Australian Perspectives on the Ethical and Regulatory Considerations for Responsible Data Sharing in Response to the COVID-19 Pandemic

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Abstract

As the rush to understand and find solutions to the COVID-19 pandemic continues, it is timely to re-examine the legal, social and ethical drivers for sharing health-related data from individuals around the globe. International collaboration and data sharing will be essential to the research effort. This raises the question of whether the urgent imperative to find therapies and vaccines may justify some temporary rebalancing of existing ethical and regulatory standards. The Global Alliance for Genomic Health is playing a leading role in collecting information about national approaches to these challenging questions. In this article, we examine some of the initiatives being taken in Australia against this global backdrop.

1 Introduction

It goes without saying to the readership of the *Journal of Law and Medicine* that the COVID-19 pandemic is raising (and exacerbating) a host of ethical, legal and social issues (ELSI). Yet despite the obviousness of this statement, the mechanisms for deciding on appropriate responses are far from clear. Given the global reach of the pandemic, whatever strategies are developed must be similarly global in reach, but they must also give appropriate consideration of local conditions. Not least amongst the multitude of ELSI is the question of how to facilitate appropriate sharing of health-related data collected from individuals, in order to maximise the potential for rapid development of therapies and vaccines. In addition to data on hospitalisation, treatment, and other health records, genomic data is likely to be particularly pertinent to the research effort seeking to explore differential responses to the infection, and to the various treatment options and vaccines that are starting to be trialled.[1]

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[1] See, for example, P Brice, COVID-19 and individual risk: the role of genomics' (2020) *PHG Foundation,* at: https://www.phgfoundation.org/blog/COVID-19-and-individual-risk-the-role-of-genomics; M Broadfoot, 'DNA Could Hold Clues to Varying Severity of COVID-19' (2020) *The Scientist,* at: https://www.the-scientist.com/news-opinion/dna-could-hold-clues-to-varying-severity-of-covid-19-67435

The concept of data sharing is not a new one for many scientific disciplines.[2] In the context of genomic research, in particular, data sharing has been broadly embraced by researchers from the start of the Human Genome Project,[3] through to more recent times.[4] The need for engagement in open data sharing is likely to become more critical in the particular context of public health emergencies. This need is well articulated by the Wellcome Trust in its Statement on Data Sharing in Public Health Emergencies: 'In the context of a public health emergency of international concern, there is an imperative on all parties to make any information available that might have value in combatting the crisis.'[5] In relation to the COVID-19 outbreak, the Wellcome Trust has been forthright in its call for open data sharing: 'We call on researchers, journals and funders to ensure that research findings and data relevant to this outbreak are shared rapidly and openly to inform the public health response and help save lives.'[6]

Notwithstanding the clear benefits in ensuring that genomic and other health data are shared as openly as possible, particularly in the context of public health emergencies, there is a long history of debate associated with the ELSI that such sharing raises, particularly when it involves highly sensitive and potentially identifiable health or genomic information. It has been well recognised from the start of the genomics revolution that data sharing and other aspects of these 'big science' initiatives raise particular ELSI, demanding scrutiny of the adequacy of existing regulatory and ethical instruments, both nationally and internationally. Now, more than ever, the volume and variety of data that can be collected, stored, linked, shared and analysed is pushing the boundaries of available ethical and regulatory frameworks.

Policy makers, governments, funding agencies, research organisations and others all recognise the data sharing imperative, but also the need for appropriate and adequate ethical and regulatory responses. Such recognition was the genesis of the Global Alliance for Genomic Health (GA4GH) in 2013. The Australian Genomic Health Alliance mirrors the work of the GA4GH at the local Australian level.[7] Other research groups are focusing particular attention on the Australian ethical and regulatory requirements for data sharing, including our own Centre for Law and Genetics (CLG).

The COVID-19 public health emergency demands assessment of the adequacy and appropriateness of our current data sharing norms. As emphasized by the GA4GH executive: 'An effective and equitable response to the COVID-19 pandemic requires rapid and sustained international collaboration and data sharing.'[8] This, likewise, demands further consideration of the adequacy of existing ethical and regulatory standards, and the extent to which the urgent imperative to find therapies and vaccines may justify relaxation of some of these standards, should this be necessary. In response, the GA4GH Regulatory and Ethics Working Group has developed a perspective statement: *Responsible Data Sharing to Respond to the*

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[2] S Hilgartner, 'Biomolecular databases: New communication regimes for biology?' (1995) 17 *Science Communications* 240-263.

[3] J Sulston J and G Ferry, *The Common Thread*, London: Corgi Books; 2003 and Bermuda Principles, 1996

[4] Toronto International Data Release Workshop Authors, 'Prepublication data sharing' (2009) 461 *Nature* 168; D Chalmers, D Nicol and M Otlowski, 'To share or not to share is the question' (2014) 3 *Applied and Translational Genomics* 116-119.

[5] https://wellcome.ac.uk/press-release/statement-data-sharing-public-health-emergencies

[6] https://wellcome.ac.uk/coronavirus-covid-19/open-data

[7] https://www.australiangenomics.org.au

[8] https://mailchi.mp/ga4gh.org/june-2019-chair-letter-2678014?e

COVID-19 Pandemic: Ethical and Legal Considerations.[9] This is an iterative document, in version 2.0 at the time of writing. The CLG team provided feedback to the first version of the GA4GH statement, with particular focus on the Australian situation.

This feedback informs this article, the purpose of which is to provide a summary of the regulatory and ethical responses to the COVID-19 pandemic in Australia, and position these within the broader global data sharing movement. This article provides a brief background on the ELSI of globalised data sharing of genomic and related health data before considering key aspects of the ethical and regulatory environment within which responses to the challenges flowing from the COVID-19 pandemic are situated. We focus on privacy and data protection, regulation of medical devices, intellectual property issues, data sharing initiatives and public health and research ethics. We note that it is not yet possible to fully evaluate the adequacy of these responses in the national and global contexts. Recognising it is only with the passage of time that it will be possible to do so, it is important to keep a watching brief on these developments in the interim.

2 Regulatory and ethical challenges in a globalised data sharing environment

Rapid innovation in genomic and other health-related technologies has yielded an exponential growth in data. Widespread data sharing, including across national borders, is becoming an essential component of clinical and research practice.[10] There is evidence of this new wave of health-related data improving clinical care, with precision medicine offering targeted treatments tailored to the individual patient's genetic characteristics and medical history.[11]

In Australia, as in other countries, legal requirements (for example, privacy laws, intellectual property rights and data transfers executed through formal means), and quasi-legal requirements (for example, research ethics obligations), may potentially limit free and open data sharing. At the same time, these requirements may collectively provide the assurances necessary to protect donors, encourage research and innovation, and promote ongoing public trust in data sharing activities. A central question is whether the ELSI associated with the movement towards data sharing can be addressed within existing regulatory and governance frameworks or whether new regulatory responses are required.

A range of considerations must be taken into account in tackling these complex issues. Given that data is shared across borders, regulations must consider international dimensions and, where possible, strive for global harmonisation without weak links in the regulatory chain. Roger Brownsword has articulated four key themes around which these regulatory responses should be evaluated: community acceptance and legitimacy; operational effectiveness; connection to the inevitable changes in data sharing and in the science itself; and

[9] https://docs.google.com/document/d/1wK_NoNYXKy0ttTQ-ySHh3ZRpvPrLV4uPwV8FSq6BQ60/edit#heading=h.gjdgxs

[10] Chalmers et al, above n4.

[11] Green E et al, 'Charting a course for genomic medicine from base pairs to bedside' (2011) 470 *Nature* 204; Gagan J, Van Allen E, 'Next-generation sequencing to guide cancer therapy' (2015) 7 *Genome Medicine* 80

cosmopolitanism.[12] Rights, responsibilities and stewardship need to be reviewed in this fluid, changing and global environment.[13]

Whilst there are similarities in regulatory frameworks between jurisdictions, there are also some significant differences. For example, data protection and privacy laws may meet Brownsword's cosmopolitanism, but are not internationally uniform, nor are judicial attitudes to their interpretation. These challenges are compounded by the General Data Protection Directive (GDPR) in Europe which entered into force in May 2018. The extent to which GDPR obligations are imposed on Australian researchers and clinicians who share data with their counterparts in Europe remains an open question.

Self-regulation by researcher and research institutions is an option for achieving international harmonization, potentially avoiding some of the cross-border challenges that national laws pose for data sharing activities. As noted on the GA4GH website, it was established 'to realize the full potential of genetic and clinical data[sets] in research' and facilitate broader benefits from genomic big data by establishing a common international framework to facilitate data collection, management and sharing in an 'effective, responsible and interpretable manner'.

In 2014, the GA4GH published a *Framework for Responsible Sharing of Genomic and Health-Related Data*, containing core elements for participant-patient consent, legally and ethically compliant data access and governance and sanction mechanisms. The idea behind this common framework of harmonized approaches is that it will 'enable effective and responsible sharing of genomic and clinical data and … catalyze data sharing projects that drive and demonstrate the value of data sharing'.[14] Voluntary standards, such as those set out in the GA4GH Framework, can thus 'regulate' the platforms required for international collaborations in large-scale genomic research and policy development.[15]

Through its Regulatory and Ethics Workstream[16] and Regulatory and Ethics Toolkit,[17] the GA4GH is well placed to respond to public health emergencies requiring urgent action. The GA4GH has taken a lead in starting the discussion on the ethical and legal considerations in responsible data sharing in the context of the COVID-19 pandemic. In exploring these questions, the GA4GH's perspective statement identifies five key areas for analysis, which we synthesise into the following five questions. We examine the Australian responses to each of these issues in the next section:

- **Privacy and data protection.** Recognising that many jurisdictions allow processing of data for public health purposes, what conditions should be imposed on such uses, and when might these conditions be relaxed?

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[12] R Brownsword, 'Regulating human genetics: new dilemmas for a new millennium' (2004) 12 *Medical Law Review* 14-39.

[13] R Brownsword, 'Rights, responsibility and stewardship: beyond consent' in H Widdows and Mullen, *The Governance of Genetic Information: Who Decides?* (Cambridge University Press; 2009) pp99-125.

[14] https://www.ga4gh.org/genomic-data-toolkit/regulatory-ethics-toolkit/framework-for-responsible-sharing-of-genomic-and-health-related-data/

[15] G Yoshizawa, et al, 'ELSI practices in genomic research in East Asia: implications for research collaboration and public participation' (2014) 6 *Genome Medicine* 39

[16] https://www.ga4gh.org/how-we-work/workstreams/

[17] https://www.ga4gh.org/genomic-data-toolkit/regulatory-ethics-toolkit/

- **Intellectual property.** What measures may be taken to ensure intellectual property does not unduly restrict the development of treatments and vaccines, while still providing the incentive to innovate?
- **Medical devices.** How can approval of medical devices for therapeutic use be expedited, whilst ensuring safety and efficacy?
- **Data sharing.** What are the appropriate limits on sharing, and what should governments be asking of their citizens?
- **Ethics.** How is justice, the bedrock of public health ethics, maintained, and how is timely, but thorough review of research ethics assured in circumstances of extreme urgency?

3 Regulatory and ethical frameworks in the context of COVID-19 – Australian responses

Australia, like the USA and a number of other countries, is a federation, and has a health-care system with a mix of state and territory-based and national providers, as well as a mix of public and private providers. There has been a concerted national response to this pandemic, with the closure of borders at the national as well as state and territory levels, quarantine measures, carrier contact tracing and social distancing requirements. This national response has extended to integrated health-care responses to emergency services, hospital care and testing, principally in the public sector. Importantly, research and the search for a vaccine is situated within this national response, and linked with international research.

3.1 Privacy and data protection

State and national privacy laws are some of the most pressing legal barriers to widespread data sharing. Privacy concerns are inevitably raised whenever personal health data is accessed and used for secondary purposes, especially where this traverses different regulatory frameworks, with potential flow-on effects for public trust.[18] Privacy and security issues are especially acute in the context of genomic data, given its unique qualities: ubiquitous, permanent and unalterable, and potentially re-identifiable even when de-identified.[19] Genomic data tests the distinctions between personal and non-personal information, which could potentially lead to unnecessary restrictions for clinical practice and medical research and consequent impact on patient care.

There are fundamental tensions between individualistic conceptions of personal privacy and relational views of information sharing,[20] creating a schism between researchers and technology companies who may argue for 'free' data-sharing for the benefits of science and medicine, and privacy advocates fearing misuse of personal information and discrimination.[21] Ultimately, privacy is not individualistic but contextual and relational, and ideas of public

[18] B Knoppers B and R Chadwick, 'Human genetic research: Emerging trends in ethics' (2005) 6 *Nature Reviews Genetics* 75-79; D Chalmers and D Nicol, 'Commercialisation of biotechnology: Public trust and research' (2004) 6 *International Journal of Biotechnology* 116-133.

[19] O Tene and J Polonetsky, 'Privacy in the age of big data: A time for big decisions' (2012) 64 *Stanford Law Review Online* 63-69; M Otlowski and D Nicol, 'The Regulatory Framework for the Protection of Genetic Privacy in Australia' in TS Kaan and CW Ho, *Genetic Privacy: An Evaluation of the Ethical and Legal Landscape* (2013) pp283-322.

[20] G Laurie, 'Managing access to biobanks: How can we reconcile privacy and public interests in genetic research?' (2010) 10 *Medical Law International* 315-337.

[21] CF Wright, ME Hurles and HV Firth, 'Principle of proportionality in genomic data sharing' (2016) 17 *Nature Reviews Genetics* 1-2.

good, as well as personal good, must be considered.[22] The core challenge is to balance privacy interests with society's legitimate interest in benefiting from scientific advances.

This privacy challenge warrants detailed reevaluation in the context of public health emergencies, where the immediate need for granular data tests traditional tools for privacy protection, such as notice, consent and de-identification. As with many other countries, Australia is actively participating in the global response to the current emergency, within the context of its own ethical, legal and regulatory environment. The Australian Information Commissioner is a member of the Executive Committee of the Global Privacy Assembly, which has issued a statement expressing their confidence that 'data protection requirements will not stop the critical sharing of information to support efforts to tackle this global pandemic'.[23]

Also, bearing in mind Australia's mix of federal and state and territory privacy laws, all privacy regulators have collectively formed a National COVID-19 Privacy Team.[24] As noted in the Australian privacy regulators' response to COVID-19, Australian privacy laws allow the use of personal information in circumstances such as these, provided that the use is reasonably necessary and the information is protected from inappropriate disclosure.[25] It should further be noted, however, that where the intended use is for the purpose of health research and it is impracticable to obtain individual consent, not only must the information be protected from inappropriate disclosure, but the use must be approved by a Human Research Ethics Committee. This provides an added layer of protection for research participants and patients where rapid responses are necessary, while still allowing research in the public interest to proceed.

3.2 Intellectual property

Institutional and individual researcher engagement in data sharing may create legal barriers to widespread dissemination. Although open access to research data is broadly accepted as an underlying norm of science, it can be in tension with national and institutional policies directed towards engagement with industry and protection of intellectual property.

Australia has provisions in its *Patents Act 1990* (Cth) allowing use of patented subject matter without the authorisation of the patent holder. There are two ways that this can be achieved. The first is through compulsory licensing, which requires application by the proposed compulsory licensee to the Federal Court of Australia. Such applicants are exceptionally rare. The second is the long-standing provision for the Australian government to step in and rely on 'Crown use' to use patented technology 'for the services of the state', or to licence other providers to do the same. Again, this provision is rarely utilised, though it remains available should the need arise.

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[22] J Wilbanks, 'Portable approaches to informed consent and open data' in J Lane et al (eds), *Privacy, Big Data and the Pubic Good* (Cambridge University Press; 2014) pp234-252; Laurie, above n20.

[23] https://globalprivacyassembly.org/gpaexco-covid19/

[24] https://www.oaic.gov.au/updates/news-and-media/covid-19-response-from-australian-privacy-regulators/

[25] For instance, section 16B of the *Privacy Act 1988* (Cth) allows relaxation of some of the information handling requirements specified in Australian Privacy Principles 3 and 6 for 'permitted health situations', which include the collection of information for research and other purposes (section 16B(2)). As noted in paragraph D.10 of the Australian Privacy Principle Guidelines, 'This permitted health situation applies when an organisation is collecting health information about an individual, if the collection is necessary for research relevant to public health or public safety.' https://www.oaic.gov.au/privacy/australian-privacy-principles-guidelines/chapter-d-permitted-health-situations/

Notably, in February 2020, this Crown use provision was significantly amended, and now explicitly includes a provision allowing Crown exploitation in emergencies.[26] The trigger for Crown exploitation in emergencies is that the relevant Minister considers that the exploitation is required, and approves in writing, the exploitation before the exploitation starts. Unlike the general Crown exploitation provisions, previous attempts at negotiating a licence with the patent holder are not required, although just and reasonable remuneration is necessary. Although this amendment to Australian patent law was not triggered by the COVID-19 emergency, it certainly provides a clearer route to use without authorisation of the patent holder, should this be necessary. It aligns with provisions in many other jurisdictions.

The governments of other countries have actively endorsed reliance on equivalent provisions in their patent legislation. These include Germany, Israel, Chile and Canada.[27] Notably, Canada has enacted legislation to give specific effect to its compulsory licensing provisions in the context of COVID-19. Part 12 of the *COVID-19 Emergency Response Act 2020* requires that 'the Commissioner of Patents, on the application of the Minister of Health, authorize the Government of Canada and any person specified in the application to make, construct, use and sell a patented invention to the extent necessary to respond to a public health emergency that is a matter of national concern'. One risk here, however, is that if the patent incentive is curtailed to too great an extent, product developers may choose to rely on trade secrecy.

An alternative is to rely on the goodwill of patent holders to voluntarily engage in open licensing of their intellectual property rights, either for the purpose of fulfilling their commitment to corporate social responsibility, or for political expediency, or perhaps more likely, a combination of both. The WHO has been proactive in this area, including its endorsement of a proposal by the Costa Rican government to establish a voluntary patent pool.[28] Separately, the newly formed Open COVID Coalition is calling for widespread commitment to its Open COVID pledge: 'to make our intellectual property available free of charge for use in ending the COVID-19 pandemic and minimizing the impact of the disease.'[29] The pledge is accompanied by an Open COVID licence. To date there appears to be no Australian involvement in either initiative, although one commentator has expressed some scepticism, querying the breadth of the COVID licence.[30]

3.3 Medical devices

In Australia, the relevant body for approving the therapeutic use of medical devices is the Therapeutic Goods Administration (TGA). The *Therapeutic Goods Act 1989* (Cth) required that any product for which therapeutic claims are made must be entered in the Australian Register of Therapeutic Goods (ARTG) before the product can be supplied in Australia. The ARTG is a

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[26] *Intellectual Property Laws Amendment (Productivity Commission Response Part 2 and Other Measures) Act 2020* (Cth).

[27] S Madar, et al, 'Patent rights during COVID-19 – can the Government step in?', 3 April 2020, at https://www.kwm.com/en/au/knowledge/insights/patent-rights-during-covid-19-can-the-government-step-in-20200403

[28] E Silverman, 'WHO director-general endorses a voluntary intellectual property pool to develop Covid-19 products' (2020) *Stat News:* https://www.statnews.com/pharmalot/2020/04/06/covid19-coronavirus-patents-voluntary-pool-world-health/

[29] https://opencovidpledge.org

[30] R De Boos, 'An Australian perspective on the "Open COVID Pledge" and the availability of compulsory licences under the Australian Patents Act' (2020) *Davies Collison and Cave:* https://dcc.com/patents/an-australian-perspective-on-the-open-covid-pledge-and-the-availability-of-compulsory-licences-under-the-australian-patents-act/

computer database of information about therapeutic goods for human use approved for supply in, or exported from, Australia. The *Therapeutic Goods Act 1989* (Cth) and subordinate regulations, orders and specifications set out the requirements for inclusion of therapeutic goods in the ARTG, including advertising, labelling, product appearance and appeal guidelines. Medical devices are included in this regulatory regime, and the *Therapeutic Goods (Medical Devices) Regulations 2002* (Cth) provides detailed procedural requirements for their registration. There are four classes of devices, from class 1 (for such devices as surgical retractors and tongue depressors) to higher classes for heart valves, hip replacements, defibrillators and the like. A conformity assessment procedure ensures that devices conform to requirements for that class. Higher classes require a higher level of conformity.

Diagnostic tests are included in the medical devices regime as in vitro devices (IVDs), which are separated into three categories: 'IVD medical devices', 'in-house IVD medical devices' and 'IVD medical devices for self-testing'. The IVD medical device category is most relevant in the context of COVID-19, since it covers IVDs manufactured in Australia or manufactured elsewhere and imported into Australia. In light of the massive increase in demand for COVID-19 diagnostic tests, the TGA has to date created two processes to facilitate the supply COVID-19 tests (recognising that further changes may be made in the future):[31]

(a) expedited assessment of tests for inclusion on the Australian Register of Therapeutic Goods (ARTG). Once approved for inclusion on the ARTG, the COVID-19 test can be legally supplied in Australia; and

(b) an emergency exemption to allow immediate supply of COVID-19 diagnostic tests to accredited pathology laboratories.[32]

These steps are similar to those taken in other jurisdictions, and have assisted in ensuring that Australia's response to testing in the COVID-19 landscape has conformed with best practice.

3.4 Data sharing

A significant aspect of international responses to this pandemic, as to all pandemics, is the process of carrier contact tracing, which inevitably raises privacy concerns. The introduction of the national 'COVIDSafe app' designed to automate contact tracing for people exposed to coronavirus has been generally supported, but not without reservations. This app uses Bluetooth technology to detect and alert people who have come into contact with someone infected with the virus. In response to concerns about privacy breaches, it was announced early, while the app was still under development, that adoption of the app would be voluntary but strongly encouraged as an important measure to facilitate easing of restrictions.

At the time of writing, over 5 million Australians had downloaded the COVIDSafe app. To enhance public confidence in the app, the federal government has augmented existing privacy protection in the *Privacy Act 1988* (Cth) (including that use of data must be confined to the purpose for which it was collected) by introducing legislation to govern the use of data collected via the COVIDSafe app.[33] The *Privacy Amendment (Public Health Contact Information) Act 2020* (Cth) creates a number of offences punishable by imprisonment

[31] https://www.tga.gov.au/legal-supply-covid-19-test-kits
[32] https://www.legislation.gov.au/Details/F2020N00032
[33] *Privacy Amendment (Public Health Contact Information) Act 2020* (Cth) (passed by both Houses 14 May 2020 and received assent on 15 May 2020).

including for any person collecting, using, or disclosing COVID app data other than in accordance with the legislation as well as any person decrypting COVID app data.

Australia's tracing response to the COVID-19 pandemic is mirrored by actions taken in Singapore and South Korea. South Korea's success in containing COVID-19 pandemic without imposing a lockdown has been largely attributed to their extensive tracing as well as surveillance of its citizens. Interventions by government focused on addressing the pandemic have raised questions about the long term effects of such measures which involve unprecedented use by governments and health care bodies of sensitive patient data.[34] Concerns about privacy are real but are currently being overtaken by the widespread desire to save lives and end lockdowns.

These developments have highlighted the vital role of community and public trust, particularly trust in government and public health authorities during a pandemic. This trust will be tested when the pandemic is under control. It is in this context that the new Australian legislation provides for the deletion of all COVID app data from the National COVIDSafe Data Store after the official end of the pandemic.[35] This provision provides that the personal data will be deleted and no longer shared.

3.5 Public health and research ethics

3.5.1 Public health policy and public health ethics

Although there has not yet been a specific response to the drive towards greater data sharing in the context of public health policy and public health ethics, this issue is integral to broader public health policy and public health ethics debates. The public health response to COVID-19 in Australia has been marked by strong collaboration and co-ordination between federal and state and territory governments. In February 2020, an *Australian Health Sector Emergency Response Plan for Novel Coronavirus (Covid-19)* was released to guide the Australian health sector response.[36] The federal Department of Health has issued a series of national guidelines,[37] which have been developed in consultation with the Communicable Diseases Network Australia and endorsed by the Australian Health Protection Principal Committee. Their purpose is to provide nationally consistent advice and guidance to public health units in responding to a notifiable disease event.

The guidelines include recommendations for surveillance, infection control, laboratory testing and contact management for COVID-19. The federal government has also developed a range of resources for health professionals, including aged care providers, pathology providers and health care managers, about coronavirus (COVID-19).[38] These initiatives have been accompanied by stringent restrictions on business activity, quarantine and social distancing requirements, and mobility restrictions, including border closures and curtailing free movement within jurisdictions - all potentially raising legal and ethical issues. Whilst

[34] D Cox, 'Alarm bells ring for patient data and privacy in the covid-19 goldrush' (2020) 369 *British Medical Journal* m1925 doi: 10.1136/bmj.m1925

[35] See: Australian Government, 'Privacy policy for COVIDSafe app (2020) https://www.health.gov.au/using-our-websites/privacy/privacy-policy-for-covidsafe-app

[36] https://www.health.gov.au/resources/publications/australian-health-sector-emergency-response-plan-for-novel-coronavirus-covid-19

[37] https://www1.health.gov.au/internet/main/publishing.nsf/Content/cdna-song-novel-coronavirus.htm

[38] https://www.health.gov.au/resources/collections/coronavirus-covid-19-resources-for-health-professionals-including-aged-care-providers-pathology-providers-and-health-care-managers

governments clearly have a responsibility to adopt preventive measures to protect the population from exposure to COVID-19 there is potential for tension between the priority of protecting public health and ensuring respect for human rights.[39]

Various international agencies have called for a transparent and measured approach in national responses to ensure minimisation of the inevitable impacts on the rights and freedoms of individuals.[40] Although 'unprecedented' in the nature and scale of interference with public and private activity, including an enormous impact on the economy and significant social impacts, there has been strong community compliance with these measures contributing to Australia's efforts to 'flatten the curve' of infections. The issue of community compliance with crisis directives, including mobility restrictions and social distancing requirements, has been a major concern in the public, political and expert debates on the effectiveness of national responses as measures to counter COVID-19 can only be effective if target populations follow instructions and abide by rules. In contrast to other jurisdictions, such as the USA and Germany, there has been relatively little organised opposition to these measures. Particularly taking into account the federated nature of Australia and the potential for division and tension between jurisdictions, the collaborative governmental approach with the creation of a National Cabinet (including state and territory leaders) to spearhead the Australian response, appears to have been relatively successful as a public policy exercise.

3.5.2 Research ethics

Regulation of data sharing activities is inextricably intertwined with research ethics codes and practices governing the conduct of research in Australia and overseas. Approval from human research ethics committees (HRECs) provides a means of ensuring that research is only conducted where it has met threshold standards of acceptability, and is a legal requirement for any waiver of consent for the use of personal health information held by Australian Government agencies or private organisations for research. However, review processes also can impose considerable barriers. Multi-centre research requires approval from multiple HRECs, often operating in different countries with somewhat different review requirements. Although HRECs tend to follow similar procedures, this does not necessarily mean that they make consistent decisions, even when reviewing the same project based on the same criteria.[41] This could slow the approval process for urgently needed research.

The human research ethics system in Australia is administered by the National Health and Medical Research Council (NHMRC). The NHMRC has reminded us:

> Compliance with or adherence to regulations, guidelines, codes, policies and other standards remains necessary. However, interpretation of research responsibilities in the context of a crisis such as COVID-19 should be informed by flexibility, consultation and good sense so as to retain the focus on the safety and well-being of those most at risk in our institutions and communities.[42]

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[39] JC Thomas, 'Ethics in a pandemic: a survey of the State Pandemic Influenza Plans' (2007) 97 *American Journal of Public Health* S26–S31.

[40] Amnesty International COVI-19: How human rights can help to protect us 20 March 2020.

[41] AL Johns, et al, 'The Path to Reducing Duplication of Human Research Ethics Review in Australia' (2017) 36 *Medicine and Law* 7-24.

[42] NHMRC, 'COVID-19: Guidance on clinical trials for institutions, HRECs, researchers and sponsors' (2019), https://www.nhmrc.gov.au/sites/default/files/documents/attachments/ctprg-statement-clinical-trials-covid.pdf

There may be some advantage in streamlining the ethics review process, both immediately in response to the COVID-19 emergency, and in the longer term to facilitate research—a process already commenced in Australia through the National Mutual Acceptance Scheme. However, this should not in any way suggest that reviews should be less robust than reviews conducted in non-pandemic times - rapid response need not mean lighter touch. As the executive of the GA4GH have pointed out in an open letter: '… in order to ensure truly equitable access to and participation in both the scientific process and its benefits, we must rigorously maintain technical and ethical standards that support the open sharing of data and knowledge—now and always.'[43]

Conclusion

This is a brief overview of some of the more significant current developments in Australia designed to respond to the COVID-19 pandemic in ways that facilitate research and encourage open data sharing, while protecting patients, research participants and the community at large.

As alluded to earlier in this article, public trust is vital in public responses to pandemics. Pre pandemic research, including our own, suggests that Australians are wary of sharing their genomic information yet realise the significant benefits that could arise.[44] Concerns around privacy, equity in relation to access of developed treatments, lack of control over the future use of information and profiteering from altruistic donations are common concerns that are juxtaposed with a desire to help others and contribute to scientific knowledge.

Preliminary results from the latest Swinburne National Technology and Society Monitor (SNTSM) in Australia suggest the tension between concern and the desire to help have been attenuated by the pandemic.[45] The survey of 978 members of the Australian public undertaken at the height of the pandemic (in April 2020) suggests that people are significantly more likely to accept an easing of restrictions on sharing medical information with both private and public research organisations during, compared to after the pandemic. Acceptance was also equally high both during and after the pandemic for strategies aimed at ensuring that patents do not interfere with vaccine development, and that if a vaccine is developed it is freely available to all. This survey, together with our earlier work, illustrates the high level of public support for the research effort aimed at finding solutions to otherwise intractable healthcare problems. It also illustrates that, during public health emergencies, people are prepared to accept some relaxation of privacy and other protections, but that this

[43] https://mailchi.mp/ga4gh.org/june-2019-chair-letter-2678014?e

[44] See, for example, D Nicol and C Critchley, 'Benefit Sharing and Biobanking in Australia' (2012) 21 *Public Understanding of Science* 534-555; C Critchley, D Nicol and M Otlowski, 'The Impact of Commercialisation and Genetic Data Sharing Arrangements on Public Trust and Intention to Participate In Biobank Research' (2015) 18 *Public Health Genomics* 160-172; D Nicol, C Critchley, R McWhirter and T Whitton, 'Understanding Public Reactions to Commercialization of Biobanks and Use of Biobank Resources' (2016) 162 *Social Science and Medicine* 79-87; C Critchley, D Nicol and R McWhirter, 'Identifying Public Expectations of Genetic Biobanks' (2017) 26 *Public Understanding of Science* 671-687.

[45] The SNTSM is an annual survey of the attitudes of Australians towards new technological developments. The report on the 2015 Monitor can be found here: https://apo.org.au/sites/default/files/resource-files/2016-12/apo-nid119121.pdf. The full dataset from the current Monitor is yet to be published. Preliminary results for the COVID-19 component of the Monitor are available from Christine Critchley on request, ccritchley@swin.edu.au.

is conditional on a range of factors. In particular, once the immediate emergency is over, these relaxations will need to be revisited.

It is widely acknowledged that the post COVID-19 world will not be the same as pre COVID-19. We should therefore consciously be planning, through enhanced collaborative efforts, to take the best of the lessons learned and the new approaches developed during this time to inform our practices for the future. We should also have strategies in place to ensure that community voices are heard in our planning for the future. In the time of COVID-19, and pandemics generally, we should be equally committed to our ethical values and protective of civil liberties to ensure that all restrictions on those values and liberties are justified, reviewable and temporary.