National Health (Privacy) Rules 2018 Review: Submission by Dr Craig Willers

Background

I am an experienced health and medical research consultant and currently National Director of the Australian Arthritis and Autoimmune Biobank Collaborative (A3BC), a ground-breaking national registry-biobank network that has wide support from clinicians, researchers and patients across Australia, with over 70 investigators. I have been passionately involved in research for over 20 years now. I have worked in projects across most Australian states, including various consultant and staff roles in university, government, hospital, biotech and charity. Most of these have been leadership roles as Project Manager or Principal Consultant regarding biobanking, informatics and business case/strategy consultancies.

Of note, I guided the primary development of biobank collections for the 45 & Up Study (Sax Institute, Cancer Council NSW) as Project Lead, and the foundations of the current NSW Health biobanking and bioinformatics strategy as Principal Policy Officer for the NSW Office for Health and Medical Research. Both activities are now well developed. I am Chair of the Kolling Institute's Data and Informatics Research Enabler Committee, which is developing innovative approaches to strengthen expertise and build capacity in bioinformatics, health informatics/ economics, statistics and AI.

In my current work, a key benefit to Australian health and medical research within the A3BC's design is the scale and scope of its data collection and linkages. As such, optimisation of the processes and regulations governing access to identifiable health information is critical to the success of the A3BC and similar initiatives in best using this data to efficiently and effectively improve the health and healthcare of all Australians.

The core aims of the A3BC are to:

- Establish a national, open-access, best-practice biobank network to collect, process and store a range of biospecimens (blood, tissue, stool etc) for enabling research;
- Combine biospecimen data with linked national data, including patient-reported outcomes, medical records, Commonwealth health and cancer/death registries;
- Apply cutting-edge analytics to these combined datasets to search for potential associations/ patterns that are significant to patient and/or population health; and
- Work with doctors, government and industry to translate data and discoveries into new decision-making practices and policies for preventing and predicting disease.

Context to Suggestions

I would like to thank the OAIC for the opportunity to comment on the *Consultation Paper: National Health (Privacy) Rules 2018 review*. My key interest is regarding the use of identifiable Services Australia (SA, previously Department of Human Services) claims information for health and medical research (mainly Question 25 of the review, below).

I have experienced, and am aware of others experiencing, significant hold-ups having best practice and Human Research Ethics Committee (HREC)-approved consent forms/materials approved for use by SA. The forms are critical to enable efficient access to MBS/PBS/AIR data, without having to re-consent participants with more forms in the future (when approved).

I have also experienced instances where it appears SA have interpretated the content required to be disclosed to research participants as part of their consent. Additional requirements seem unnecessary and different to those requested by the NHMRC and approved by NHMRC-approved HRECs.

Given the core business and priority demands of SA, especially appreciating their COVID-19 workload, it would likely be the best use of resources for all parties, if consent matters regarding MBS/PBS/AIR linkage were managed by state-based NHMRC-approved HRECs that participate in the National Mutual Acceptance (NMA) scheme.

Suggestions

12 Disclosure of identifiable claims information for medical research purposes

(1) Claims information that identifies an individual may only be disclosed for medical research if:

(a) the Department of Human Services is satisfied that the individual to whom the information relates has given their informed consent to the use of that information in the research project; or

(b) the disclosure is made for the purposes of medical research to be conducted in accordance with guidelines issued by the National Health and Medical Research Council under section 95 of the Privacy Act 1988.

(2) Before disclosing claims information undersection 12(1), the Department of Human Services must obtain a written undertaking from the researcher that the claims information will be securely destroyed at the conclusion of the research project.

Of note, Rule 12 (1) (a) indicates that the SA must be satisfied that the individual has given their informed consent. I suggest that the NHMRC-approved HRECs are the most suitable and resource-efficient authority to govern the nature of disclosure required given the high standard of rigour applied through NHMRC Certification and the efficient ratification of this through the NMA scheme – for multi-site research. The HRECs could manage this during their regular sessions or within special sessions dedicated to research needing access to SA data. If SA do not agree with using NHMRC HRECs in this manner and/or have notably different Patient Information Sheet and Consent Form (PISCF) requirements, these PISCFs should be made publicly available and associated process be guided by clear policy directives and guidelines to save all parties time and possible confusion.

It is my experience that NHMRC HRECs have fit-for-purpose experience and member representation to safely manage this SA disclosure, and in doing so, fulfil all community expectations and Commonwealth agency requirements in ensuring compliance with Rule 12 (1) (a) of the National Health (Privacy) Rules 2018.

<u>As such, I would advise that Rule 12 (1) (a) be changed to the following:</u>

(a) <u>the Department of Human Services is satisfied that there is appropriate (NHMRC-approved) Human Research Ethics Committee approval of the informed consent to use claims information in the research project;</u>

<u>I note that HRECs are empowered to approve Rule 12 (1)(b) relating to Waiver of Consent under s95 of the Privacy Act and SA should not add additional requirements to this.</u>

With respect to Rule 12 (2), SA should be aware that cohort studies, clinical trials and other studies are obligated to retain data for a defined duration as described by the NHMRC or Therapeutic Goods Administration Act. As with the A3BC, the conclusion of a research project may be more than 20 years in some instances.

As such I would advise that Rule 12 (2) is changed to the following:

> (2) Before disclosing claims information undersection 12(1), the Department of Human Services must obtain a written undertaking from the researcher that the claims information will be securely destroyed at the conclusion of the research project…or as required by other regulatory requirements."

I would like to thank you again for the opportunity to comment *Consultation Paper: National Health (Privacy) Rules 2018 review*.