

Guidance on applying for a waiver of consent when conducting retrospective record reviews

In any research involving human participants – **including information about or linked to human participants** such as medical records or other health-related data – **written informed consent** is generally required.

The Undergraduate Research Ethics Committee (UREC) and/or its parent committee, the Health Research Ethics Committee (HREC), may waive the requirement to obtain informed consent provided that:

- The research involves no more than minimal risk to the participants;
- The waiver or alteration will not adversely affect the rights and welfare of the participant(s);
- The research could not practicably be carried out without the waiver or alteration; and
- Whenever appropriate, the participants will be provided with additional pertinent information after participation.

Students conducting retrospective record reviews may apply for a waiver of consent. Such waiver of consent requests should include the following:

1. Indication that the **above conditions** have been met,
2. The **degree of risk** that the research poses to participants to whom the data is linked, as well as the degree of risk posed to participants in the waiving of consent,
3. Justification regarding **why participant consent cannot be obtained**,
4. Whether the **data will be anonymised** (not merely de-identified) at the point of data collection – i.e. no identifying information such as patient file numbers, names or contact details will be recorded, and
5. Whether the **data will be aggregated** and anonymised in the reporting of findings – i.e. no individual cases will be reported on.

Definitions

Anonymised data: Data is considered anonymised when no identifying information that can link the data back to the source or patient/participant – such as patient file numbers, names, contact details – is recorded in any way during data collection. Once data has been collected, there is no way of tracing it back to the original patient/participant.

De-identified data: Data is de-identified when any form of identifying information – such as patient file numbers, names, contact details – is recorded during data collection, and then de-linked from the data by storing these identifying details in a password protected database separate from the rest of the data. A code is usually assigned to the data, which provides a way of linking the data from each participant with their identifying information. It may be acceptable to de-identify data instead of completely anonymising it if it is anticipated that results might reveal issues (e.g. medical problems) that need to be communicated back to the patient/participant, or where patients/participants need to be contacted for feedback or follow up. This should be clearly justified.

Researchers are referred to relevant sections pertaining to consent / secondary use in to the HREC (2016) Standard Operating Procedures (SOPs) and guidelines (v. 4.3), and the Department of Health (2015) Ethics in health research: principles, processes and structures (2nd ed.) for detailed guidance and regulatory criteria pertaining to waivers of consent.