

**WAIVER OF CONSENT JUSTIFICATION
for inclusion in your Protocol**

*Replace italicised text with relevant information and remove this instruction along with the “Introduction – What is a Waiver of Consent”*

**Introduction – What is a Waiver of Consent?**

Patients consent to their information being used for their medical care. When patient details are to be used for *purposes other than their medical care* (e.g. research), patient consent is sought, or a request to ‘waive consent’ is applied for. Australian ethics committees may provide a “waiver” of the need for informed consent, in accordance with the relevant guidelines in the National Statement on Ethical Conduct in Human Research 2007 (updated 2018) and in the Guidelines under section 95A of the Privacy Act 1988.

In most cases a waiver of consent is sought by researchers who are looking to conduct retrospective studies that involve the use of personal information in patients’ medical charts, or by researchers wishing to pre-screen potential participants for eligibility before approaching them for participation in research. Other situations also exist and if you are unsure whether you need to apply for a waiver of consent for your project please contact the HREC Office to discuss.

When a waiver of consent is sought by a researcher, there must be adequate justification provided, showing that the waiver of consent is an appropriate application in their research based on both the [National Statement](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018) (p21) and [Privacy Act Guidelines](https://www.nhmrc.gov.au/about-us/publications/guidelines-approved-under-section-95a-privacy-act-1988#block-views-block-file-attachments-content-block-1)

The template below has been designed to help you with the wording for your waiver of consent justification. This wording should be included in your protocol.

**Request for waiver of consent**

*Provide a brief description of why you are seeking a waiver of consent.*

* *Is it for retrospective data collection?*
* *Is it for pre-screening potential participants prior to approaching them to gain consent for participation in your study?*
* *Is it to compare data from a retrospective patient group with an interventional group?*

*Also include the following information:*

* *Which organisation holds the records?*
* *How many charts will you be looking at? (general estimates of number of charts/records to be accessed are acceptable)*

*You will also need to include the following sentence:*

We believe this request satisfies the criteria for providing a waiver of consent as outlined in the National Statement (2007 updated 2018 section 2.3.10):

*Expand on points a) to i) below, being specific on* ***how/why*** *they relate to* ***your study****.*

1. Involvement in the research carries no more than low risk
2. The benefits from the research justify any risks of harm associated with not seeking consent
3. It is impracticable to obtain consent
4. There is no known or likely reason for thinking that participants would not have consented if they had been asked
5. There is sufficient protection of their privacy
6. There is an adequate plan to protect the confidentiality of data
7. 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
8. 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
9. The waiver is not prohibited by State, federal, or international law.

*Also include the following sentence:*

We believe this justification is also in accordance with S95A of the Privacy Act 1988.

*The HREC Office is here to help, if you have questions, please don’t hesitate to contact us on* *research.ethics@mater.uq.edu.au*