Queen's REB Guidelines on Alterations to Standard Consenting Procedures

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 employ an alteration to standard consenting procedures (i.e., through partial disclosure or deception).

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 it may be necessary to alter these consent requirements. In order to do this, an alteration of consent requirements request must be submitted to and approved by the Research Ethics Board (REB). Researchers must adhere to all applicable regulations and guidelines when seeking an alteration of consent requirements to ensure the protection of research participants' rights and well-being.

Criteria for alterations of consent requirements

Applying for an alteration of consent requirements by the REB must meet **all** the following conditions, as outlined in the TCPS 2, Article 3.7A and Article 3.7B:

- Research is safe and low risk (i.e. is minimal risk to the participants).
- Not obtaining consent will not harm participants.
- It would be impossible or very difficult to conduct the research and answer the research question properly if participants' consent is required beforehand.
- If a change is suggested, the exact details and extent of the change are clearly explained.
- The plan for debriefing (if applicable) will allow participants to refuse consent, withdraw their data, or remove human biological materials, following Article 3.7B.

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.

Alteration to standard consent: Research involving partial disclosure or deception

Sometimes, research may only be carried out if the participants do not know the true purpose of the research in advance. For example, if the participant knows the true nature of the research, or observation, they may change their behaviour or naturalistic response.

Alterations to consent requirements may include providing prospective participants with only partial disclosure about the purpose of the study, deceiving prospective participants entirely about the purpose of the study, and not informing participants that they (or their data or biological materials) are involved in a study.

Partial disclosure

Partial disclosure involves a researcher withholding or omitting information about a certain aspect of a study.

Examples include:

- Informing the participant about the purpose of the study in general terms, which are accurate, but omitting the specific focus of the study.
- Describing the study procedures in general terms, but not providing enough details to reveal the specific objectives for the procedure.

Deception

Deception occurs when an investigator gives false information to participants or intentionally misleads participants about one or more aspects of the research study with the purpose of making false beliefs. Deception can range from mild deception (i.e., a slight misrepresentation of the study purpose) to a more severe deception (i.e., giving false feedback to participants about themselves).

Examples include:

- Creating a false cover story about the true purpose of the study.
- Incorrect information about research procedures (e.g., incorrect instructions for study tasks)
- Giving participants false feedback (negative or positive) about their performance.
- Creating false beliefs about aspects of self or personal behaviour.
- Use of confederates.

The REB will not approve the use of partial disclosure or deception if **any** of the following criteria is applicable:

- the deception is expected to cause emotional distress or physical pain
- When the harm of deception is expected to be long lasting
- If the risks of the study do not outweigh the benefits
- If the study goal can be met using an alternative approach

Alteration to standard consent: Research involving deferred consent

There are situations where an individual may require urgent medical care and is unable to provide consent due to loss of consciousness or decision-making capacity and seeking an authorized third-party consent may compromise that individual's health. In these cases, and subject to all applicable legal and regulatory requirements, research involving medical emergencies may be conducted only if it addresses the emergency needs of the individuals involved.

The REB may allow research that involves medical emergencies to be carried out without the consent of participants, or of their authorized third party, if **all** the following criteria are met:

- A serious threat to the prospective participant requires immediate intervention.
- Either no standard of care exists, or the research offers a possibility of direct benefit to the participant compared with standard care.
- Either the risk is not greater than that involved in standard of care, or it is justified by direct benefits to the participant.
- The prospective participant is unconscious or lacks capacity to understand the risks, methods and purposes of the study.
- Third party authorization cannot be secured in sufficient time, despite efforts to do so.
- No relevant prior directive by the participant is known to exist.

If the participant regains capacity, or when an authorized third party is found, consent should be obtained at that time for continuation in the study and for subsequent examinations or tests related to the research.

Debriefing process after alteration to standard consent procedures

Where alterations to standard consent procedures have been used, debriefing must be provided to participants at the end of their involvement in the study. Researchers must explain why participants were temporarily led to believe that the research, or some aspect of it, had a different purpose, or why participants received less than full disclosure. A post-study debriefing letter is a method by which researchers can provide full disclosure and an explanation for why less than full disclosure was used.

When feasible, it is recommended that the debriefing occurs face-to-face to ensure there is the opportunity to alleviate any misconceptions or diminish negative feelings, and to re-establish trust in the research process.

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.

Steps to debriefing process after waiver of consent

1. **Inform participants:** Researchers must explain the purpose, methods, and goals of the study to the participants. This information will help participants understand what the research was.
2. **Share findings:** Researchers provide a summary of the research findings, so that participants can learn what was discovered during the study.
3. **Clarify waiver:** If consent was waived for some or all of the study, the researchers will clarify why this happened and why it was necessary.
4. **Answer questions:** Participants are given the opportunity to ask any questions they might have about the study.
5. **Provide choice:** In some cases, participants may be given the option to withdraw their data or any human biological materials collected during the research, even if they initially agreed. This is to ensure that participants still have control over their information.
6. **Ensure privacy:** Researchers should reassure participants about the privacy and confidentiality of their data and materials, even after the study is complete.