consideration of whether it is necessary to reorder the test could reduce risk and inconvenience to the patient, reduce the workload of hospital and pathology staff, and save money.

Public support for using data for research

There is strong support for, and even an expectation, that data held by governments will be used for public benefit. This includes personal health data.

Research Australia undertakes annual opinion polling on health and medicinal research.[3] We regularly ask the public about matters relating to health and medical research, its links to belter health and public participation in health and medical research.

In our 2017 Annual Opinion Poll, we asked people about health consumer data and research. 93% of Australians supported the use of health records for research. The same poll also reported strong levels of trust in researchers to use personal health information, trusted almost as much as the health professionals we rely on to treat us.

In our 2018 Poll, we asked people about the use of de-identified medical records by health and medical researchers for research purposes. Once again there was strong support; only 10% were opposed. In our 2019 and 2020 polls we have revisited this question; while a little lower, the vast majority still reported support for the use of deidentified medical records for research.

The question of what motivates people to provide their data has itself been the subject of research. The main motivation is altruism.

How do consumers feel about the sharing their health data for research? Kalkman et al (2019) undertook a narrative review to explore patients' and public attitudes around the use of health data for this purpose.[4] Their analysis of the empirical evidence found broad, albeit conditional consumer support, with 93% of patients and public participants reporting a strong willingness to give broad consent for secondary data use. Most also expressed a desire that their data was made available for as many research studies as possible.

From a consumer perspective, the motivation and perceived benefits of sharing data in this way included:

- Helping future patients
- Improving patients care and advancing understanding of treatment risk and side effects
- Improving health outcomes or health care.

Whilst there were perceived risks to the sharing of their data, the research found that 98% considered that the altruistic benefits outweighed the risks. Other research also found that most patients provided consent for data sharing for altruistic, and other 'pro-social' reasons including

[3] Research Australia, Opinion Polling for health and medical research, multiple years, available at https://researchaustralia.org/reports/public-opinion-polling-2/

[4] Kalkman S, van Delden J, Banerjee A, et al. Patients' and public views and attitudes towards the sharing of health data for research: a narrative review of the empirical evidence. *Journal of Medical Ethics* Published Online First: 12 November 2019. doi: 10.1136/medethics-2019-105651

reciprocity; solidarity; and gratitude.[5] This suggest that, for consumers, there is a strong desire for their health data to be used for the social good and to assist with future research that benefits other patients.

Why we need a new framework for sharing data

Delays and inconsistent processes

The implementation of research is currently frequently delayed by inconsistent approaches, poorly resourced and trained staff in Government departments and agencies, and a lack of coordination. This can occur even in situations where it is the Government that both wants the research to be done and is funding it. These delays and barriers make the research more expensive to undertake and can reduce its effectiveness and timeliness.

Research Australia's support for the Bill is driven by a belief that it will introduce a new framework that will improve the consistency and timeliness of the consideration of requests for access to data by Australian Government departments and agencies. This will improve the conduct of research in Australia, and ultimately lead to better health social and economic outcomes.

Case study: barriers to accessing to publicly held health data – COVID-19 Surveillance Data

The COVID-19 pandemic has highlighted the critical need for real-time surveillance data during public health emergencies. Timely sharing of data and information is one of the core components of the Australian Government's *Australian Health Sector Emergency Response Plan for COVID-19*[6], and is crucial for understanding the status of disease spread, informing public health interventions, providing guidance to clinical management, informing the public, and enabling a coordinated response.

To address these needs, a team from the University of Queensland and the Australian National University has been funded by the Australian Government's National Health and Medical Research Council (through the APPRISE Centre for Research Excellence) to develop a publicly available COVID-19 Real-time Information System for Preparedness and Epidemic Response (CRISPER).[7][8] The system aims to provide interactive data visualisation dashboards and mapping tools to enable easy access to information related to cases, deaths, testing, and contact tracing alert locations.

While one of the key requirements for the CRISPER system is access to accurate and reliable COVID-19 surveillance data from official sources, **gaining access to these data has been the**

[5] Richter, G, Borzikowsky, C., Lieb, W. *et al.* Patient views on research use of clinical data without consent: Legal, but also acceptable? *Eur J Hum Genet* **27,** 841–847 (2019). https://doi.org/10.1038/s41431-019-0340-6

[6] Australian Health Sector Emergency Response Plan for Novel Coronavirus (COVID-19) https://www.health.gov.au/resources/publications/australian-health-sector-emergency-response-plan-for-novel-coronavirus-covid-19

[7] Emma Field, Amalie Dyda, Colleen Lau. COVID-19 Real-time Information System for Preparedness and Epidemic Response (CRISPER). Medical Journal of Australia 2021. In press.

[8] Research Australia. Mapping the spread of COVID-19 in real time. In: COVID-19 How Australia's health and medical research sector is responding, page 15. https://issuu.com/researchaustralia/docs/ra0032_covid_report__1__/2

major challenge for the project. The team has submitted data requests to two state health departments and the National Notifiable Diseases Surveillance System (NNDSS) but is yet to receive any official data. The data sought is de-identified data about individuals. No name, address, or date of birth has been sought. They have asked for age, sex, ethnicity, and residential postcode, as well as COVID-related data such as date of diagnosis, date of hospital admission and date of death.

For one of the states, the team began discussions about data access in March 2020 and completed all the required steps and application forms many months ago but is still waiting for a decision. Therefore, CRISPER currently uses publicly available postcode-level data from health department websites where possible, and although not ideal, the system also uses third party databases (e.g. https://github.com/M3IT/COVID-19_Data) that have been collated from websites, press conferences, media reports, social media, and other sources.

State health departments post regular updates on COVID-19 on their websites (including some interactive functions for some states), but the data are generally too aggregated for the information needs of specific users. For example, a GP might want to know the number of locally acquired cases in their practice's neighbourhood over the past two weeks so that they can assess the current risk of infection for their staff and patients. Of all the states and territories, NSW currently provides the most detailed publicly accessible databases, with daily postcode-level data and contact tracing locations available in csv format on their website (https://data.nsw.gov.au/nsw-covid-19-data). Victoria provided similar data for some time, but data updates were suspended at the end of Jan 2021.

The difficulties with gaining access to official surveillance data has severely hindered the progress of the real-time information system. The CRISPER system is ready to absorb data from the whole of Australia, but the interactive mapping tool is only functional for NSW (and to a lesser extent for Victoria) because of lack of data. To our knowledge, there is currently no other interactive information system in Australia that provides easy access to official COVID-19 data at a national level. The barriers to data access have also restricted opportunities for academic studies and research activities, which are key actions recommended in the Australian Health Sector Emergency Response Plan for COVID-19.

COVID-19 has seen a rapid national response, and the declaration of a state of emergency by several state and territories. At the national level, a human biosecurity emergency period has been in place under the Biosecurity Act 2015 since 17 March 2020 and has recently been extended by an additional three months to 17 June 2021. Despite these measures, this project to implement national real time monitoring and awareness of COVID-19 cases has been hampered by continual delays in getting access to deidentified data.

Consent does not ensure access

Even where individuals are participating in the research and have provided their consent, barriers to getting access to data from government agencies remain. The following case study highlights some of the difficulties researchers encounter, and how it can frustrate important research, as the following case study highlights.

Case Study: QSkin Sun and Health Study

The QSkin Cohort Study being conducted at QIMR Berghofer, an independent not for profit medical research institute, aims to understand the incidence and risks of two types of skin cancer-basal cell carcinoma (BCC) and squamous cell carcinoma (SCC) and how we can better to treat and prevent them.

The study comprises 43,794 men and women aged 40-69 years recruited from the Queensland Electoral Roll in 2010-2011. The QSkin study has received continuous funding from the Australian Government's National Health and Medical Research Council (Chief Investigator Professor David Whiteman).

Each QSkin participant has given their consent for record linkage to Cancer Registries, Medicare (MBS/PBS), pathology providers (private and public), the Queensland Hospital Admitted Patient Data Collection (QHAPDC), which collects demographic and clinical information on all patients admitted to public and private hospitals and day surgeries in Queensland) and other health databases including the National Death Index. These linkages ensure virtually complete follow-up of all clinical events in the cohort.

Applications for data linkage for the cohort take considerable time and human resources for a relatively small research team. Approval for linkage to the Queensland Cancer Registry took only a few months; approval to link with the national Australian Cancer Database took approximately 8 months. For the latter approval, the research team was required to first seek approval from each of the State and territory cancer registries, and once these approvals were in place, they could apply for overarching approval from the Australian Institute of Health and Welfare. Approval to link with QHAPDC data took several years, and they have only conducted one linkage to date. The process of obtaining approval to link the consented participants to MBS/PBS databases took approximately 9 months, and the cohort is linked bi-annually.

The research team recently conducted new recruitment into the QSkin Study, to increase the size of the cohort, recruiting an extra 8,200 participants. They started the process of applying for linkage with Services Australia (previously the Department of Human Services) for MBS/PBS data in July 2018. Services Australia had instigated new procedures in approving consented studies, with a new step involving their cyber security and legal teams. Because of the stringencies of Medicare, our study participants had to sign TWO separate consent forms: a comprehensive QSKIN consent form requesting permission to access medical records, pathology, Medicare records, future use of data etc.; and then also an MBS/PBS consent using arcane MBS/PBS language.

For participants, this could be confusing and somewhat distressing; the forms are provided as an appendix to this submission.

After protracted negotiations, and complying with repeated requests to make minor changes to the study documents, the research team was advised in October 2019 that the under the new guidelines for consent and data release they were required to provide specific justification for requesting individual MBS categories and PBS anatomical groups, and that **Services Australia would not provide participants' full MBS/PBS history for the consented time period.**

The researchers did not proceed with the application as they could not prioritise sufficient resources to meeting this request. They are also in the process of seeking approval for linkage of this newly recruited cohort with the Australian Cancer Database. There are extra steps in this approval process now, compared with when approval was sought for the original cohort back in 2012.

The researchers are seeking access to the records of **voluntary participants in the research, who have provided their consent to the release of their records**. Participation in the research is being prevented by onerous bureaucratic processes.

The Bill introduces a new approach to data sharing with a focus on the risks and the benefits of data sharing. It also provides a new framework within which risks can be mitigated, and should go some way to alleviating the issues identified in the above case studies.

Issues and concerns about data sharing and the Bill

As noted in the introduction, Research Australia supports the passage of the Bill by the Senate. Through our participation in the three-year consultation process on the Bill conducted by the Department of Prime Minister and Cabinet we have considered and been made aware of many of the concerns about the legislation that have been raised by different groups. While the Committee has not issued a Terms of Reference, we are aware of the Scrutiny of Bills Committee report published on 29 January; many of the issues it raises are the same as those raised by stakeholders in the consultation process. In this section of our submission, Research Australia provides our response to some of these issues and concerns.

Enabling the sharing of data including personal information has the potential to trespass on an individual's right to privacy.

The potential for privacy breaches or for trespass on individuals' privacy already exists, and data is already being shared for a range of different purposes. The Bill does not create this potential, and Research Australia believes the Bill has the capacity to reduce the risk to individuals' privacy.

In respect of the sharing of data for health and medical research and innovation, the current approaches taken by different departments and agencies appear to be ad hoc, and in many cases rely on an individual's discretion. There is no clear and consistent approach for how data sharing requests should be considered or assessed.

The Bill provides a framework for the making of decisions about sharing data which includes an assessment of the risks of doing so and the benefits. By providing such a framework, Research Australia expects the Bill will lead to better decision making about the release of data, including more appropriate consideration of the privacy risks of doing so. Other measures, such as increasing the resources and capability of Australian Government departments and agencies to effectively and securely collect, curate and use data, complement the measures contained in this Bill.

Research Australia also hopes that the Bill will, over time, lead to greater sharing of data for the purpose of research and development. If this occurs to a greater extent than it does now, and we hope it will, the simple fact that more data is shared can increase the risk of privacy breaches. However, there are several measures in the Bill and the Framework that will sit underneath it which are intended to mitigate these risks. While the risk of a privacy breach exists whenever personal data is collected, used or shared, regardless of the scheme employed or the measures put in place, these risks can be assessed and mitigated as appropriate by the measures contained in this Bill.

The risk of privacy breaches needs to be balanced against the potential health benefits of greater data sharing. We also need to recognise that the benefits cannot be realised without accepting some degree of risk and it is beholden on the Government and the research community to help consumers understand this risk and also the benefits from sharing data.

> *'In deciding which datasets to make more available, the risks and costs of wider release need to be carefully considered, along with policy frameworks and precautions that might be adopted to mitigate these (examined in detail in other sections of this Report). But the potential benefits of wider data use should not be dismissed in favour of undue risk aversion. The benefits already being achieved from innovative uses of data — and the open-ended potential for uses that have yet to be conceived — are simply too large to ignore. Perhaps the biggest risk is that Australia will be left behind in a world that is increasingly embracing and harnessing the opportunities data presents.'*[9]

The research and polling cited on page 8 of this submission indicate there is generally strong support for using data for research, and that the public can understand and assess both the risks and benefits of doing so.

Case Study: The Australian Longitudinal Study on Women's Health

The Australian Longitudinal Study on Women's Health (ALSWH) is a longitudinal population-based survey which has been examining the health of over 57,000 Australian women for 25 years. The study comprises four cohorts of women: born in 1921-26, 1946-51, 1973-78 and 1989-95 who have all agreed to participate.

ALSWH has been linking to the Medicare Benefits Schedule since 1997, the National Death Index since 1999, and Pharmaceutical Benefits Scheme since 2002 (the inception of this scheme). From 2013 to 2021, state based collections (hospital admissions, perinatal and emergency department data) have been progressively added. In 2014 the ALSWH incorporated the first round of national aged care program data, with similar service data from the Department of Veterans' Affairs added in 2017. The ALSWH continues to update and add to these collections to build a de-identified research base to inform public health policy. This rich resource is also available to external collaborators (subject to strict access conditions and current privacy regulations). There has not been a privacy or security breach in the history of the ALSWH.

The following two examples show the value of ALSWH survey data linked with administrative data and how these data are used to inform government policy.

Example 1. Survey data from the ALSWH linked with Medicare items, records of dispensed endometriosis-specific medications subsidised under the Pharmaceutical Benefits Scheme, and hospitalisations was used in the 2019 Australian Institute of Health and Welfare (AIHW) report "Endometriosis in Australia: prevalence and hospitalisations"[1]. This collaboration between the ALSWH and the AIHW enabled accurate nationally representative data on prevalence and health service use due to or related to endometriosis to be determined. For the first time it enabled a complete picture of women's experiences of endometriosis across their reproductive lifespan.

Example 2. Survey data from the ALSWH linked with Medicare, Pharmaceuticals Benefits Scheme data, cancer registry, perinatal, aged care, and hospital inpatient datasets was used in a submission and public hearing to the House of Representatives Standing Committee on social policy and legal affairs: Family, domestic and sexual violence.[2,3] These data were also used in a

[9] Productivity Commission 2017, Data Availability and Use, Report No. 82, Canberra, page 100

policy brief used by the Australian Government Department of Health to inform the National Women's Health Strategy 2020-30[4].

The submissions highlighted the concerning physical and mental health outcomes of domestic violence, some of which can last for 20 years. The data showed between about 20 and 30 per cent of women had lived with a violent partner or spouse, and this increased for the first 30 or 40 years of life. The data also showed the onset of violence among middle-age and older age women. Findings reinforced that the use of survey data linked with datasets such as Medicare, hospital and cancer registry data creates a very comprehensive and powerful dataset, enabling one of the few longitudinal datasets on women in the world to collect, interpret and use data about family and domestic violence and sexual violence to inform policy.

The (Scrutiny of Bills) committee is concerned that there is a significant amount of flexibility in the meaning of 'unreasonable or impracticable' in this context, and that this may undermine the effectiveness of clause 16 as a safeguard against undue trespass on the privacy of individuals whose data may be shared under the scheme.

Under the Privacy Act, personal information is 'information about an individual whose identity is apparent, or can reasonably be ascertained, from the information or opinion.'

Research Australia believes that such information will only be shared without an individual's consent for the purpose of research and development in rare circumstances. The expression 'unreasonable and impracticable' is used in the Privacy Act and provides consistency across the two Acts, which is very valuable. It ensures that personal data is only shared to the extent that it is necessary to do so for the data sharing purpose to be fulfilled. The public interest test seeks to ensure that this will only occur where the public interest is sufficient to warrant such sharing of public data.

The provisions of the Privacy Act and the public interest test in the Bill operate consistently with the Data Principle in the Bill, which similarly provides that:

> '(a) only the data reasonably necessary to achieve the applicable data sharing purpose is shared;
>
> (b) the sharing of personal information is minimised as far as possible without compromising the data sharing purpose.'

There are no requirements for sharing only de-identified data in the Principles or elsewhere in the bill.

The Bill is not intended to prevent in every circumstance the sharing of personal data that enables a person to be identified.

The Data Sharing Principles (Clause 16) apply to all data sharing under the Bill framework. The Data principle provides that:

> '(a) only the data reasonably necessary to achieve the applicable data sharing purpose is shared;
>
> (b) the sharing of personal information is minimised as far as possible without compromising the data sharing purpose.'

This Data Principle ensures that the sharing of personal information only occurs to the extent that it is necessary for the purpose for which it is being shared.

Research Australia expects that data which identifies individuals is most likely to be shared for the purpose of delivery of government services. In this situation, where the objective is to assist the individual in dealing with a Government agency and getting access to services or benefits, the use of personal information is central to the purpose. For example, pre-filling forms used to apply for Government services with details such as the person's name, address and contact details necessarily involves using identifying information.

In the context of research and development it is only rarely that identified data will be shared with a researcher without a participant's consent. In most such cases it will be done with the consent of the individual; for example, an individual who is voluntarily participating in a clinical trial may authorise the researcher conducting the clinical trial to access their medical records, or prescription history, as illustrated in the case study above.

There are circumstances in which some identifying data may be shared with an accredited data service provider (ADSP) for the purpose of link two or more datasets. The use of identifying information as part of the data linkage exercise may be necessary to ensure the data linked from the two datasets relates to the same individual. The ADSP will then provide a linked dataset to the researcher from which the identifying data has been removed. Accreditation of ADSPs is provided for in the Bill.

The committee notes that 'public interest' is also not defined in the bill, and the explanatory memorandum does not provide guidance about the factors that might be considered when evaluating public interest for the purposes of data sharing.

In contexts where commercial and economic interests may be considered to factor into the 'public interest', the committee is concerned that privacy interests are not clearly central to the operation of the scheme.

The Bill does not oblige data custodians to share data; it applies in situations in which they are legally able to share data and provides a framework within which they can consider data sharing requests. Historically, and in the absence of such a decision-making framework, the easiest and safest option for data custodians has been to refuse data sharing requests. This has the least 'downside' for the data custodian in a context in which the upside of sharing - the benefit to the community of the sharing of data - is often not a relevant or pertinent consideration to them.

> 'In Australia's current data policy environment, limited benefits accrue to public sector data custodians as a result of sharing their data, while risk to the custodians increases. For example, there is the potential for embarrassment at the quality of data, or the facts it contains; these risks create disincentives to share the data. Legal restrictions and a risk-averse culture need to be addressed before such benefits can be realised.'[10]

The overly legalistic approach to data sharing has led to a situation where even the wishes of the person to who the data relates are not given sufficient weight.

[10] Productivity Commission 2017, Data Availability and Use, Report No. 82, Canberra, page 94

Case study: CARE Trial

Even where individuals want to provide their data for research purposes, under current arrangements they can be prevented from doing so by the Australian Government Department or agency holding the data.

The Clinical Trial, Cannabinoids for Symptom Control in Advanced Cancer, (CARE NSW) is funded by the NSW Ministry of Health to investigate the efficacy of cannabis products for symptom control in people with advanced cancer.[11]

Patients who meet the inclusion criteria, and consent to participate, are prescribed a cannabis medicine from a range of oral oils available for human use in Australia. They also provide consent for their MBS and PBS records to be provided to the Trial researchers. This data provides vital information about the patient's medical history, including their other therapies and treatments, and helps Trial researchers understand how these might interact with the cannabis product. It can also assist to understand how the patient's condition progresses. Gathering this evidence not only supports the Trial participant directly, but can guide the prescribing of cannabis medicines for patients with advanced cancer more broadly.

Data access and linkage can help research to identify what works best, when, and for whom. These are fundamental questions to be addressed by any health system. CARE NSW is only one of a number of similar studies in Australia. The future opportunity to potentially link the multiple trial data sets from the government funded trials in advanced cancer or cannabis medicines with health datasets (such as MBS/PBS) would save unnecessary repetition of similar projects and result in time, cost and consumer savings and benefits.

Yet despite the accepted value of data linkage, the use of the consented MBS/PBS data remains highly restricted and for Trials like CARE NSW, access to MBS/PSB, even where patient consent has been given, has not been enabled.

At present, CARE NSW participants can only consent to the use of MBS and PBS data for the specific use within the boundaries of the CARE NSW clinical trial. They cannot consent for this data to be used in any other related future research. Services Australia, the Government Department dealing with the request for data on behalf of the Department of Health has stated that the individuals involved cannot consent to their data being used for future research without knowing specifically *what* that future research is and exactly *how* their data will be used.

This is a major predicament for Trials like CARE NSW where the participants are at the end of their life and all will die before the study is finished. They are not able to consent to provide their MBS/PBS data for future related research, which will occur posthumously, unless the specifics are detailed at the time of consent. This is not possible. As a consequence no future research can be conducted using their data, despite the participants' desire and consent for their data to be provided. More simply: the trial participants are happy for the researchers to use *their* data for future research, yet the Australian Government, as appointed custodians of the patient's data, is saying 'no'.

This begs the question: whose data is it anyway, and what is the value of consent?

[11] The study is led by Professor Jennifer Martin alongside a research team of specialists in cancer, palliative care, public health, addiction medicine, pharmacology and health economics. The federally funded NHMRC Australian Centre for Cannabinoid Clinical and Research Excellence (ACRE) is responsible for the day-to-day management and oversight of the study. https://www.australiancannabinoidresearch.com.au/

The Bill introduces a Framework within which the Data Custodian can more effectively consider the risks associated with data sharing and how these can be mitigated. It also introduces consideration of the potential benefits of sharing data through the public interest test.

Research Australia expects that it will be the responsibility of the data sharing applicant to explain why the proposed data sharing agreement is in the public interest.

Research Australia submits that what constitutes 'public interest' will vary depending on the nature of the data sharing request and the purpose for which the data will be used, but that the assessment of public interest should not be necessarily burdensome or need detailed guidance. In many cases it will be very clear, as in the CARE case study provided above.

Clause 19 (7) of the Bill requires a data sharing agreement to include information about how the public interest is served, and Clause 130 of the Bill requires this information to be publicly available in the register of data sharing agreements. These provisions provide the opportunity for third parties to understand and monitor how the public interest test is being applied. Similarly, Clause 24 requires a custodian to provide reasons why it has rejected a data sharing request, which could include an assessment that the request is not in the public interest. While reasons for refusal are not part of the public register, the number of requests received, and the reasons data custodians refuse data sharing requests are a matter on which the National Data Commissioner is required to report annually.

Research Australia believes these measures provide a degree of transparency around how the public interest test is applied and allow for public scrutiny. **Research Australia submits that 'public interest' should not be defined in the Bill in the first instance, and that the application of the public interest test be the subject of the periodic reviews of the operation of the Act required under clause 142 of the Bill.**

Case Study: LifeSpan Suicide Prevention Trial

As a research institute that performs a significant amount of suicide prevention research using datasets from health and justice agencies, Black Dog Institute has obtained **de-identified** datasets without an individual's consent. Such data has been obtained within the current landscape of the Privacy Act 1988.

In the context of the LifeSpan Suicide Prevention Trial that implemented multiple suicide prevention strategies in communities, Black Dog Institute has had many positive experiences with Human Research Ethics Committees and data custodians to facilitate access to administrative data pertaining to suicide and intentional self-harm across Australia.[12]

Given that suicide and suicidal thoughts remain a leading health and social concern for Australians of all ages, it was feasible for these ethics bodies and custodians to grant permission to collect **deidentified information** without the consent of the individual to whom it relates. The benefits of using the data for research and the subsequent improvements to suicide prevention activities were clear.

On the matter of commercial and economic interests, Research Australia recognises that there will be situations in which a commercial benefit may accrue to one or more parties. Such an

[12] https://www.blackdoginstitute.org.au/research-centres/lifespan-trials/

occurrence should not be a barrier to data sharing, but nor should it be a sufficient justification; the need to demonstrate a public benefit still exists.

Development of COVID-19 vaccines and therapies are a case in point. Such development has been undertaken by commercial companies, but has a clear public benefit in saving lives, improving recovery from illness and preventing the spread of the virus. The use of publicly held data such as hospital admission records to identify individuals who might benefit from participation in a clinical trial of a new therapy to treat COVID-19 could meet the public interest test, notwithstanding that a private company might ultimately profit from the sale of the therapy. (They can also provide a direct benefit to the individual involved, through earlier access to a treatment which may be of benefit to them.)

The (Scrutiny of Bills) committee also notes that the application of the data sharing principles will be clarified in 'data codes', legislative instruments made by the Data Commissioner that serve as binding codes of practice for the data sharing scheme. The explanatory memorandum notes:

> **'a data code may set out how data scheme entities are to apply data definitions in clause 10, or comply with requirements for sharing in Chapters 2 and 3. This could include prescribing how to apply the data sharing principles in different situations, such as when sharing via an ADSP (Accredited data service provider), or assess requests against the data sharing purposes. Use of data codes in this manner will clarify core requirements for sharing, and standardise their application by data scheme entities.'**

The committee's view is that significant matters, such as privacy safeguards for data sharing, should be included in primary legislation unless a sound justification for the use of delegated legislation is provided. In this instance, while the explanatory memorandum explains the approach of using legislative instruments rather than regulations to establish data codes, there is no explanation of why these matters cannot be included in primary legislation.

The primary privacy safeguard for data sharing is contained in the Data Principles at clause 16.

This Data Principle ensures that the sharing of personal information only occurs to the extent that it is necessary for the purpose for which it is being shared.

Research Australia understands the role of the data codes is to elaborate the Data Principles and provide guidance on their application in specific circumstances. **Research Australia submits the Bill as currently drafted strikes a reasonable balance between the primary legislation and the use of delegated legislation, and is an appropriate use of a delegated legislative power.**

Clause 15 establishes permitted data sharing purposes, which are: delivery of government services, to inform government policy and programs, and research and development. These purposes are not clearly defined; rather, the explanatory memorandum emphasises that the purposes are to be construed broadly:

> **'Sharing to inform design and implementation of government policy and programs is permitted under subclause (1)(b). Both terms should be construed broadly, using their ordinary meaning. For instance, a "government policy" is a rule or principle that guides government decisions, usually related to a specific topic such as education. Similarly, a 'government program' refers to an organised system of services, activities, or opportunities to achieve a goal or outcome.'**

The committee notes that a broad construction of the permitted purposes for data sharing risks interpretations which may unduly trespass on privacy.

It is not immediately clear how the broad construction of permitted purposes could unduly trespass on privacy, as any data sharing agreement is subject to the same safeguards. In relation to 'research and development', Research Australia is satisfied that these terms have a generally well understood meaning, and we note that data sharing applications for the purpose of research and development can only come from accredited users, which provides an additional level of oversight and control from the Office of the National Data Commissioner.

The committee's scrutiny concerns in this regard are heightened by the breadth of the application of the bill, in particular that data may be shared with private sector entities with no requirements that the safeguards that apply to, for example, university research, apply to these entities.

For the Research and Development purpose, data can only be shared with accredited users. An accredited user is subject to the eligibility requirements set out in Clause 77. This imposes requirements in relation to the capability and resources of the entity, and provides the National Data Commissioner with a range of grounds on which an application for accreditation can be refused, including national security. The Commissioner can also impose a range of conditions and restrictions on an accreditation. The accreditation requirements and the other safeguards in the Bill apply equally to universities and other entities.

Given the potential impact on an individual's right to privacy as a result of the use and disclosure of personal information under the proposed data sharing scheme, the committee requests the minister's advice as to whether the bill can be amended to:

- **include a public interest test which prioritises privacy interests in decision making under the scheme;**
- **provide guidance on the face the bill about the circumstances in which it will be 'unreasonable or impracticable' to seek an individual's consent for sharing their personal information;**
- **require that, where possible, data that includes personal information is shared in a de-identified way;**
- **clarify the scope of the permitted data sharing purposes, and include guidance on the face of the bill about precluded purposes; and**
- **provide minimum standards for ethics approvals for private entities seeking to use data that includes personal information.**

Research Australia believes the prioritisation of privacy and the requirement that where possible, data is shared in de-identified way, is already provided for by the Data Principle in Clause 16. The Data principle provides that:

> '(a) only the data reasonably necessary to achieve the applicable data sharing purpose is shared;
>
> (b) the sharing of personal information is minimised as far as possible without compromising the data sharing purpose.'

The question of ethics approval is potentially fraught. Research Australia is concerned about the Bill being amended in a way that approval by a Human Research Ethics Committee (HREC) of a research proposal might be automatically required by a Data Custodian as part of their own assessment criteria.

The Ethics Approval process is mandated by the National Statement on Ethical Conduct In Human Research (the Statement) and has been developed jointly by the National Health and Medical Research Council, the Australian Research Council and Universities Australia.

The primary purpose of the Statement is to ensure that research subjects are protected from harm and treated with respect.[13] It is a framework designed to cover a range of different types of research and risk, including experimental surgical procedures and new medicines where there is a risk of serious injury, disability and death.

The Statement recognises that many research proposals pose little or no risk to research subjects, in which case approval by an HREC may not be necessary. This research is described as low risk and negligible risk research. The expression 'low risk research' describes research in which the only foreseeable risk is one of discomfort. Research in which the risk for participants is more serious than discomfort is not low risk. The expression 'negligible risk research' describes research in which there is no foreseeable risk of harm or discomfort; and any foreseeable risk is no more than inconvenience.[14']

Low risk research can be given ethics approval through an alternative process that does not require approval by a HREC. (This assessment and decision is made by an approved person at the institution, not the researcher.) Negligible risk research can be entirely exempted from the requirement for approval by a HREC by the researcher's institution. (Once again, this assessment and decision is made by an approved person at the institution, not the researcher.)

Research using existing data sets with deidentified data is regularly determined to be negligible risk research. Research using existing datasets with deidentified data could be characterised as low risk research, depending on the nature of the data and the consequences for the individual if that data was to be made public and the individual was somehow identified.

Assessment by a HREC can be a time consuming, lengthy and resource intensive process, hence the alternatives provided by the Statement for negligible risk and low risk research. While some Data Sharing proposals by health and medical researchers will require approval by an HREC, there is likely to be some which would be negligible risk research projects under the Statement, and others which would be low risk.

Research Australia submits that there should not be an expectation that all Data Sharing proposals under the Research and Development purpose require the approval of a Human Research Ethics Committee.

There should also be no expectation that a Data Custodian should require a Data Sharing proposal to obtain approval from a HREC as part of the Data Custodian's own vetting and assessment of a Data Sharing application. In the context of data sharing, the objective of avoiding harm to research subjects and treating them with respect is met by the Data Principle, and Ethics Approval should not be seen as a substitute for, or a prerequisite to, the public interest test.

On the subject of private companies, Research Australia notes that the statement is available for use by the private sector and could be used by a private company if and where this was appropriate, potentially including the provisions relating to low risk and negligible risk research.[15]

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[13] National Statement on Ethical Conduct in Human Research 2007(Updated 2018). The National Health and Medical Research Council, the Australian Research Council and Universities Australia. Commonwealth of Australia, Canberra. P.6

[14] Ibid, p.13

[15] Ibid, page 6

Research Australia submits the assessment of ethical considerations by the Data Custodian and the role of the National Statement for Research Ethics should be addressed in guidance by the National Data Commissioner rather than in the Bill.

Finally, Research Australia notes that Data Sharing for the purposes of policy and program development and service delivery can also raise ethical considerations.

The committee is concerned that there is a risk that individuals' interests in their personal information being kept private may not be given sufficient weight in an evaluation of public interest. Further, it does not appear that the Commonwealth entity making initial decisions with respect to sharing of data must consult experts or seek other external input.

Research Australia accepts that there are risks to individuals' privacy from sharing data and that while the Data Sharing and Transparency Bill can, and does, mitigate these risks, it cannot eliminate them. It is important however that the risks are considered together with the benefits.

The benefits from the better use of data enabled by of sharing data are many. They include the more effective (and cost effective) delivery of government services, enabling more and better services to be provided at lower cost to the taxpayer; the detection and reduction of harm caused by existing policies and practices; and the introduction of new services and products that benefit the community. Overall, the better use of data can improve the health, prosperity and wellbeing of the Australian community.

This is the key conclusion reached by the Productivity Commission in its 2017 report on Data Availability, and which is the genesis for this legislation.

The Bill cannot achieve all of this by itself; it is part of a broader plan which includes better resourcing of Government Departments to utilise data more effectively. It is however, an important enabler of the better use of data. It is essential that the risks to individuals' privacy are not considered in isolation but as part of this broader risk/reward trade off.

Case study: Effectiveness of the HPV vaccine

Between 2007 and 2009, Australia vaccinated over half of its young women aged 12–26 years against several strains of human papillomavirus using the quadrivalent HPV vaccine. These HPV strains cause over 90% of genital warts, 35% of low-grade cervical intraepithelial neoplasia (CIN), 50–60% of high-grade CIN (higher in younger women) and 70–80% of cervical cancers.

The three-dose course was generally offered at the recommended spacing of 0, 2 and 6 months, with an accelerated schedule of 0, 1 and 4 months also used in the first year of the program in order to facilitate course completion within the school year. However, not all women completed the course, with dose 1 coverage in the population at least 15% higher than dose 3 coverage across the age range. Is receiving only one or two doses effective in protecting against cervical disease?

Data from the Victorian Cervical Cytology Registry (VCCR) and the National HPV Vaccination Program Register (NHVPR) was linked and deidentified. Researchers then analysed the data to determine the relative effectiveness of receiving one, two and three doses of the Vaccine in preventing cervical disease.

The research found that even an incomplete vaccination course (less than 3 doses) reduced the impact of cervical disease, although protection does not appear to be equivalent to that provided by three doses.[16]

[16] Brotherton JM, Malloy M, Budd AC et al. Papilloma Virus Research. 2015. 1:59-73. https://doi.org/10.1016/j.pvr.2015.05.005.

1.23 The committee therefore requests the minister's advice as to why individuals whose privacy interests may be affected by the data sharing scheme should not have access to merits review and the dedicated complaints process established in Division 1 of Part 5.3.

Paragraphs 1.18 to 1.23 deal with the rights of individuals to make complaints about decisions made under the Bill.

Research Australia does not have a particular view on the question of the complaints mechanisms and a right to merits review. It appears the Australian Information Commissioner would have jurisdiction to deal with many complaints about activity related to a data sharing agreement and has the existing mechanisms for dealing with complaints from individuals. The provision of data in a data sharing agreement may also only be one element of an individual's complaint and it seems sensible to ensure that the whole of a person's complaint can be addressed by a single dispute resolution mechanism rather than requiring different parts of a complaint to be handled by different bodies.

Conclusion

Australia undertakes world class health and medical research to deliver health social and economic benefits tot eh Australian community. Researchers adhere to high standards and are subject to significant regulation of their activities. The Bill will add an extra level of accountability and regulation to researchers' use of datasets held by the Commonwealth that does not currently exist.

In doing so it will enhance the protections available to individuals whose data is used for research purposes. Research Australia also expect the Bill will improve access for researchers to Commonwealth data sets. The benefits of providing greater access to data are significant. In fact, in its final report on Data Availability and Use, the Productivity Commission highlighted the greater use of health data as one the areas of greatest benefit to the Australian community.[17]

Research Australia recognises that whilst the collection, storage and use of data carries definable risks, these should be managed by proportionate approaches that permit use of this data understanding that such use often brings greater benefits that more than justify the incremental risk associated with making more use of data.

The Bill has been developed over a course of three years' extensive consultation; Research Australia believes it provides the right balance between protecting individuals' privacy and deriving greater benefit from the more effective use of data. Research Australia urges the Committee to recommend the passage of the Bill to the Senate.

Research Australia is pleased to have had this opportunity to make this submission and is willing to provide further information that would assist the Committee in its deliberations.

[17] Productivity Commission 2017, Data Availability and Use, Report No. 82, Canberra, Appendix E

Appendix- Q Skin Participant Consent Form

Q Skin PARTICIPANT CONSENT FORM – PART 1 OF 2

Q Skin relies on Queensland people sharing information about themselves. WE ARE ASKING YOU TO SIGN TWO FORMS. By signing this form (part 1 of 2) you are agreeing to take part in the Q Skin Study and for the Study team to follow your health over time. The second form (on the other side of this page) is required by Medicare Australia. By signing the second form you are agreeing to the release of Medicare information for the purposes of the Q Skin Study. Participation is completely voluntary, and you are free to ask questions or to withdraw from the Study at any time, by calling the Study helpline on 1800 222 600.

I agree to have my health followed over time through:

the Q Skin Study team following health and other records relating to me, including hospital records, cancer records, death records and other health-related records (such as Medicare Australia), as outlined in the Study information sheet Q Skin: Information for participants;

being contacted in the future to provide information on changes to my health and lifestyle. I may also be asked to provide further information including survey responses or biological samples; my participation in any of these would be completely voluntary.

I give my consent on the understanding that:

my information will only be used for the purposes outlined in the Study information sheet entitled *Q Skin: Information for participants*, of which I have a copy;

my information will be kept strictly confidential and will be used for health research only;

reports and publications from the Study will be based on de-identified information and will not identify any individual person taking part;

my participation in this Study is entirely voluntary and my consent will continue to be valid following death or disablement unless withdrawn by my next of kin or other person responsible. I am free to withdraw from the Study at any time by calling the Study Helpline on 1800 222 600.

my decision on whether or not to take part in the Study or in any additional research will not disadvantage me or affect my future health care in any way.

I have been provided with information about the Q Skin Study including how it will gather, store, use and disclose information about me, in the Study information sheet. I have been given an opportunity to ask questions and have been fully informed about the Study.

Signature | Today's date D D M M Y Y Y Y

If you have any questions about the study please contact the Study Helpline on 1800 222 600. If you have any complaints you may contact the Chairman of the QIMR Human Research Ethics Committee by phoning the Secretary, on (07) 3362 0117.

Contact details

Your home phone no.: ( ) | Your mobile no.:

Your postal address: Street number and name | Suburb | State | Post Code

It would be very helpful if we could contact you in future by email. It would also reduce Study costs and our carbon footprint. If you are happy for us to do this, please write your email address below:

Email address:

Sometimes we find that people have moved when we try to contact them again. It would be very helpful if you could give us the contact details of someone close to you (such as a relative or friend) who we could contact if we are unable to reach you. We would only get in touch with that person if we were unable to contact you directly and we would need to tell them our reason for contacting you. Please leave this section blank if you do not wish to provide these extra contact details.

Full name of contact person:

Residential address of contact person: Street number and name | Suburb | State | Post Code

Phone number of contact person: ( )

Email address of contact person:

PLEASE TURN THE PAGE AND COMPLETE THE OTHER SIDE >>

Page 11 *Please complete and return in the envelope provided*

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Q Skin PARTICIPANT CONSENT FORM – PART 2 OF 2

By signing this form you are agreeing to the release of **Medicare and/or Pharmaceutical Benefits Scheme** information for the purposes of the Q Skin Study.

1. I agree to be a Participant in the Q Skin Study.
2. I have been provided with information about this study including how this study will access, store, use and disclose information about me. I have been given an opportunity to ask questions and have been fully informed about this study. I understand that my participation is entirely voluntary and that my participation will not have any effect on my personal dealings with Medicare Australia.
3. My participation in this study will be from the consent/data extraction specified on this form, or to the end of this study.
4. I understand that this study is/may be ongoing, unless I am otherwise notified. In the event that this study exceeds the 10 year maximum period of consent, this study will be required to obtain a new consent form signed by me.
5. I understand that my details on this consent form will be provided to Medicare Australia.
6. I agree to Medicare Australia releasing the specified Medicare and/or Pharmaceutical Benefits Scheme (PBS) claims information about me to the Q Skin Study Team, and understand that this specified information will be collected, stored and analysed only for the purposes of this study.
7. I understand that the specified Medicare and/or PBS claims information about me, released by Medicare Australia to the study, will be stored in secure facilities and accessed only by authorised personnel.
8. I understand that the specified Medicare and/or PBS claims information about me will not be published in a manner that could identify me as an individual, during or after the conclusion of this study.
9. I understand that I can, at any time, withdraw my consent to participate in this study (and to the further release of my Medicare and/or PBS claims information). I understand that the effective date of this notification will be the date on which my withdrawal notice is received by the study, and that information about me collected prior to this date will continue to be used and form part of this study. Should I wish to withdraw my consent, I can do so by calling the study helpline on 1800 222 600. I also understand I may become ineligible should I no longer meet the criteria for the study.
10. I understand that specified information about me collected for the purposes of this study could be stored for a period of at least 10 years after the conclusion of this study, or until the completion of the evaluation of this study, whichever date occurs last. At the end of this period, this information will be destroyed.

Full Name: Gender: ☐ Male ☐ Female

Medicare card number: Date of birth: D D M M Y Y Y Y

Residential address: Street number and name Suburb State Post Code

Contact Phone Number: ( )

I consent for this study to obtain my Medicare (MBS) and Pharmaceutical Benefits (PBS) claims history.

Consent/data extraction valid from today *(please fill in the date below)* **to: 30/09/2020**

Signature **Today's date** D D M M Y Y Y Y

ONLY if participant is unable to sign:

Signature of witness **Today's date** D D M M Y Y Y Y

Full Name of Witness:

Reason Participant is unable to sign:

Relationship to Participant:

Thank you very much for taking part

Please complete and return in the envelope provided Page 12

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