



Director, Privacy Act Review
Attorney-General's Department
Via email: privacyactreview@ag.gov.au

Dear Director

NHMRC Submission: Privacy Act Review Discussion Paper

Thank you for the opportunity to provide a submission to the Discussion Paper released as part of the Attorney-General's Department's review of the *Privacy Act 1988* (the Privacy Act).

The National Health and Medical Research Council (NHMRC) is the Government's lead agency for funding health and medical research. NHMRC invests in the creation of new knowledge about the origins, prevention and treatment of disease and the promotion of health and wellbeing. Through clinical, public health and environmental health guidelines and other pathways, NHMRC supports the translation of research into health practice and policy. By providing guidance on responsible research practices and ethical issues, NHMRC fosters the highest standards of ethics and integrity in the conduct of research and the delivery of health care.

Governed by the *National Health and Medical Research Council Act 1992* (NHMRC Act), NHMRC's functions are to pursue activities designed to:

- raise the standard of individual and public health throughout Australia
- foster the development of consistent health standards between the various States and Territories
- foster medical research and training and public health research and training throughout Australia
- foster consideration of ethical issues relating to health.

NHMRC collects, holds, uses and discloses personal information to carry out these functions or activities. NHMRC also collects, holds, uses and discloses personal information to carry out its other responsibilities, including those under the:

- *Medical Research Future Fund Act 2015*
- *Research Involving Human Embryos Act 2002* (RIHE Act)
- *Prohibition of Human Cloning for Reproduction Act 2002* (PHCR Act)
- *Public Governance, Performance and Accountability Act 2013* (PGPA Act)
- *Freedom of Information Act 1982* (FOI Act)
- *Therapeutic Goods Act 1989*, in relation to the registration of Human Research Ethics Committees (HRECs).

NHMRC supports the Government's aims in conducting the review of the *Privacy Act 1988* (Privacy Act) to ensure privacy settings empower consumers, protect their data and best serve the Australian economy. At the same time, we wish to ensure any legislative amendments do not result in placing unintended constraints on health and medical research.

Below are comments against the proposals of most relevance to NHMRC. NHMRC consents to this submission being published on the AGD website.

Proposal 2 – Broaden the definition of personal information

NHMRC is responsible for the development and publication of the [National Statement on the Ethical Conduct of Research](#) (National Statement), which is intended for:

- any researcher conducting research with human participants
- any member of an ethics review body reviewing that research
- those involved in research governance
- potential research participants.

The National Statement requires researchers, and ethics review bodies (including Human Research Ethics Committees) approving research, to ensure that the collection, use and management of data and information is in accordance with four core ethical values: *Research Merit and Integrity, Justice, Beneficence and Respect*.¹ NHMRC does not fund research that has not obtained the required ethics approval.

The National Statement makes specific reference to the *Australian Privacy Principles Guidelines*, particularly in the context of consent and the handling of personal information. The definition of ‘personal information’ included in the National Statement reflects the current Privacy Act definition. Any expansion of the definition may have implications for research, particularly where personal information was collected and managed under the current definition. Should the definition be expanded, we ask that explicit provision be made where personal information has been collected for health and medical research purposes based on the current definition – for example, transitional provisions which provide for a grace period to ensure that the research sector, including ethics review bodies, can integrate any new definition into their research proposals, protocols and review processes.

In this context, we note that certain documents, such as the National Statement and Guidelines published under sections 95, 95A and 95AA of the Privacy Act, include references to the definition of ‘personal information’ and will require updating to ensure alignment with any legislative amendments (see below).

We note the proposals in the Discussion Paper relating to the anonymisation of personal information rather than de-identification. We understand that as anonymisation is irreversible, it will require new IT solutions and look forward to any whole of government approach to resourcing. In addition, we propose that more in-depth consideration be given to the unforeseen consequences this proposal would have on health and medical research, as identified by respondents to the Issues Paper. We assume that personal information can continue to be de-identified and will therefore continue to fall outside the Privacy Act.

Proposal 8 – Notice of collection of personal information

NHMRC strongly supports the proposals concerning APP5 collection notices, particularly the recommendation that they be drafted in a more easily understood form, and that consideration be given to the development of standardised privacy notices, to be tested with consumers/stakeholders.

Proposal 9 – Consent to the collection, use and disclosure of personal information

We also note the proposed change to the fundamental definition of ‘consent’ by removing implied consent, and requiring positive action by the person consenting. In our view, this does not recognise the objective and pragmatic approach taken over the years by the government sector and the real possibility of ‘consent fatigue’. In addition, any requirement for a periodic refresh of consent would in our view be disproportionately burdensome on agencies, and potentially intrusive for the affected individual. The need for this should be outweighed by agencies having processes in place to deal with personal information no longer required for the performance of their respective functions and activities.

¹ National Statement on Ethical Conduct in Human Research 2007 (Updated 2018). The National Health and Medical Research Council, the Australian Research Council and Universities Australia. Commonwealth of Australia, Canberra (p.10)

Proposal 15 - Right to erasure of personal information

NHMRC understands and supports the right to erasure of personal information under certain circumstances and agrees with those responses to the Issues Paper that highlight that exceptions will be necessary. The National Statement provides guidelines around consent for the purposes of research involving humans. The guiding principle for researchers is that 'a person's decision to participate in research is to be voluntary and based on sufficient information and adequate understanding of both the proposed research and the implications of participation in it'.² Participants may withdraw from the research at any point. However, there is a point at which research has been conducted and the results finalised where the erasure of a person's data would be difficult, if not impossible, and could undermine the integrity of the research and its findings. For this reason, any right to erasure must be conditional, rather than absolute, and the relevant conditions should be specified.

Guidelines issued under sections 95, 95A and 95AA of the Privacy Act

There are three sets of Guidelines issued by NHMRC under sections 95, 95A and 95AA of the Privacy Act:

- *Guidelines under section 95 of the Privacy Act 1988*
- *Guidelines approved under section 95A of the Privacy Act 1988*
- *Use and disclosure of genetic information to a patient's genetic relatives under Section 95AA of the Privacy Act 1988 (Cth) Guidelines for health practitioners in the private sector.*

These guidelines are likely to require review if amendments are made to the Privacy Act. While NHMRC developed and issued these Guidelines (last reviewed in 2014), under the Act the Information Commissioner (OAIC) is the approver. NHMRC is also required to report annually to the OAIC about all three Guidelines³. With the proposed strengthening and broadening of the Office of the Australian Information Commissioner, it may be timely to consider developing one set of Research Guidelines regulating the collection, use and disclosure of health information in the conduct of research, to be issued by the Information Commissioner, as originally proposed by the Australian Law Reform Commission in 2010.⁴ This would facilitate understanding, consistency and compliance across the research sector, reduce the reporting loop and permit the Information Commissioner to have more effective oversight over research approved under the Guidelines.

These Guidelines should be developed with engagement from the research sector and should be drafted to align with the National Statement. NHMRC would welcome the opportunity to be involved in any guideline development or re-drafting.

NHMRC also supports any proposed extension of the application of the section 95 and 95A guidelines to all human research.

Proposal 22 - Overseas data flows

NHMRC supports the proposed amendment to prescribe countries and certification schemes under APP 8.2(a) and the provision of standard contractual clauses being made available to APP entities to facilitate overseas disclosures of personal information.

Agency level considerations

NHMRC is a small agency, with a direct stakeholder base consisting primarily of health and medical researchers and providers and the associated academic sector. We recognise that our staff and stakeholders value their privacy and, guided by our Privacy Policy, we seek to ensure that documents held by NHMRC containing personal information are handled in accordance with the standards set by the Privacy Act and the *Australian Government Agencies Privacy Code*.

² *Ibid.* (p.16)

³ NHMRC has always absorbed the resource impact of guidelines development and reporting activities.

⁴ [For Your Information: Australian Privacy Law And Practice \(ALRC Report 108\) \(2010\) / 65. Research: Recommendations For Reform / Section 95 And 95A Guidelines.](https://www.alrc.gov.au/publication/for-your-information-australian-privacy-law-and-practice-alrc-report-108/65-research-recommendations-for-reform/section-95-and-95a-guidelines-2/) (<https://www.alrc.gov.au/publication/for-your-information-australian-privacy-law-and-practice-alrc-report-108/65-research-recommendations-for-reform/section-95-and-95a-guidelines-2/>)

From an administrative perspective, as a small agency subject to the *Australian Government Agencies Privacy Code*, certain of the proposals, if they become law, will have significant resource implications in terms of reviewing and updating policies and procedures to ensure compliance.

We ask that the Government considers the resource implications on NHMRC and similarly affected agencies, including consideration of an incremental approach to commencement of the provisions where possible.

Yours sincerely



Executive Director, Research Quality and Priorities Branch

20 January 2022