**Introduction**

A waiver of consent is requested when a researcher seeks approval from an HREC in order to use a participant’s personal and/or health information without obtaining consent directly from the participant for the purposes of research. In most instances, a waiver of consent is sought by Researchers for retrospective research that involves using the personal and health information from a patients’ medical files, or by researchers wishing to pre-screen potential participants for eligibility before approaching them for participation in research. Other situations also exist, typically where a researcher is seeking to collect personal and/or health information from a group of participants without their consent.

Please refer to the flowchart on the following page to determine if you require a waiver of consent, and if you are still unsure, contact the HREC office either by email [HREC.RHC@ramsayhealth.com.au](mailto:HREC.RHC@ramsayhealth.com.au) or [RamsayHREC.WA-SA@ramsayhealth.com.au](mailto:RamsayHREC.WA-SA@ramsayhealth.com.au) or phone: (02) 9433-3854 to discuss.

All application for a waiver of consent must be reviewed by a Ramsay HREC, as per Sections 2.3.9 and 2.3.10 of the [*National Statement on Ethical Conduct in Human Research*, 2023](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023) (National Statement). The HREC must consider whether the public interest in the proposed activity substantially outweighs the public interest in the protection of privacy. The HREC must also consider whether it is impracticable for the Researchers to seek consent from Participants. Factors that HREC may be used to assess this include:

* 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, 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

Approval of the waiver is required in order for full project approval to be granted.

In order to grant a waiver of consent, the HREC must also be satisfied that the conditions for a waiver of consent also meet [the Australian Privacy Principles](https://www.oaic.gov.au/privacy/australian-privacy-principles/australian-privacy-principles-guidelines/chapter-6-app-6-use-or-disclosure-of-personal-information). If***identifiable***personal or health information are requested to be released to an external party under a waiver of consent, the HREC must also consider whether this is permissible under [Section 95A of the *Privacy Act 1988* (Cth)](http://www5.austlii.edu.au/au/legis/cth/consol_act/pa1988108/s95a.html)*,* with reference tothe approved[*NHMRC Guidelines under Section 95A of the Privacy Act* 1988](https://www.nhmrc.gov.au/about-us/publications/guidelines-approved-under-section-95a-privacy-act-1988) *(Section 95A Guidelines).*

**Definitions (as per section 95A guidelines)**

**Collection:** Under the Privacy Act, an organisation collects personal information if it gathers, acquires or obtains personal information from any source and by any means.

**Use:** In general terms, use of personal information refers to the handling and management of personal information by an organisation, where the organisation retains control, or a right to control, the information.

**Disclosure:** In general terms an organisation discloses personal information when it actively releases information to others outside the organisation and is no longer able to exercise control over the information.

**Other important considerations**

Your data management plan should include consideration of the following (as per Section B of the *Section 95A Guidelines*). You may include your data management plan within your protocol or develop this as a separate document. *Please see the Ramsay Health Care Research website for templates.*

* the identity of the custodian(s) of the health information collected and a list of personnel who will have access to the health information collected,
* the estimated time of retention of the health information and the security standards that will be applied.
* proposed methods of disposal of the health information upon completion of the research
* If there is any proposal to send data overseas for the purpose of the research project, you must including the names of the countries to which it is proposed the data be sent and how the research project will comply with APP 8 (cross-border disclosure of personal information) of the Privacy Act.

**Key resources**

* Australian Privacy Principle Guidelines, APP6 2019: <https://www.oaic.gov.au/privacy/australian-privacy-principles/australian-privacy-principles-guidelines/chapter-6-app-6-use-or-disclosure-of-personal-information>
* Guidelines approved under Section 95A of the Privacy Act 1988, 2024: <https://www.nhmrc.gov.au/about-us/publications/guidelines-approved-under-section-95a-privacy-act-1988>
* National statement on ethical conduct in human research, 2023: <https://www.nhmrc.gov.au/research-policy/ethics/national-statement-ethical-conduct-human-research>
* Privacy Act 1988: <http://www.comlaw.gov.au/Series/C2004A03712>
* The Australian Code for the Responsible Conduct of Research, 2018: <https://www.nhmrc.gov.au/research-policy/research-integrity>

**See flowchart on following page**

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Ref: Flowchart determining whether the s95A guidelines apply <https://www.nhmrc.gov.au/file/2271/download?token=OQiJA4pc>

**Please complete the Request for Waiver of Consent application below and upload this with your HREA application in REGGS. You must complete Part A and Part C. Part B is required if identifiable data will be shared with a 3rd party.** We recommend providing a thorough explanation, including justification and evidence for claims made. Including information about consultation or assessments made by researchers of key criteria regarding impracticability, for example, will assist the Committee in its assessment. If anything is unclear, please contact the HREC Office.

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|  | **Part A.**  *Please provide the following information to assist the HREC in determining the suitability to grant a waiver of consent for the proposed research.* | | | | |
|  | The names of the organisation(s) proposing to collect, use and/or disclose personal and/or health information for this project.  *(eg Ramsay Health Care facility, Doctor’s private rooms)* | | Click or tap here to enter text. | | |
|  | List the data variables sought from the organisation(s) or to be used by the organisation(s) and approved by the HREC.  *(note: you may refer to the relevant section of your protocol if these variables are clearly articulated there)* | | Click or tap here to enter text. | | |
|  | Provide:   1. An estimate of the number of records involved. 2. The study period (*eg records dated from July 2020 to June 2024*)   *(note: you may refer to the relevant section of your protocol)* | | Click or tap here to enter text. | | |
| D.5a  D.5b | Which S95A considerations does this project fit into?  Please refer to page 6 and the other relevant sections of the Section 95A Guidelines “When should the Section 95A Guidelines be applied? | 1. The collection of health information under section 16B(2)(d)(iii) for the purposes of:    1. research relevant to public health or public safety,    2. the compilation or analysis of statistics, relevant to public health or public safety,    3. the management, funding or monitoring of a health service.      1. The use and disclosure of health information under section 16B(3) for the purposes of:    1. research relevant to public health or public safety,    2. the compilation or analysis of statistics, relevant to public health or public safety. | | |  |
| D.5  c) i-vi | Is the research likely to contribute to:   * Management of illness, injury or disease? * Scientific understanding related to public health or safety? * The protection of the health of individuals and/or communities? * Improved delivery of health services? * Scientific understanding or knowledge? * Social science knowledge related to public health or safety? | | | Yes  No  Yes  No  Yes  No  Yes  No  Yes  No  Yes  No | |
| D.5f | Provide confirmation that reasonable steps will be taken to de-identify the information and how this will be done.  *(note: you may refer to the relevant section of your protocol or data management plan)*  If the purpose of the research cannot be served by collecting, using and/or disclosing de-identified information please provide a reason why (and answer Part B of this form).  *(such as: identifiers required in order to link data from multiple sources such as patient files and imaging reports).* | | Click or tap here to enter text. | | |
| D.5g  D.5h | Explain how the collection, use and/or disclosure of personal health information in this project is reasonably necessary for research in the public interest.  What would be the costs to the Public in not undertaking this research? | | Click or tap here to enter text. | | |
|  | Is identifiable data to be disclosed to parties external to Ramsay Health Care or Doctor’s private rooms? *Answer* ***YES*** *if:*   * *You or a member of your research team will access medical records from a Ramsay Hospital for the purposes of Research under a waiver of consent.* * *You seek to conduct research under a waiver of consent and intend sharing identifiable data with a 3rd Party collaborator external to Ramsay or Doctor’s Private Rooms*   ***If YES, complete both Part A and Part B of the Form****.* | | | **Yes**  **No** | |
|  | **Part B.** Please provide the following information **if identifiable data** are requested to be collected, disclosed and/or used to parties external to the Health Service Provider. | | | | |
|  | Please justify the necessity of disclosing identifiable data to the external party and provide and explain as to why a de-identified dataset cannot achieve the same result. | | Click or tap here to enter text. | | |
|  | Outline the measures to be used by the recipient of the dataset to ensure:   1. the security of the dataset and 2. to restrict its use to permitted scope.   e.g. who would have access, where would the data be stored. Will there be some form of Data Transfer agreement or other contractual relationship protecting the use of the data?  *(note: you may refer to the relevant section of your protocol or data management plan if outlined there.)* | | Click or tap here to enter text. | | |
| D.4 | Please provide justification on how the ‘public interest in the proposed research, or compilation or analysis of statistics, or health service management activity substantially outweighs the public interest in the protection of privacy’.  (Section D.4 of the [Section](https://www.nhmrc.gov.au/about-us/publications/guidelines-approved-under-section-95a-privacy-act-1988) 95A Guidelines) | | Click or tap here to enter text. | | |
|  | Any other information to note to the HREC: | | Click or tap here to enter text. | | |
|  | **Part C**  **Justification for a waiver of consent as per Section 2.3.10 of *The National Statement*.**  **(You MUST complete this section for your Waiver to be considered)** | | | | |
| *D.4j* | *a) involvement in the research carries no more than low risk to participants.*  *(refer to section 2.3 of the National Statement).* | | Click or tap here to enter text. | | |
| *D.5d* | *b) the benefits from the research justify any risks of harm associated with not seeking consent.*  *(outline the benefits of the study vs any risks involved)* | | Click or tap here to enter text. | | |
| *A1.3* | *c) it is impracticable to obtain consent*  *(are there concrete and substantial obstacles to obtaining consent, as opposed to mere inconvenience, eg, due to the quantity, age or accessibility of records? Include information on any consultation you may have undertaken).* | | Click or tap here to enter text. | | |
|  | *d) there is no known or likely reason for thinking that participants would not have consented if they had been asked.*  *(Provide a reasoning why this would be the case. Consider how sensitive the information)* | | Click or tap here to enter text. | | |
|  | *e) there is sufficient protection of their privacy.*  *(Explain the steps that will be taken to ensure privacy. Explain why these steps are sufficient)* | | Click or tap here to enter text. | | |
|  | *f) there is an adequate plan to protect the confidentiality of data*  *(Outline your data protection plan to ensure confidentiality of data e.g. how you will prevent others from deliberately or accidently seeing/using the data.)* | | Click or tap here to enter text. | | |
|  | *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 (for example, via a disease-specific website or regional news media)* | | Click or tap here to enter text. | | |
|  | *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*  *(if applicable, explain how this would be managed)* | | Click or tap here to enter text. | | |
|  | *i) the waiver is not prohibited by State, federal, or international law.*  *(eg Privacy legislation, legislation relating to participants with impaired capacity to provide consent for research where they receive treatment, Guardian provisions etc)* | | Click or tap here to enter text. | | |
|  | Any other factors an HREC may consider when assessing if it is impracticable to seek consent in the circumstances (as per State guidelines) | | Click or tap here to enter text. | | |