Adventist HealthCare Research

Apply for a Waiver of Consent

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A - BACKGROUND

A.1 What is a Waiver of Consent

In the context of medical research, it means that identifiable data may be used in a research context without prior consent from the patients.

RESEARCH CONSENT ON INTAKE FORMS

If patients have consented to the use of their personal information for research at the time of admission, or when filling in a medical intake form at a private practice, this may be sufficient for conducting research and no application for a Waiver of Consent may be required.

Please contact the Research Office if this applies to your research proposal to discuss further.

A.2 Definition of retrospective and prospective research

In retrospective research, events are assessed that have already occurred usually by using information that was collected as a result of those past events. In the context of the work conducted at the Sydney Adventist Hospital, retrospective studies are often conducted with health data that was collected as part of routine medical care. In prospective research, projects start with the present and follow participants forward in time to examine trends, predictions, and outcomes[1].

[1] https://dictionary.apa.org/prospective-research

A.3 Primary and secondary use of information

The Australian privacy laws protect an individual's fundamental right to privacy and differentiate between two scenarios for the collection and use of information, the primary and the secondary purpose. A 'secondary purpose' is any purpose other than the primary purpose for which the personal and identifiable data was originally collected[2]. For example, in a health service environment identifiable health data is collected for the primary purpose of providing a health service. The data can be used for research, i.e. a secondary purpose, but requires patient consent. However, in some circumstances obtaining patient consent is not possible or appropriate.

Therefore, the right to privacy must be weighed against matters that benefit society as a whole and therefore there are some exceptions from this general rule. The conduct of research, and the compilation or analysis of statistics, relevant to public health or public safety and health service management fall within these circumstances[3]. Should this apply to your research proposal, please continue with an application for a Waiver of Consent.

A.4 The role of HRECs in the process of review

As stated in clause D.2 of the *NHMRC Guidelines approved under Section 95A of the Privacy Act 1988 (2014, updated 2024)*[3]

> *"In making decisions under these guidelines, an HREC must consider whether the proposal complies with the relevant APPs [Australian Privacy Principles] in the course of:*
>
> *a) the collection of health information for the purposes of:*
> *i. research relevant to public health or public safety; or*
> *ii. the compilation or analysis of statistics, relevant to public health or public safety; or*
> *iii. the management, funding or monitoring of a health service;*
>
> *or*
>
> *b) the use and disclosure of health information for the purposes of*
> *i. research relevant to public health or public safety; or*
> *ii. the compilation or analysis of statistics, relevant to public health or public safety.*
>
> *This would include considering whether the purpose of the proposed activity can be achieved using de-identified data and whether it is impracticable to collect, use or disclose health information for the proposed activity with the consent of the individual(s) involved."*

[2] APP 6: Use or disclosure of personal information (www.oaic.gov.au/privacy/australian-privacy-principles/read-the-australian-privacy-principles)
[3] *NHMRC Guidelines approved under Section 95A of the Privacy Act 1988 (2014, updated 2024)* (www.nhmrc.gov.au/about-us/publications/guidelines-approved-under-section-95a-privacy-act-1988#block-views-block-file-attachments-content-block-1)

To put this process into some context, HRECs generally factor in considerations such as those listed below when assessing whether it is impracticable to seek consent for the proposed collection, use or disclosure:

- ✓ The size of the population involved in the research;
- ✓ The proportion of individuals who are likely to have moved or died since the health information was originally collected;
- ✓ The risk of introducing potential bias into the research if consent needs to be sought first (a proportion of the study population may not be available to consent), thereby affecting the generalisability and validity of the results;
- ✓ The risk of creating additional threats to privacy by having to link information in order to locate and contact individuals to seek their consent;
- ✓ The risk of inflicting psychological, social or other harm by contacting individuals with particular conditions in certain circumstances.

GOOD TO KNOW

Every granted Waiver of Consent will be reported to the Information and Privacy Commission NSW.

HRECs need to confirm that each granted Waiver of Consent complies with all relevant privacy laws.

B - APPLICATION PROCESS

B.1 Meeting conditions to obtain a Waiver of Consent for research

There are a number of conditions which are governed by various Australian state and commonwealth laws and regulations that need to be met for a Waiver of Consent to be approved by a HREC.

A justification is required that states why the proposed project is necessary in the public interest, and why it is impracticable to gain consent. If the HREC is not unanimously satisfied with the justification, they cannot grant a Waiver of Consent. Waivers can also only be granted for research no more than low risk. Prospective studies should use a consenting process, however, in certain circumstances a HREC may grant a waiver of consent for prospective research.

Please refer to the table below or reach out to the Research Office for assistance in determining the risk level of your project. Further description of risk categories is available in Chapter 2.1 of *NHMRC National Statement on Ethical Conduct in Human Research (2025)*.[4]

Lower risk		**Higher risk** (Individual, group, community, societal or global)	
Minimal	**Low**	**Greater than low**	**High**
No risk of harm or discomfort; potential for minor burden or inconvenience*	No risk of harm; risk of discomfort (+/- foreseeable burden)	Risk of harm (+/- foreseeable burden)	Risk of significant harm (+/- foreseeable burden)

Source: *NHMRC National Statement on Ethical Conduct in Human Research (2025)*

[4] *NHMRC National Statement on Ethical Conduct in Human Research (2025)* https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2025

B.2 Justification for a waiver of Consent

Below is general information about waivers of consent. As HRECs requirements differ in terms of how justifications should be addressed, please contact the chosen external HREC to ascertain the appropriate templates and processes.

1. Below is the criteria for justification for a HREC to grant a Waiver of Consent (from section 2.3.10 of the National Statement[4]).

IMPORTANT

Only stating 'confirmed' or 'yes' after each point is not accepted by HRECs

Clauses from section 2.3.10 of the National Statement to be addressed in your protocol

(a) involvement in the research carries no more than low risk to participants

(b) the benefits from the research justify any risks of harm associated with not seeking consent

(c) it is impracticable to obtain consent (e.g. due to the quantity, age or accessibility of records)

(d) there is no known or likely reason for thinking that participants would not have consented if they had been asked

(e) there is sufficient protection of their privacy. Please confirm that reasonable steps will be taken to de-identify the information, or if the purpose of the research cannot be served by using or disclosing de-identified information, please provide additional information e.g. by referring to a previous section of this protocol, regarding the steps that will be taken to protect patient confidentiality

(f) there is an adequate plan to protect the confidentiality of data

(g) in case the results have significance for the participants' welfare there is, where practicable, a plan for making information arising from the research available to them (e.g. via a disease-specific website or regional news media)

(h) the possibility of commercial exploitation of derivatives of the data or tissue will not deprive the participants of any financial benefits to which they would be entitled

(i) the waiver is not prohibited by state, federal, or international law.

2. Below are the sections from the *Privacy Act (1988)* which must be addressed in your protocol: Section 16B (3) and Australian Privacy Principle 6.2(d). These criteria are included in *AHCL Protocol Template – Observational or Experimental Design (not sponsored clinical trial)*, available on the Research Office website at: www.sah.org.au/research-ethical-review.

Privacy Act (1988) clauses to be addressed in your protocol

Data will be sourced from a private institution and the research team seek to apply the *Guidelines approved under Section 95A of the Privacy Act 1988*, pursuant to APP 6.2(d) and Section 16B(3).

S16B(3)

(3) A *permitted health situation* exists in relation to the use or disclosure by an organisation of health information about an individual if:

(a) the use or disclosure is necessary for research, or the compilation or analysis of statistics, relevant to public health or public safety; and
(b) it is impracticable for the organisation to obtain the individual's consent to the use or disclosure; and
(c) the use or disclosure is conducted in accordance with guidelines approved under section 95A for the purposes of this paragraph; and
(d) in the case of disclosure--the organisation reasonably believes that the recipient of the information will not disclose the information, or personal information derived from that information [NB: confirm that **you** will not disclose the information].

APP 6.2(d)

The APP entity is an organisation and a permitted health situation exists in relation to the secondary use or disclosure of the personal information by the organisation.