Queen's REB Guidelines on Waiver of Consent

Queen's University RESEARCH

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Queen's University is situated on **traditional Anishinaabe and Haudenosaunee Territory**.

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Purpose

The purpose of this guideline is to:

- Provide clear guidance on what is required to qualify for a waiver of consent.

Background

Obtaining informed consent from participants is a fundamental ethical requirement. Informed consent ensures that participants understand the research, the risks and benefits. Article 3.2 in TCPS 2 specifies that “researchers shall provide to a prospective participant, or authorized third parties, full disclosure of all information necessary for making an informed decision to participate in a research project.”

There are some types of research where obtaining informed consent might not be necessary. In these situations, a waiver of consent request must be submitted to and approved by the Research Ethics Board (REB). Researchers must adhere to all applicable regulations and guidelines when seeking a waiver of consent to ensure the protection of research participants' rights and well-being.

Criteria for a waiver of consent

Applying for a waiver of consent by the REB must meet **ALL** of the following conditions, as outlined in the TCPS 2, Article 3.7A and Article 3.7B:

- Research is safe and low risk
- Not obtaining consent will not cause harm participants
- If obtaining consent is not an option, (i.e. it is impossible or impracticable to carry out the research and address the question properly) then you must be able to explain this to REB
- In the case of any changes to consent process, the changes will be clearly defined
- When feasible a plan for debriefing the participants will be defined. Participants will be given the opportunity to refuse consent and/or withdraw data and/or human biological materials.

It is the responsibility of the researcher to demonstrate that a particular research project fits into the above criteria. This should be done by listing each of the criteria accompanied by an explanation as to how the research meets it.

Research that may qualify for a waiver of consent

Research that may qualify for a waiver of consent are presented below:

Secondary use of data

Secondary use of data refers to the use in research of information originally collected for a purpose other than the current research purpose.

Examples include use of:

- School records
- Unemployment records
- Health care records
- Retrospective chart reviews

The secondary use of coded information (collected for a different purpose and has been 'coded' with a unique participant identifier and has a corresponding master linking log) may receive a waiver of consent if the researcher does not have access to the master linking log and therefore cannot reidentify participants.

Secondary use of data/human biological materials with identifiable information

Secondary use of data/human biological materials with identifiable information refers to the use in research of data/biological materials originally collected for a purpose other than the current research purpose.

A waiver of consent may be obtained if **all** the following conditions are met according to the TCPS 2 Articles 5.5A and 12.3A:

- The use of identifiable information/human biological materials is required (essential) to the research.
- The use of the identifiable information/human biological materials without the participants consent will not harm the participant.
- The researchers will ensure that all identifiable information/human biological materials are protected and privacy is safeguarded.
- If a participant has previously stated that they are not interested in having their. data/information or biological materials included in research, the researchers will respect this past preference.
- If obtaining consent is not an option, (i.e., it is impossible or impracticable to carry out the research and address the question properly) then you must be able to explain this to the REB.

- If the researcher is obtaining information or human biological materials for research purposes from an existing database or an equivalent, the researcher will obtain other necessary permission for secondary use of information.

The REB will not approve a waiver of consent if **any** of the following criteria is applicable:

- If the risks of the study do not outweigh the benefits.
- If the study goal can be met using an alternative approach.

Recontacting a participant after waiver of consent

When a waiver of consent was granted by the REB and a researcher now wants to re-contact a former participant (to obtain further information or for reasons related to their welfare) without their explicit consent for re-contact, the researcher must provide the REB with a plan for making contact. This plan must be approved by the REB before contact is made. The plan should include the potential benefit outweighs the risks to individuals for re-contact, outline who will contact and invite the individuals to participate and describe the nature of the relationship between participants and the person making contact.

Debriefing process after waiver of consent

Where a waiver of consent has been used, debriefing must be provided to participants at the end of their involvement in the study. Researchers must explain why a participants' consent was not obtained.

For situations when debriefing is impossible, impracticable, or inappropriate, the researcher is responsible for justifying the REB. When seeking an exception to the requirement to debrief, researchers must also provide a plan to disseminate information about the study to participants and/or their communities.