Professor Ross Coppel
Deputy Dean and Director of Research

3 June 2020

Office of the Australian Information Commissioner
GPO Box 5218
Sydney NSW 2001

4 June 2021

Response to Consultation Paper: National Health (Privacy) Rules 2018 review

Thank you for the opportunity to provide feedback on the Office of the Australian Information Commissioner's review of the *National Health (Privacy) Rules* 2018 ("Rules"). This submission has been prepared by members of Monash University's Data Linkage Working Group, composed of a cross section of the University's research community who are involved in, or support, data linkage activities.

Monash University, including through its School of Public Health at Monash (SPHM), engages in a high volume of research activity that 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.

While Monash University is not directly bound by the Rules, Monash researchers regularly seek access to public national datasets for research and linkage purposes, including the Medicare Benefits and Pharmaceutical Benefits Scheme (MBS, PBS) datasets. Some examples of the work Monash has been involved in that includes MBS and PBS data are:

- Linkage with PBS to inform prescribing practices in the elderly population (ASPREE);
- 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
- Linkage of clinical quality registries with MBS and PBS data to improve the monitoring of quality of care and outcomes

Monash University supports the review of the Rules and a framework that takes a principles-based approach to allow efficient and streamlined access by its researchers to MBS and PBS data, while also protecting individuals' privacy.

Faculty of Medicine, Nursing & Health Sciences
Monash University
Level 1
43 Rainforest Walk (formerly Building 64)
Clayton VIC 3800

Telephone: +61 3 9902 9147
Email: ross.coppel@monash.edu
www.monash.edu
ABN 12 377 614 012 CRICOS Provider #00008C

Monash University has attached its feedback on the rules in the Attachment, which provides the perspective of the University which has one of the largest public health schools in Australia and which is involved in a range of significant research activities that use public datasets.

We look forward to hearing of the outcomes of the review and would welcome the opportunity to engage further with the Office of the Australian Information Commissioner on any updates to the Rules.

Should you require more information, please contact Associate Professor Nadine Andrew, Chair, Helix Data Linkage Working Group, Monash University, at nadine.andrew@monash.edu

Yours Sincerely,

Ross Coppel MBBS, PhD, DTM&H, FAHMS
Senior Deputy Dean and Director of Research

Submission to Consultation Paper: National Health (Privacy) Rules 2018 review

1. What provisions in the Rules work well and should remain as they are or with minimal changes?

The Rules allow the disclosure of information that was obtained in connection with a claim for payment or benefit under the MBS or PBS for medical research. We support the Rules' ongoing support of medical research. However, in light of advancements in research capability within the field of 'big data' to improve human health, and improvements in privacy preserving technologies for linking and storage of sensitive data, we submit that the Rules should be updated to take account of these advancements to allow the storage and release of data in a broader range of circumstances. Our more detailed feedback on this point is included below.

2. What provisions in the Rules are no longer fit for purpose?

3. Do the Rules get the balance right between protection of privacy on the one hand and use of claims information on the other? Why or why not?

In answer to the two questions above, our view is that the use by researchers of MBS and PBS data specifically for medical research is adequately governed by the existing framework provided by the Privacy Act, the Australian Privacy Principles (APP)s, National Health and Medical Research Council (NHMRC) guidelines and any applicable state and territory legislation (the "Privacy Framework").
Our view is that not all of the provisions in the Rules are required to effectively govern the way researchers use MBS and PBS data and create unnecessary duplication of processes for researchers.

We note that the existing Privacy Framework includes provisions for consent, waiver of consent and 'opt-out' approaches for the use of personal and health information in medical research. The Privacy Framework recognises that the right to privacy is not an absolute right and in certain circumstances, it must be weighed against the rights of others and against matters that benefit society as a whole. The NHMRC guidelines also provide for Human Research Ethics Committees to have a role in undertaking this balancing exercise to ensure research is beneficial but also ethical and respectful of individuals' privacy.

A more flexible, principles-based approach that uses the existing Privacy Framework would, in our view, more effectively support the rapidly evolving landscape of medical research and benefits of the use of MBS and PBS data by researchers to gain new knowledge relevant to the health of the Australian population.

There are a range of administrative health data available to researchers from other Commonwealth and State government datasets that are not subject to the additional requirements imposed by the Rules. We submit that MBS and PBS data should be subject to the same standards that apply to other forms of personal health data.

Specific issues faced by researchers

A more flexible, principles-based approach using the existing privacy framework would address the following issues currently experienced by researchers as a result of the Rules as they are presently configured:

A. Designated Consent Forms

Current processes under the Rules for release of data for research involve additional consenting processes beyond those required by the NHMRC guidelines. This can have negative impacts on the timeliness, quality and completeness of data made available to researchers as outlined in our case studies on page 5 (***case study 1***, Largest Non-Pharmaceutical-Company RCT in the World; ***case study 2***, Largest Australian cohort of people prescribed opioids for chronic pain; ***case study 3***, Large Collaborative Study with Cancer Institute).

In most instances, these additional requirements under the Rules make the informed consent process more complex (e.g. signing of multiple forms), potentially reducing participants' ability to understand the information presented to them. Long and complex consent documents and processes may obscure the information most relevant to the potential research participant. We suggest that any specific requirements for the use of MBS/PBS data, where it is feasible to obtain consent, be incorporated into the HREC-approved Participant Information and Consent Form (PICF) in a format that is compatible with HREC requirements and easily understood by study participants. This could be by way of wording approved by the custodians of the MBS and PBS datasets.

B. Restrictions on Data Available for Studies Without Express Consent

Under the current Rules, research studies where it is not possible or practical to obtain express consent are subject to additional constraints whereby de-identified data are not directly released to the researchers. Instead, all data regardless of the custodian, are required to be submitted to the AIHW for upload into an AIHW managed secure environment (usually SURE).

This process results in significant delays in researcher access to data and significant costs to the research team. The cost makes it prohibitive for most researchers to maintain linked datasets for extended periods such that the value of the data is not maximised and long-term insights are not gained as outlined in our case studies on page 6 (***case study 4***, Most comprehensive stroke data linkage study in Australia; ***case study 5***, State based and Bi-National Cardiac Quality and Safety Registries)

We note that the Privacy Framework does provide for the use of personal and health information for medical research without express consent of individuals, where HREC approval is obtained and certain conditions are met to ensure the privacy of research participants. These conditions would include that their data will be adequately protected from unauthorised access, modification, use and disclosure.

Further, recent advances in technology such as remote access, curated gateway, customisable permission levels, data tracking, regular security and ISO compliance assessments, mean that many more researchers now have access through their institutions, to world class infrastructure to manage sensitive data with extremely high levels of security and governance.

We submit therefore, that the Rules should not prohibit direct release of MBS and PBS data to researchers, where the researchers can demonstrate that they are able to comply with the requirements of the Privacy Framework, including where they can show that the data will be stored in accredited fully controlled secure virtual research environments.

C. Availability of Data for Other Non-Research, Quality Improvement Purposes

The use of linked MBS and PBS data have value beyond situations that may be traditionally classified as medical research such as clinical quality and safety initiatives. This would include release of MBS/PBS data for routine linkage with clinical quality registries or health service data.

These linkages are crucial for providing person-level insights into the impact of quality of healthcare on a range of person-level outcomes for clinical or population sub groups. As outlined in case study 6, the provision of patient level outcome data to clinicians can contribute to improved adherence to clinical quality indicators and monitoring of long-term outcomes related to changes in clinical practice. Advancements in the ability to link data across multiple sectors has also opened new opportunities for the use of MBS/PBS data in population research that extends beyond the traditional realms of health such as environmental and social sciences.

The Rules should support the release of MBS/PBS data to researchers and other appropriate entities for health-related quality improvement activities and other research types that have the appropriate HREC approval in compliance with guidelines under section 95 or s95A of the Privacy Act or otherwise with the APPs.

D. Rules Prohibiting Enduring Linkages and 5 year Limit of Stored Data

The Rules related to the separate storage of data and retention of linked claims information hinder research. This is not sustainable given the volume and size of data linkage research projects that have been performed over the last few years. These Rules require Services Australia to undertake resource intensive processes to re-establish links for each set of requested data. This not only results in significant inefficiencies and duplication of effort by Services Australia but hampers the timely provision of linked data for research. The timeframe from study commencement to receipt of MBS/PBS data by researchers is, on average 2-3 years. This reduces the impact of the research findings on current healthcare policy as by the time the researchers receive the data, policy changes may have occurred and the research findings may not be as relevant or impactful (see ***case study 5***).

In addition, the specific requirements around “old” claims information (i.e. more than five years old) appear arbitrary and are burdensome for conducting longitudinal cohorts. For example, for a five-year cohort study, where participants were recruited over a 12-month period (or longer), a single data linkage request could not be submitted to collect data for

the entire cohort period, as the first person was recruited 6 years before data collection ends for the cohort (see ***case study 2***). This means that multiple linkage requests must be submitted for cohorts that follow people for 5 years or longer (see ***case study 1***). This rule limits the use of these data in studies where associations between medication or treatment exposures and long-term outcomes are investigated e.g. childhood exposures where the outcome may not become apparent until adulthood and prevents enduring linkages for population cohorts.

We suggest that the Rules do not differentiate between "old" information and new information (less than 5 years old). This would mean that old information could be stored with identifiers such as the Medicare card number or pharmaceutical entitlement number allowing enduring linkages that could be maintained within the Department of Health and released to researchers for approved research. The rules regarding separation of claims information from enrolments and entitlements should also be relaxed to facilitate efficient linkage of data at scale for both internal and external research purposes. Advancements in information security, storage and management as well as secure environments for data access should mitigate the privacy and function creep risks for which the Rules were originally established. Further, existing obligations under the Privacy Framework require researchers to ensure that personal and health data they handle is accurate, up to date and complete and destroyed when no longer required.

E. The Rules should be aligned with the development of accredited research environments under the new Data Availability and Transparency Bill

Finally, as mentioned above, research institutions now have access to highly secure and well governed research environments. The Data Availability and Transparency Bill 2020 proposes a framework and standard under which research institutions' infrastructure can be accredited to hold particular types of data. Thus any changes to the Rules should be aligned with this proposed legislation and we suggest that the Rules should recognise any accreditation as per the Data Availability and Transparency Bill and allow data to be released to these environments.

Case Study 1

Largest Non-Pharmaceutical-Company RCT in the World

An international, multi-million dollar, decade long, randomised control trial to investigate the impact of taking aspirin on an elderly population commenced in 2010. The Participant Information and Consent Form (PICF) that all 16,700 Australian participants signed at study entry contained specific wording about agreeing to the release of one's Medicare number, health and prescribing information held by Medicare and PBS, for the purposes of the study.

As a result of the Rules, the PICF required amendment in 2015 to require an additional specified consent form to be supplied, collected, collated, stored and transferred for individual sighting by the Commonwealth for all 16,700 Australian participants. Given the size of the cohort, this was a significant undertaking of time and tens of thousands of dollars.

The findings of the initial clinical trial began to be released in 2018, resulting in clinical guidelines for the use of aspirin with the elderly amended globally. The linked data set, however, has yet to be completed.

The initial clinical trial was so significant that the study was to continue to follow up the cohort as part of an observational study. In order to continue to link the cohort with available MBS/PBS data sets for the duration of this extension phase however, the Rules required a further prescribed consent form, which remains a work in progress. As a result, the MBS/PBS datasets for this study are still incomplete.

Case Study 2

Largest Australian cohort of people prescribed opioids for chronic pain

This is an NHMRC funded cohort study of > 1500 people prescribed opioids for chronic pain. This national study involves linking cohort survey data over 5 years with MBS and PBS data. To be able to access MBS and PBS data we had to complete an additional consent process, requiring participants, who were predominantly older adults with multiple morbidities, to complete two separate consent forms, adding burden to the participants. In addition, as it took more than 12 months to recruit the cohort, multiple data requests were required as by the time the first participants had reached the 5-year mark, requiring the data to be requested before the 5-year limit was exceeded, with a separate request needing to be made for the later participants, again, adding additional administrative burden to the study.

Case Study 3

Large Collaborative Study with Cancer Institute

A collaborative study was undertaken in 2015 that analysed phenotype data and genetic tumour data extracted from patients with solid tumours. The project completed an initial linkage with MBS and PBS and a second later one as the project ran longer than expected.

All participants had signed consent forms to have their tumour samples and genetic data included in the research but there was an additional requirement to have a separate form explicitly allowing the linkage to their MBS\PBS data. In many cases the patients were confused by this separate form - particularly as they had already consented to their more sensitive genetic data to be used.

In addition, as the project ran for more than 5 years, there was a requirement for the participants to be re-consented because of the Rules. Over 90% of those who were still alive consented, but, as you would expect in a cancer study, some participants had passed away and could not be re-consented. There were also a number of participants whose disease had progressed and who were too ill or lacked capacity to undertake this administrative

task. Not having access to MBS/PBS data for these groups with poor outcomes, limits the generalisability of the results using MBS/PBS data for these important patient groups and may introduce bias to some of the study outcomes.

Case Study 4

Most comprehensive stroke data linkage study in Australia

This is an NHMRC funded comparative effectiveness study of models of primary care used in the long-term management of people with stroke. This study involved multi-jurisdictional linkages between ten datasets: registry data, MBS, PBS, National Aged Care Clearing House, National Death Index, hospital and admission data from two states, and survey data.

Initial linkages for this study took two years, with the AIHW linkages taking significantly longer than those done by the state data linkage units. We had performed a linkage two years prior between the registry and MBS/PBS data. However, due to the restrictions imposed by the Rules, these prior linkages were destroyed. Allowing enduring linkages within Services Australia would have reduced the time taken to perform the linkages for this current larger study.

Additional layers of privacy preservation were imposed on our project. In our original AIHW ethics application content data from the various data custodians were to be submitted into SURE through the curated gateway and merged using a project specific ID. Content data from the state and registry data custodians were submitted into SURE prior to the AIHW submitting their linked content data. When the AIHW data were ready to submit their data we were informed that the processes agreed to in our ethics application were no longer applicable and that all content data needed to go through the AIHW so that they could apply their own project ID. This meant that all of the data custodians were required to remove their content data from SURE and submit it to the AIHW for re-submission into SURE. This process added an additional 6 months to our project timeline.

We are required to store our study data in SURE which is expensive, incurs large annual fees and is charged on a per user basis. This limits the number of researchers that are able to access the data and the study timeframe and is particularly problematic for studies such as ours that involve large numbers of datasets (N=10) that need to be cleaned, harmonised and analysed. The SURE costs means that all of the project outputs need to be produced within a limited timeframe and the value of these large linkage projects are not fully realised. Being allowed to store the project data in a secure University hosted environment such as Monash SeRP, would mitigate these costs.

Case Study 5

State based and Bi-National Cardiac Quality and Safety Registries

These cardiac registries utilise an opt-out approach, approved by an HREC, as a legal basis to collect their data. In addition, the state based registry has an HREC approved waiver of consent for some of their deceased participants.

There is a desire to link these Registries with the PBS and MBS, spanning the pre-morbid and post-morbid phases, to assist in both the risk adjustment and identification of events or complications to measure outcomes. Ideally this would be an enduring linkage to ascertain a complete view of the outcomes of the interventions. This information could inform strategies to reduce rehospitalization as well as assist in developing guidelines related to, in particular, anticoagulation and antiplatelet type medicines.

The Rules have acted as a barrier to such enduring linkages in opt-out registries. Of particular concern is the cost of such linkage as projects are obliged to use the SURE environment. Previous experience has shown these linkages to be very expensive with the cost for 2000 patients to be linked to MBS/PBS costing approximately $10,000. If these types of costs are extrapolated to large Registries such as these with between 80,000 to 180,000 patient procedures overall and another 10,000+ procedures being added each year, the cost of linkage becomes unviable.