CAHS Research Ethics Guideline:

Addressing Section 2.3.10 of the National Statement – Waiver of Consent

Consent in Research

According to the *National Statement on the Ethical Conduct in Human Research, 2023* (National Statement): Consent to participate in research must be voluntary and based on sufficient information and adequate understanding of both the proposed research and the implications of participation in it (Section 2.2.1).

Consent to a child's or young person's participation in research should be obtained from:

a) the child or young person whenever he or she has the capacity to make this decision;

AND

b) either

i) one parent, except when, in the opinion of the review body, the risks involved in a child's participation require the consent of both parents

or where applicable

ii) the guardian or other primary care giver, or any organisation or person required by law.

(Section 4.2.7)

However, in some research, consent may not be possible. This may be because of the age of records, a characteristic of the cohort or for some other reason. In these cases, researchers may request a HREC to consider waiving the requirement to seek consent. Though research without informed consent may appear to violate fundamental rights, when conducted with appropriate safeguards, it provides the opportunity for significant benefits to the public as well as specific groups who may not be able to provide consent. However, there is low public tolerance for the use of information or material without consent and doing so must be justifiable.

The National Statement provides a framework for a HREC to assess a project and determine if the waiver is appropriate, the merits and benefits are sufficient to justify waiving consent and that researchers have sufficient processes in place to protect participants' rights to privacy and confidentiality.

National Statement Section 2.3.10

Before deciding to waive the requirement for consent, an HREC or other review body must be satisfied that:

a) Involvement in the research carries no more than low risk to participants.

b) The benefits from the research justify any risks of harm associated with not seeking consent.

c) It is impracticable to obtain consent (for example, due to the quantity, age or accessibility of records).

d) There is no known or likely reason for thinking that participants would not have consented if they had been asked.

e) There is sufficient protection of their privacy.

f) There is an adequate plan to protect the confidentiality of data.

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).

h) The possibility of commercial exploitation of derivatives of the data or tissue will not deprive the participants of any financial benefit to which they would be entitled.

i) The waiver is not prohibited by State, federal, or international law.

What does this mean for your ethics submission?

The conditions for each criterion listed in section 2.3.10 must be met by researchers. Researchers are expected to carefully consider and address each point. HREC members will review this carefully when deciding on granting a waiver of consent.

Common mistakes regarding addressing Section 2.3.10 as a whole:

1. A common error is for researchers to reiterate the criterion i.e. in response to point 2.3.10a stating "*This research is low risk*" without providing a basis for that assertion. Each criterion must be substantively addressed. Responses that reflect due consideration of the criterion and the principles they reflect are far more likely to receive approval without further questions being asked by HREC.
2. Another common error is not adequately describing indirect risks. The HREC is aware that access to data or samples that are surplus to clinical requirements is not likely to result in physical harm. The HREC will consider risks which relate to the potential for privacy/confidentiality breaches and the subsequent potential for emotional distress amongst participants, public loss of faith in the integrity of the health service, damage to the hospital's reputation and the potential that members of the public may become disinclined to be completely forthcoming with health information as a result, even when relevant to their care.

A breakdown of each of the criteria of Section 2.3.10 and what is expected of researchers when addressing them are described below.

a) Involvement in the research carries no more than low risk to participants

The criterion for low risk according to the National Statement is, the potential for harms *greater than discomfort* as a result of research participation. This is not a particularly functional definition because discomfort is subjectively experienced; what may be innocuous to some may induce trauma in others. Each project and the experience of participants, particularly paediatric participants, is considered holistically by the HREC.

Figure 1: Risk profiles of research

Lower risk		**Higher risk** (Individual, group, community, societal or global)	
Minimal	**Low**	**Greater than low**	**High**
No risk of harm or discomfort; potential for minor burden or inconvenience*	No risk of harm; risk of discomfort (+/- foreseeable burden)	Risk of harm (+/- foreseeable burden)	Risk of significant harm (+/- foreseeable burden)

Chapter 2.1, Figure 1, *National Statement on Ethical Conduct in Human Research 2023*.

When addressing 2.3.10a, a researcher must address *why* their project fits into a particular risk classification, rather than just stating it is "low risk."

The risk of projects that seek to collect data is typically dependent on the procedures in place to mitigate the risks to privacy or mismanagement.

b) The benefits from the research justify any risks of harm associated with not seeking consent

Beneficence is one of the primary principles upon which ethical research is founded. It requires that research should provide the potential for benefit that outweighs the potential harms or burdens of participation. Research may provide benefit in several ways: it may benefit participants or their community directly, lead to a clinical or service improvement, contribute important knowledge in a particular area, explore an unmet need and/or provide healthcare professionals with research experience.

A question which may help in addressing this criterion is: "*If I were asked to justify this approach to an individual involved or their parent/guardian, what case would I make for the study and the lack of informed consent?"*

c) It is impracticable to obtain consent (for example, due to the quantity, age or accessibility of records)

In this context, *impracticable* is synonymous to *virtually impossible,* NOT *difficult.*

Examples of addressing this criterion include:

- Previous attempts have failed to gather consent from a parent/guardian.
- Exclusion of those unable or unwilling to provide their consent would lead to the introduction of bias, not be representative of the cohort, affect sample size etc.
- The project spans over a large time period and participants would have likely changed contact details, moved or died.
- The number of individual datasets required in order to achieve a statistically significant result in the analysis is so large (hundreds/thousands) that it is *impracticable* to seek consent from all parents/guardians prior to commencing the study.

d) There is no known or likely reason for thinking that participants would not have consented if they had been asked

The assumption that a parent/guardian would have consented to their child's data being used for research if asked is difficult to prove. The rationale for the inclusion in the National Statement is that participants should not be included in research that does not align with their values or it is unlikely they would have consented to. An example of this is the evidence to suggest that the public are less inclined to donate their data or biospecimen samples to commercial research without consent. The researchers should consider whether it is reasonable to believe, based on what is known about the cohort under investigation, that a parent/guardian would have consented to involvement.

This assertion may be supported by engaging with members of this cohort, consumer groups or groups who advocate on behalf of this community. Also, evidence from past studies of a high level of engagement in research by that community may also address this criterion.

e) There is sufficient protection of their privacy

Privacy is the right of an individual to control how their personal information (or personal health information) is collected, used, and/or disclosed. In the context of research with consent, providing sufficient protection of privacy frequently involves the removal of personal information (identifiable information) from data collected as soon as possible, or preferably, not collecting personal information at all. Where this is not possible, it must be clearly articulated when personal information is removed, whether the information will be re-identifiable, who will have access to the data in both identifiable and de-identified forms.

f) There is an adequate plan to protect the confidentiality of data

Confidentiality is the duty to ensure information is kept secret to the extent possible. In the context of research, this means limiting access to data only to those who are required access (members of the research team), ensuring secure storage and clear processes for management and destruction. Providing a clear description for HOW the collected data will be kept confidential is sufficient to satisfy this criterion.

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)

Research should be just. In order to maintenance justice, "*outcomes should be made accessible to research participants in a way that is timely and clear*" (section 1.5). Medical journals can be costly, are written in scientific language not easily understood by the general public and are not available to the general public, hence do not fulfill this criterion. Social media posts, posters displayed in areas where participants can see them and lay summaries made available at the hospital or through advocacy groups are examples of ways which researchers can publish their findings to the general public.

h) The possibility of commercial exploitation of derivatives of the data or tissue will not deprive the participants of any financial benefit to which they would be entitled

While it is an important consideration, it is rare that research using data under a waiver of consent has the potential for direct commercialisation. If there is no potential for commercialisation, it is sufficient to state that this is the case.

Where some financial benefit may arise from the research using data or samples collected under a waiver of consent, researchers should address how their use in the research will not deprive participants of financial benefit. The sale of data or samples to a commercial party would not be supported by the HREC.

i) The waiver is not prohibited by State, federal, or international law.

The HREC does not expect researchers to seek advice on the legal acceptability of the waiver of consent. An assurance that, so far as the applicant is aware, the waiver if not prohibited by law is generally sufficient. A component of site (RGO) review is a consideration of the legality of the waiver in its specific context and the applicant will be notified if a waiver is not legally supported.

However, the collection and transfer of personal, or personal health, information outside of a WA Health Service Provider (HSP) without consent may contravene the Health Services Act, 2016 (HSA) or the Commonwealth Privacy Act. In that case, an HREC is required to consider whether the purpose/s of the study are within the scope of the disclosure allowed within those Acts.

In general, the National Statement and the HSA are compatible. However, they serve different purposes and inconsistencies can arise on a case-by-case basis. The National Statement provides ethical guidance as to obtaining consent for the purposes of human research, the HSA and Health Services Information Regulations set out legal obligations of confidentiality and information sharing and legal consideration has to be given before the release of any information.