What is a waiver of consent?

The *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS 2 (2018)* contains “default requirements for seeking the consent of individuals to participate in research. However, there are some research questions that cannot be answered without an alteration to these consent requirements.” (Article 3.6b) In these situations, researchers are granted a “waiver of consent” by the Research Ethics Board approving their research.

What is needed for a waiver of consent?

The TCPS2 identifies five criteria that must be met in order to grant a waiver of consent (Article 3.7a):

1. The research involves no more than minimal risk to the participants;
2. The alteration to consent requirements is unlikely to adversely affect the welfare of participants;
3. It is impossible or impracticable to carry out the research and to address the research question properly, given the research design, if the prior consent of participants is required;
4. In the case of a proposed alteration, the precise nature and extent of any proposed alteration is defined;
5. the plan to provide a debriefing (if any) that may also offer participants the possibility of refusing consent and/or withdrawing data and/or human biological materials, shall be in accordance with Article 3.7B.

What do I need to do?

If your research needs a waiver of consent, here are some sample responses to assist you with your ethics application:

Criteria A: The research involves no more than minimal risk to the participants

Sample Responses:

* This research is limited to minimal privacy risks with no other notable risk to participants.
* The probability and magnitude of harm is no more than what this group of participants would experience in their ordinary lives.

Criteria B: The alteration to consent requirements is unlikely to adversely affect the welfare of participants.

Sample Responses:

* This research is non-interventional and as such is unlikely to adversely affect participants.
* This research is minimally risky and those risks have been controlled as much as possible, as such this research is unlikely to adversely affect participants.

Criteria C: It is impossible or impracticable to carry out the research if the prior consent of participants is required.

Sample Responses:

* This project involves more than 10,000 charts; it is impracticable for the research team to contact 10,000 people.
* This data set is more than 15 years old, and the data set does not include up-to-date contact information for these prospective participants. It is impracticable to carry out the research if we need to contact each participant.
* Given the nature of the data analysis, an incomplete cohort would invalidate the research findings. Failure to obtain consent from a portion of participants would make the research futile; therefore it is impracticable to carry out this research with consent.
* The relevant data is de-identified and as such contacting participants is impossible.

Criteria D: In the case of a proposed alteration, the precise nature and extent of any proposed alteration is defined.

Sample Responses:

* The research team is requesting a partial alteration to the consent requirements wherein the participants will not be consented prior to their participation, but they will be debriefed after their participation.
* The research team is requesting a total waiver of consent.

Criteria E: The plan to provide a debriefing (if any) shall be in accordance with Article 3.7B.

Sample Responses:

* The research team will debrief participants after the completion of the research (*add detailed description of that process here*) and participants will be offered the chance to withdraw their data from the study.
* It is impracticable to consent participants as per the response to Criteria A, by the same token it is also impracticable to debrief participant. As such the research team is requesting a waiver of the debriefing requirement.

Ethics Policy

For more information, see the TCPS2, Chapter 3 “The Consent Process,” and in particular please see Articles 3.5, 3.7A, and 3.8: <https://ethics.gc.ca/eng/documents/tcps2-2018-en-interactive-final.pdf>