# Queen's REB Guidelines on Waiver of Consent

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# Contents

# 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 specifes 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.”

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## Research that may q

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 als to p