

Office of the National Data Commissioner
PO Box 6500
Canberra ACT 2600

23 October 2019

Data Sharing and Release Legislative Reforms Discussion Paper – Monash University Feedback

Thank you for the opportunity to comment on the Discussion Paper – Data Sharing and Release Legislation.

Monash University is committed to excellent research whilst meeting high standards of ethics, data protection and privacy. Monash University therefore welcomes a data sharing and release framework to streamline and enhance access by its researchers to national public datasets within which data sharing and release can occur in a safe and ethical manner.

Monash University makes the following submission to clarify certain aspects of the Data Sharing and Release Legislation. In support of this submission, attached is more detailed feedback from Monash University's School of Public Health and Preventive Medicine, which provides the perspective of the School as one of the largest public health schools in Australia which is involved in a range of significant research activities that use public datasets.

Monash University welcomes any opportunity for further engagement with the Office of the National Data Commissioner.

1. Definition of public sector data

"Public sector data" is defined in the Discussion Paper as "*information collected or generated by Commonwealth entities (such as departments), and Commonwealth companies, or through research programs funded by the Australian government.*"

Monash University seeks clarification on what type of "research programs funded by the Australian government" and related data would fall under this definition. For example, will Monash University become a Data Custodian under the Data Sharing and Release Legislation if public sector data is envisaged to include research data created by Monash University pursuant to Commonwealth grant funding agreements?

Monash University does not fall within the current definition of "Data Custodians," which are "Commonwealth entities and companies as defined under the *Public Governance, Performance and Accountability Act 2013.*" There would be a number of complexities for the university sector should it be anticipated to become a Data Custodian under the Data Sharing and Release Legislation, including ownership of research IP, Ethics Committee approvals, consent management and the ability to share and release combined datasets of other research institutions.

2. Definition of data

"Data" is defined in the Discussion Paper as "*any facts, statistics, instructions, concepts, or other information in a form capable of being communicated, analysed or processed (whether by an individual or by other means, including a computer, electronic and automated means.*"

Monash University has established arrangements to access public aggregated (reporting-level) data. This data is not unit-level or record-level and we welcome clarification that aggregated data will continue to be available as open data. We are concerned to ensure that the Data Sharing and Release Legislation will not impose any additional restrictions.

3. De-identified data

Monash University understands the risks of re-identification of data that is released as open data.

We support further consultation and consideration of how "de-identified" data is shared and released under the Data Sharing and Release Legislation.

4. Accredited users

Monash University supports an accreditation process for all users participating in the proposed data sharing enabled by the Data Sharing and Release Legislation and accepts the broad support received by the Office of the National Data Commissioner for Accredited Users to include universities.

Monash University welcomes further consultation and clarity on a defined accreditation process for Accredited Users that can draw on our experience as trusted data custodians in our university research activities.

5. Public benefit and data sharing with commercial entities

Monash University supports the application of a purpose test to the proposed uses of public data.

Monash University seeks further clarification on how a proposed use would be assessed as a public benefit and how the changing nature of community expectations could be factored in to this assessment.

Monash University notes that a primary focus of its use of public sector data is to support better outcomes for the community, for example, improvement of health services capabilities, and to inform evidence-based policies and recommendations for the public, private and not-for-profit sectors, all of which Monash University views as falling within the proposed purpose test.

In the context of proposed commercial uses, a number of Monash University's clinical registries in the School of Public Health and Preventive Medicine manage data access requests from commercial entities that incorporate consideration of the broader public interest. Similar processes could be used in the Data Sharing and Release Legislation to ensure that any data sharing with commercial entities is appropriate. Examples of these processes are included in the School of Public Health and Preventive Medicine's submission, appended to this submission.

6. Consent

Monash University agrees with the adopted position of not requiring consent in all instances of data sharing, by building in an accreditation process and the purpose test to support the use of public data for public benefit.

Monash University welcomes further consultation on the issue of consent within the Data Sharing Principles, particularly in ensuring there is consistency between the Data Sharing and Release Legislation and other schemes that may impact on the conduct of research incorporating public sector data.

We look forward to hearing the outcomes of the consultation and welcome the opportunity to work with the Office of the National Data Commissioner on the next stages of the Data Sharing and Release Legislation.

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c/- School of Public Health and Preventive Medicine
Monash University

Office of the National Data Commissioner
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23 October 2019

Re: Data Sharing and Release Legislative Reforms Discussion Paper

Thank you for the opportunity to provide feedback on the *Data Sharing and Release Legislative Reforms Discussion Paper*. This submission has been prepared by Associate Professor Susannah Ahern on behalf of the School of Public Health, Monash University.

The School of Public Health and Preventive Medicine at Monash (SPHPM), adjacent to the Alfred Hospital in Melbourne, is one of the largest public health schools in Australia, comprising over 1200 staff and over 1000 students. The School's research activity relies heavily on the collection, management, analysis and reporting of health and related datasets through our extensive programs of clinical trials, clinical registries, cohort studies, public health policy and evaluation, and public health genomics.

In particular, the SPHPM currently manages the largest clinical trial in Australia, the Aspirin in Reducing Events in the Elderly (ASPREE) clinical trial, and also manages the largest number of clinical registries in Australia, at thirty. Our registry, trial and cohort studies cover clinical areas of emergency, trauma and critical care; cardiac and pre-cardiac disease; surgical procedures and cancer; implantable devices; musculoskeletal disease; medical and rare diseases; infectious diseases; occupational diseases; air pollution and health; and health insurance outcomes. The SPHPM undertakes its research activities under the oversight of NHMRC-approved ethics committees, as well as complying with national and state-based legislation.

The SPHPM researchers regularly seek access to public national datasets for research and linkage purposes, such as those held by the Australian Institute of Health and Welfare (AIHW) including but not limited to the National Death Index (NDI); the Australian Bureau of Statistics (ABS); the Medicare Benefits and Pharmaceutical Benefits Scheme (MBS, PBS); the Australian Cancer Database; the national Aged and Residential Care datasets; the National Disability Insurance Scheme; and others. Examples of the use of such linked data include:



- Linkage with NDI data to inform survival analyses in cancers and rare diseases such as cystic fibrosis
- Linkage with the ABS to determine postcode socioeconomic status rating for the purposes of risk adjustment of benchmarking analysis
- Linkage with PBS to inform prescribing practices in the elderly population (ASPREE)
- Linkage of the Australian Firefighter's Health study to national death and cancer data to determine occupational risks for around 250,000 paid and volunteer firefighters.
- Linkage of the Gulf War Veteran's cohort to national death and cancer data, MBS, PBS, as well as Department of Veteran's Affairs Health datasets to monitor the on-going health of returned servicemen from the Gulf War.

Efforts by the Commonwealth Government to streamline and enhance access by researchers to national public datasets are very welcome, and the SPHPM is keen to constructively engage in ongoing dialogue with the Office of the National Data Commissioner regarding this.

Feedback regarding the Discussion Paper

Public Sector data

The proposed scope of the legislation relates to **public sector data**, which is defined as 'data held by the Australian government as it fulfils its various functions (pg 2).' We understand this to mean administrative and other data currently collected by existing government bodies and agencies. We also note that 'data' for the purposes of this legislation has a broad meaning and can include both unit level data and aggregated information that is able to be communicated.

The SPHPM also has agreements with the Commonwealth to establish and manage various clinical datasets including registries, such as those for breast devices, bariatric surgery, pelvic surgery and the establishment of a national cardiac registry. The data under these agreements is owned by or licensed to the Commonwealth. It would be useful to know whether such SPHPM datasets would be considered **public sector data**, and whether therefore in relation to these datasets, SPHPM would be considered a **Data Custodian (or a Data Service Provider)** under this legislation. In respect to *access to public government data sets*, our assumption is that the SPHPM will be considered a **Data User**.

Shared data

The proposed scope of the legislation relates to **shared Data** i.e. 'controlled access to the right people for the right reasons (pg 3)', which is considered separate to closed data (internal agency access only) and open data (public access to open data), with the aim of 'unlocking the value' of much of existing government-held data in a safe, and transparent manner.

It is worth noting that in relation to the SPHPM clinical registries and some other datasets, that these currently have existing **data access policies and procedures** that allow access by third parties



to data or for provision of information in the form of reports held within the registry. We can provide further information regarding our policies/procedures upon request, if this would be of benefit to the Office of the National Data Commissioner as it considers Data Sharing Agreements. It is also worth noting that the number of requests for data from our clinical registries is increasing as more stakeholders (both public including jurisdictional governments, and private) are becoming aware of these datasets and their value for research and evaluation.

Proposed Regulatory Framework

'Data Custodians' are defined (pg 55) as Commonwealth entities and companies under the *Public Governance, Performance and Accountability Act 2013*, such as agencies and departments. As noted above, it is assumed for the following feedback that the SPHPM does not meet the definition of a Data Custodian under this legislation, and will be considered a Data User.

The SPHPM agrees with the overarching principles of the new legislation that will be to (pg 14):

- consistently safeguard public sector data sharing and release
- enhance the integrity of the data system
- build trust in use of public sector data
- establish institutional arrangements
- promote better sharing of public sector data.

We also note that the information likely exempted from the scope of the legislation includes (1) information collected/held by the National Intelligence Community, and (2) information provided under the My Health Record scheme. The SPHPM notes that in the longer term that access to My Health Record will likely be of significant value to our research activities as described above. We also note that initially that State and Territory data will not be in scope, however strongly advocate for their participation in a similar process when possible. In particular we note that currently some of the Commonwealth datasets (such as the AIHW cancer datasets) are a collation of each individual state's data sets that all require their own approval. Ideally, these jurisdictional sets that ultimately form the national data set should come under the scope of this legislation.

We note that the process for sharing public sector data under the legislation (pg 16) asks whether data can be shared easily under existing authority, and if so, to use this existing process. A majority of our data linkage requests to government bodies require **ethics committee approval** as well as approval by the data custodian of the linked data (e.g. the AIHW's ethics committee). Further consultation on how these existing processes would interact with the legislation would be welcomed.

The SPHPM agrees that data sharing must satisfy the **purpose test** (i.e. inform government policy, programs, service delivery, or be in support of research and development, pg 17), and align with the five **Data Sharing Principles** (of project, data, settings, people and outputs). We note that one of the tests of use of similar data in the UK is whether the person would be 'surprised' to know that their data were being used for research and whether there is a reasonable expectation that the data



could be used for research. We also agree with the development and making publicly available the **Data Sharing Agreement** for transparency purposes (pg 17).

Commercial use of public sector data

The SPHPM agrees that the purpose test and Data Sharing Principles should be the basis on which data is shared, not necessarily the sector with which it is shared. In health in particular, public and private partnerships exist in every sphere – from payers (e.g. private health insurers; transport accident and workcover insurers), to providers (e.g. the private hospital and community services sector), to suppliers (e.g. device, biotechnology, and pharmaceutical companies). Such bodies are integral to the Australian health system, and theoretically should not be denied access to information that could assist them in evaluating and improving their services. Nevertheless, access to public data may also provide competitor and customer information that may not be considered to pass the purpose test.

There may be some specific options to apply the legislation to the commercial/private sector. For example;

- Rather than commercial entities being offered an accreditation process as data users, instead their applications for data could be considered on a case by case basis. This would allow review of each application against the purpose test.
- Alternatively, commercial users could become accredited if they partner with an accredited academic institution, and if data requests are submitted by the academic institution (where they will be assumed to meet the public interest test).
- Commercial users could have restrictions on the level/type of data that could be accessed, such as aggregate (non-identified) data/information only.
- Commercial users could also have additional conditions on the use and disclosure (particularly external) of data accessed from public sources.
- Commercial users would need to provide evidence of systems in place for appropriate management, and security of any data received by public datasets.

A number of the SPHPM clinical registries currently have a number of processes in place to manage data access requests from commercial entities (including pharma and medical device companies) that utilise these sorts of principles. Further information regarding this may be provided on request.

Consent

The SPHPM agrees that the issue of consent warrants careful consideration, but that the position adopted by the proposed legislation, of not requiring consent in all instances of data sharing, strikes the right balance in enhancing the use of public data for research purposes. We agree that when (opt-in) consent is required that this is likely to lead to limited uptake and biased samples, which may significantly impact on the outcomes and validity of the research or evaluation.



We understand that in the UK that data can be made available to researchers without consent in specific circumstances (e.g. as long as certain criteria is met under relevant privacy legislation) allowing much data linkage without individual informed consent, with a legal basis, and in a transparent way.

In particular, where patient health data will be shared to determine aggregate or population-level outcomes, the risk to the patient of such data-sharing is negligible (assuming the accredited data users have appropriate security and privacy protections in place), compared with the benefit to the public and the broader health sector.

It is obviously important from a research perspective, that any new information created through data linkage that did not require individual consent or data custodian ethics approval, may be able to be utilised for secondary research and be published.

Accreditation of Data Users

The SPHPM notes that the National Data Commissioner will oversee a process of accrediting **data service providers** and **data users** to participate in the data sharing and release system (pg 39), and that these will comprise (i) skills and capability to protect, manage and use data; (ii) privacy standards if handling personal information; and (iii) effective governance to manage and use data.

These accreditation principles are an appropriate basis for a process. The SPHPM also notes that in healthcare that the Australian Commission for Quality and Safety in Healthcare (ACSQHC) is working towards an accreditation framework for Clinical Quality Registries in 2019-2020. It would be useful if this activity could be coordinated between the ACSQHC and the Office of the National Data Commissioner so that similar accreditation standards and expectations apply across the health sector for data custodians and data users.

Once accreditation criteria are established, the accreditation process itself needs to be fit for purpose. The discussion paper notes that accreditation will need to apply to both institutions (valid for 5 years) and individuals (valid for 3 years) (pg 44-5). It is anticipated that this will involve a paper-based review of applicant's credentials and capability by a nominated individual/committee. We note the recommendation (pg 45) for accredited individuals to undertake training and pass a test provided by the Office of the National Data Commissioner. This would seem a reasonable approach, and is consistent with similar requirements in the UK, such as the Safe Researcher Training.

Other issues

The SPHPM also recommends that the proposed data sharing and release framework acknowledge the transaction costs involved in data sharing and that these should be made explicit and transparent.



Conclusions

Once again, thank you for the opportunity to provide feedback on the *Data Sharing and Release Legislative Reforms Discussion Paper*. We look forward to hearing of the outcomes of the consultation and would welcome the opportunity to work with the Office of the National Data Commissioner on the next stages of the legislation's development.

Should you require more information, please contact Associate Professor Susannah Ahern at the Registry Science and Research Unit, Monash University, at [REDACTED]

Yours sincerely

Susannah Ahern

Appendix – List of academic and professional personnel at Monash School of Public Health and Preventive Medicine who provided feedback in relation to this response.

Professor Peter Cameron, Professor of Emergency and Divisional Head of Health Services Research

Professor Belinda Gabbe, Head of the Prehospital, Emergency and Trauma Research Unit

Professor Sally Green, Co-Director Cochrane Australia

Professor John Zalberg, Head, Cancer Research, SPHPM

Associate Professor Susannah Ahern, Head Registry Science and Research

Brooke Backman, Program Manager, Bariatric Surgery Registry

Angela Brennan, Program Manager, Cardiac Registries, SPHPM

Anthony Del Monaco, Monash Centre for Occupational and Environmental Health

Marina Skiba, SPHPM Research Governance

Jenni Williams-Spence, Program Manager, ANZSCTS Database