



Ms Angelene Falk  
Australian Information Commissioner and Privacy Commissioner  
Office of the Australian Information Commissioner  
GPO Box 5288  
Sydney NSW 2001

Dear Commissioner

**RE: *Privacy Act 1988*: NHMRC guidelines issued under Part IX (Miscellaneous)**

I write regarding three guidelines developed by the National Health and Medical Research Council (NHMRC) that support the research sector as it applies the *Privacy Act 1988* (the Privacy Act) in certain activities:

- [Guidelines issued under Section 95 of the Privacy Act 1988](#) (s95 guidelines) provide a framework in which medical research involving personal information obtained by Commonwealth agencies should be conducted to ensure the information is protected
- [Guidelines approved under Section 95A of the Privacy Act 1988](#) (s95A guidelines) provide a framework for human research ethics committees and others to weigh the public interest in research activities against the public interest in the protection of privacy
- [Guidelines approved under Section 95AA of the Privacy Act 1988](#) (s95AA guidelines) specify the requirements that must be met by health practitioners if they choose to use or disclose genetic information without patient consent.

These guidelines were last reviewed in 2013 utilising the expertise of NHMRC's Australian Health Ethics Committee (AHEC) and Council. These guidelines provide an additional layer of privacy guidance to the research sector. They also provide participants in health and medical research and the community at large with confidence that Australia's privacy requirements are applied by the health and medical research sector in a consistent and appropriate way, effectively balancing personal privacy against the public good that flows from research.

Legislative instruments relating to the s95A and s95AA guidelines, issued by the Privacy Commissioner under the Privacy Act, sunset on 1 April 2024. The instrument relating to the s95 guidelines, issued by the NHMRC CEO under the Privacy Act following receipt of approval from the Privacy Commissioner, sunsets on 1 April 2025.

In such circumstances, I would generally write to advise that a review of these guidelines for currency and relevance would be undertaken. However, I note that the Government's review of the Privacy Act (Privacy Act Review) will directly affect the guidelines.

The Privacy Act Review commenced in October 2020 with the release of an [Issues Paper](#), followed by a [Discussion Paper](#) in 2021 which put forward potential reforms of the Privacy Act for consultation. In February 2023, the Attorney-General's Department released the [Privacy Act Review Report](#) which contained 116 proposals for reforming the Privacy Act drawn from the culmination of over two years of consultation.

The Privacy Act Review Report included three research related proposals in Chapter 14 (Research):

- **Proposal 14.1** – Introduce a legislative provision that permits broad consent for the purposes of research
- **Proposal 14.2** – Consult further on broadening the scope of research permitted without consent for both agencies and organisations
- **Proposal 14.3** – Consult further on developing a single exception for research without consent and a single set of guidelines, including considering the most appropriate body to develop the guidelines.

The Government released its response to the Privacy Act Review Report on 28 September 2023. The [Government's response](#) agreed with all three research-related recommendations, stating:

*The Government recognises that the changes to consent may present challenges for research organisations conducting research in the public interest. The Government agrees that researchers should also be able to rely on 'broad consent' due to difficulties in obtaining 'specific' consent from individuals in research contexts (proposal 14.1). The Government agrees further consultation should be undertaken on expanding the scope of the Act's exceptions from requiring consent in research contexts to apply to human research generally that is in the public interest, and on agencies and organisations being covered by a single research exception and set of guidelines developed by the Privacy Commissioner in consultation with relevant stakeholders (proposals 14.2 and 14.3).*

Implementation of the Government's response will be led by the Attorney-General's Department and, if consultation on the Research Chapter recommendations leads to changes in laws governing privacy management in research, this will likely have a substantial impact on the next review of these guidelines.

I have consulted with AHEC and the Council of NHMRC on the ongoing status of these guidelines in light of the Government's response to the Privacy Act Review. They advise that whilst there would be marginal improvements in currency and utility that could be made, the guidelines are essentially sound and remain fit-for-purpose. In these circumstances, it is NHMRC's view that the existing guidelines should remain active until the Attorney-General's Department has completed its consultation on the Research Chapter's recommendations and any subsequent changes in laws governing privacy management in research are enacted. Once there is clarity as to the future of laws governing privacy management in research in Australia a comprehensive review of these three guidelines should then be conducted.

To facilitate this, I seek your agreement to approve, and, as appropriate, to re-make the legislative instruments relating to the section 95, 95A and 95AA guidelines, as currently published, for a further five years, with a self-repeal provision.

There are competing rights to individual privacy that must be balanced against the public good of health and medical research when considering whether to remake these guidelines. I acknowledge that before you can give your approval, you must be satisfied that the public interest tests under relevant clauses of the Privacy Act have been met. To support your deliberations, I offer the following:

#### *Section 95 guidelines*

Medical research that involves the use of personal information held by an agency, including the compilation or analysis of statistics, provides important information to health care providers and health policy decision-makers. It may underpin good decision-making on health care policies and the development of health programs within the Australian community. Translation of research into service delivery enables ongoing quality improvements in Australia's health care sector and assists service providers, non-government organisations and governments to minimise wastage in the health care sector.

To support such research it may, at times, be necessary for personal information to be collected, used or disclosed without consent from an individual. These guidelines support the conduct of such activities in a way that minimises intrusion on individual privacy. On balance, noting the public good that flows from health and medical research, NHMRC considers that the public interest in the facilitation of research of the kind to which these guidelines relate outweighs to a substantial degree the public interest in maintaining adherence to the Australian Privacy Principles (APPs).

*Section 95A guidelines*

The provision of health care services and health care decision-making protocols informed by strong evidence base derived from high-quality health and medical research is necessary to ensure individuals and the community receive the best possible health and medical care. Research, the compilation or analysis of statistics, or the management of a health care service, should be carried out in a way that minimises intrusion on people's privacy. However, it may be necessary for personal information to be collected, used or disclosed without consent from an individual in order for these activities to proceed.

These guidelines provide a framework for researchers and human research ethics committees to balance the public benefit from proposed research, statistical or health service management activities against the public interest in the protection of privacy. On balance, noting the collective and individual good that flows from health and medical research, NHMRC considers that the public interest in the facilitation of research of the kind to which these guidelines relate outweighs to a substantial degree the public interest in maintaining the level of privacy protection afforded by the APPs.

*Section 95AA guidelines*

These guidelines set out how health practitioners may use and disclose genetic information about a patient to the patient's genetic relatives, in circumstances where the patient has not consented to such use and disclosure. They also set out how health practitioners should first discuss with the patient the need for the use or disclosure and attempt to obtain the consent of the patient. Such a disclosure would only be for the purposes of lessening or preventing a serious threat to the life, health or safety of an individual who is a genetic relative of the individual to whom the genetic information relates.

I note that the scope of these guidelines does not include: general information about genetic assessment, clinical information to support diagnosis, use of medical records, stored genetic samples or general consent issues; genetic screening; or the use of genetic information in human research (this is addressed in Chapter 3.5 of the [National Statement on Ethical Conduct in Human Research](#)).

The requirements set out in these section 95AA guidelines is prescriptive and aligns with the expectations set out in section 16B of the Privacy Act (Permitted health situations in relation to the collection, use or disclosure of health information) and APP 6.2(d) (exceptions to the disclosure of personal health information without consent). These provisions effectively form the public interest test for these guidelines.

I hope this information is useful and thank you for your consideration of these matters. My team and I are available to provide additional information as needed and can be contacted at [ethics@nhmrc.gov.au](mailto:ethics@nhmrc.gov.au).

Yours sincerely



Professor Steve Wesselingh  
Chief Executive Officer

7 November 2023