What is a waiver of consent?
A waiver of consent requires a researcher to seek approval from an ethical review body in order to use a person’s personal information or personal health information without actually obtaining consent directly from the individual in order to use that information in a research project.

What are the conditions for seeking a waiver of consent and who reviews the request?
The National Statement (section 2.3.9) states that ‘Only an HREC may grant waiver of consent for research using personal information in medical research, or personal health information. Other review bodies may grant waiver of consent for other research.’ Before deciding to waive the requirement for consent the HREC or other review body must be satisfied that:

(a) involvement in the research carries no more than low risk
(b) the benefits from the research justify any risks of harm associated with not seeking consent;
(c) it is impracticable to obtain consent
(d) there is sufficient protection of their privacy;
(e) there is an adequate plan to protect the confidentiality of data;
(f) 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
(g) 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;
(h) the waiver is not prohibited by State, federal, or international law

What is Personal Information?
The Privacy Act 1988 (Privacy Act) defines personal information as:

…information or an opinion, whether true or not, and whether recorded in a material form or not, about an identified individual, or an individual who is reasonably identifiable.

Common examples of personal information are an individual’s name, signature, address, telephone number, date of birth, medical records, bank account details and commentary or opinion about a person.

What is Personal Health Information?
The privacy Act defines “health information” as:

a) Information or opinion about the health or a disability (at any time) of an individual; or an individual’s expressed wishes about the future provision of health services to him or her; or a health service provided, or to be provided, to an individual;

b) Other personal information collected to provide, or in providing, a health service; or other personal information about an individual collected in connection with the donation, or intended donation, by the individual of his or her body parts, organs or body substances; or) genetic information about an individual in a form that is, or could be, predictive of the health of the individual or a genetic relative of the individual.
How do you seek a waiver of consent?

If a waiver of consent to access personal health information for medical research if being sought, the relevant sections at section 3.0 is required. An example of the information to be provided in the ethics application form can be found in figure 1 below.

Figure 1 Ethics Application Form

If your project does not involve access to personal information for use in medical research or for the use of health information, an example of how to request a waiver of consent using the Negligible Risk Application form can be found in figure 2 below.
Section 3: Participant Consent

3.1 Was participant consent originally obtained for the data to be used for future research purposes? [ ] Yes [x] No

3.2 Are you requesting a waiver of consent? [x] Yes [ ] No

3.3 Does your research intend to use personal information in medical research, or personal health information? [ ] Yes [x] No

Section 4: Project Description

Please provide a brief description of the project. This should include the following details:

- Aims of the study
- An outline of the research methods and recruitment methods (if you will be recruiting participants). Please ensure you attach a copy of the Participant Information Statement and Consent Form if applicable to your research.
- Importance of the study

Please ensure you attach to your submission any documentation relevant to your project (for example PISCF, survey questions, etc.).

Waiver of consent Justification

- The data to be accessed in this research will be de-identified before it is provided to the research team. The use of the data in this research project carries no more than low risk as the data that will be accessed will not in any way identify the participants who provided the information.
- Given the number of records to be accessed, it would be impracticable to re-contact the individual participants in order to obtain consent.
- The data will be de-identified by the organisation before it is provided to the research team; the information will then be transferred in a secure and encrypted manner.

Plan for protection of privacy

Step 1: Before the information is provided to the research team

Example: The data custodian of the data or tissue bank will remove any identifying information from the biospecimens samples or data set. The organisation will not provide any members of the research team with any information that will allow potential identification of the participants.

Step 2: Transfer of data to the research team

Example:
1. All research files will be compressed and encrypted before they are transferred from the data/tissue bank to the research team.
2. Once compressed and encrypted the files will be sent from the data bank to the research team via email file.
3. Once received the research team will transfer the data to the secure RtosSned system for analysis.
4. All encrypted files received via email will then be deleted.

Figure 2 Negligible Risk Application Form