Guidance on applying for a waiver of consent when conducting research using secondary data

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 research using secondary data (e.g., 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 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.

For detailed guidance and regulatory criteria pertaining to waivers of consent, researchers are referred to relevant sections pertaining to consent / secondary use in to the HREC Standard Operating Procedures (SOPs) and guidelines, and the most recent version of the Department of Health guidance on Ethics in health research: principles, processes and structures.