

This *Data Sharing and Release Legislative Reforms Discussion Paper* submission has been prepared by Dr Stefanie Elbracht-Leong and Dr Matilda Haas, representatives of the Australian Genomics Health Alliance (Australian Genomics) at the roundtable event in Melbourne on 19<sup>th</sup> September, 2019.

Australian Genomics is supported by a \$25M NHMRC Targeted Call for Research in Genomics grant (2016-2020) with the remit of building evidence to inform the integration of genomic medicine into Australian healthcare. Clinical flagship projects in the areas of rare disease and cancer are recruiting approximately 5,000 research participants nationally for genomic sequencing. This provides real-world evidence on the diagnostic utility of genomic sequencing for specific health conditions. The evidence on diagnostic utility has greater impact when combined with cost-effectiveness analysis when compared to standard diagnostic investigations, and lifetime costs of living with an undiagnosed genetic condition. For these reasons we have sought access to de-identified Commonwealth MBS and PBS data, as well as Department of Health Hospital and Emergency datasets in each State and Territory, on our research participants. We therefore have recent experience with Commonwealth and jurisdictional policy and data access procedures for researchers requesting personal and sensitive health information. Further, we are currently developing our own data access policies and procedures to facilitate researcher access to data held within our genomic data repository and accompanying phenotypic data.

An initial observation was that the roundtable event was overrepresented by stakeholders from the health and medical research sector, which concentrated the discussion in that area. Furthermore, the unstructured approach to the discussion did not permit a thorough exploration of two of the key outstanding issues we identified in this discussion paper and proposed legislation - consent and commercial access to data. The purpose of our submission is to provide further comment particularly on points that were not fully discussed during the roundtable.

#### **Consent:**

- We agree that it would be difficult to gain retrospective consent for the use of historical data, and therefore understand the premise for exploring a similar waiver to the GDPR use of personal data for “research for the public benefit” clause. Noting, however, that the GDPR’s broad definition of research encompasses public and private research entities.
- The strategy for seeking prospective consent to data sharing was not clear from the discussion paper or roundtable event. Not having the “technology infrastructure” in place, as was cited as one reason for not obtaining consent during the roundtable, is not justifiable. The Australian Government should utilise its resources and expertise to develop an online, preferably dynamic, consent strategy.
- Will data potentially travel outside Australia? This was not explicitly mentioned, and if not, compliance with the GDPR, and citing GDPR as a source of guidance, is of less relevance.
- Waiving consent, particularly for prospective data sharing, poses a risk to public trust.
- Consent should be gained where possible, particularly where personal information is to be shared. Consent could be simple and delivered via an online platform, for example leveraging the existing myGov infrastructure. Although, this suggestion assumes that a high proportion of Australians access myGov periodically.
- Individual government agencies could alternatively seek consent with community members at the point of access of their service.
- We have assumed that personal information as defined by the Privacy act will only be available for data sharing (and not release). It would be beneficial to make this explicit in future legislation planning.
- We fully support the sharing of information for the purpose of streamlining service delivery, with consent. This raises the question of whether consent to data sharing for research and policy could

be gained in a similar way to that planned for obtaining consent for data sharing for the purpose of service provision.

- A person should be able to withdraw consent at any time, through an easy, transparent process. Consent should not be “opt-out”.
- The Australian My Health Record and UK Care.data experiences should be considered, to understand and respond to public perceptions of the use of their personal data.
- If the final decision is to not seek consent, the alternative recommendation is to develop an effective, well-timed public engagement and education campaign. There should be a clear strategy around establishing, maintaining and evaluating the social license, before data sharing begins. Again, lessons can be learned from the failed Care.data public engagement strategy.
- Involving people in research – a community group should be involved in the data access approval process.

#### **Commercial access:**

We are generally supportive of the proposed commercial access to government agency data. Sharing data with commercial companies can, within an adequate framework, enhance research and innovation as well as drive consumer competition which will directly and indirectly benefit the public. Competition between public research and commercial companies (as seen in the 90’s with the Human Genome Project) can greatly advance and accelerate sciences as well as technologies and benefit the public faster and better. Perhaps one of the challenges will be to educate the public on the benefits of commercial sector research.

Overall, research for the public benefit is a good and beneficial model. However, the proposed plan during the legislation table was not very clear on “how” this commercial access would or could happen. Will the data analyses be performed by a public department that will tailor each analyses to the commercial entity’s needs and present back the aggregated results only (similarly to the linked data access model in ICES Ontario)? Or will the data be shared with the commercial entity within a restricted computational environment? Will public department-led data sharing and analyses incur a fee?

Alternatively, a collaboration between the commercial entity and a public sector research institute could be made mandatory to be able to access public sector data. This has the potential to be a good model and generate good synergy between public and private research, but also has a risk of cultivating ingenuine partnerships and / or see the researchers publications restricted or censored by agreements from the commercial companies, which has the well-documented follow on effect on researchers’ ability to apply for and gain grant funding in the future.

#### **Terminology:**

- In contrast to group opinion on the day, we feel comfortable with the “Data Sharing and Release” description and recognise the differentiation between the terms.

#### **Reporting:**

- The planned annual reporting on the performance of Commonwealth agencies on managing data access requests is in our opinion not sufficient, and we would strongly recommend real-time, publicly accessible web-based tracking and reporting. This would ensure that issues are identified prior to prolonging access requests for a year or more, as well as having advantages like real-time benchmarking across agencies.
- Reporting should include: a brief data access application project summary, including specific research questions; which agency the requestor applied to; whether approval was granted; the turnaround time to access to the requested data, and outcomes, where available.

- If the plan is for agencies to manage data access requests and prepare the data themselves, the risk is this could lead to time delays (particularly if agencies are not being allocated additional resourcing to manage requests) and could further foster the culture of risk aversion. These potential risks could be avoided by establishing a central data repository model, as implemented in the UK.
- A similar reporting strategy should be mandated for State and Territory data linkage access requests, although we appreciate this comment is outside the scope of this legislation.

**The proposed data sharing and release framework:**

- Is the future aim to have a central data repository (similar to the open data UK model)? During the roundtable you mentioned each agency holding its own data. This could prove time consuming and decelerate the process, particularly in the case of required linkage between datasets. A further benefit of a central repository will be an increased skill concentration and capability, promoting a consistent and harmonised approach to data de-identification and privacy standards, and result in more robust data security processes.
- A semi-automated data access application system would also help with timely delivery of data access or datasets. In such a system, access permission codes would be attached to the datasets and access applications would be automatically matched to those codes. Data Access Committees would then be able to focus on reviewing the matched result of the system, hence fast tracking the entire process and see researchers accessing data within reasonable timeframe. Such a system would also reduce human bias and risk aversion in assessing data access requests.
- A standardised model should be developed for citing the use of public data in publications and other reports. One suggestion would be a similar model to the DOI publication citation system. This would encourage data sharing and further promote the potential research value of public datasets. Such a system would also provide transparency and accountability to the public on which agencies are sharing their datasets and with whom, as well as the outcomes of data sharing.
- What model will the technical access to data follow: download of datasets to be analysed on researcher's own computational systems or visitor access where the researcher applies their analyses scripts and programs to the data repository? The issue with data being downloaded is the lack of traceability, control and consequence enforceability in case the data is illegitimately on-shared. A short destroy date should be provided to avoid datasets being sitting idle or being on-shared erroneously.

**Public engagement:**

- As a final remark, with regards to your call for Australian research institutes and researchers engaging the public by showing the benefits of data sharing in use, Australian Genomics would, in principle, be happy to participate under the appropriate circumstances. To ensure success in gaining trust of the public, the researcher's advocacy for data sharing will need to be supported by a well-managed public education campaign. Gaining and retaining the public's trust will be key to the success of the Data Sharing and Release Act.