

SOP Title:	Waiver or Alteration of Consent		
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Approved By:	Dr. Elizabeth Stephenson		

1.0 PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to describe the general requirements that must be met in order for a waiver or alteration of informed consent to be approved by the SickKids Research Ethics Board (REB).

2.0 POLICY STATEMENT

The SickKids REB may waive or alter some or all of the elements of the informed consent form (ICF) or process as described in SOP VII.01.001 (Informed Consent Form Requirements) and SOP VII.02.001 (Informed Consent Process).

A waiver of consent implies that no consent process is required. In other words, given a waiver of consent, there is no information and consent form or verbal review of study information with participants.

An alteration of consent implies a departure from the elements or the ICF or the consent process as in SOP VII.01.001 (Informed Consent Form Requirements) and SOP VII.02.001 (Informed Consent Process).

3.0 DEFINITIONS

See Glossary of Terms

4.0 RESPONSIBILITY

All REB members and REB Office Personnel are responsible for ensuring that the requirements of this SOP are met

5.0 PROCEDURES

5.1 Waiver or Alteration of Informed Consent

5.1.1 The REB may approve research without requiring that the Investigator to obtain the participants' consent where it is satisfied, and documents, that all of the following apply:

- The research involves no more than minimal risk to participants;
- the alteration to consent requirements is unlikely to adversely affect the welfare of the participant;
- It is impossible or impracticable to carry out the research and to answer the research question properly, given the research design, if the prior consent of the participant is required;
- The precise nature and extent of any proposed alteration is defined;
- Whenever possible and appropriate, after participation, or at a later time during the study, participants will be debriefed and provided with additional pertinent information;
 - Participants in such research must have the opportunity to refuse consent and request the withdrawal of their data and/or human biological materials whenever possible, practicable and appropriate
- The REB may also consider:
 - The manner in which the research data/information will be kept confidential;
 - Whether the public interest in conducting the research outweighs the public interest in protecting the privacy of the individuals; and,
 - The vulnerability of participants who do not have the capacity to consent.

5.2 Research Involving Partial Disclosure or Deception

5.2.1 In cases where the researcher wishes to withhold or partially disclose pertinent information or deceive participants, the REB may approve research that meets the requirements of a waiver or alteration of consent as described in 5.1 above.

5.2.2 Additionally, the researcher must:

- Describe the nature of the information to be withheld;
- Describe the plan for debriefing participants including:
 - an explanation of why participants received less than full disclosure and the
 - necessity for deception
 - details about the importance of the research
 - an expression of concern for the welfare of participants
 - details regarding the timing for debriefing participants.
- Prepare a script that the researcher will follow for debriefing participants.
- Obtain consent from the participant or their authorized third party prior to using the data that was obtained through partial disclosure or deception.
- Offer to remove the participant's research data if they or their authorized third party refuses to provide consent. If the research design does not allow for removal of data, the researcher must ensure that the identity of the participant is protected at all times during and following completion of the project.
- Refer participants to the REB office if they express concern about the conduct of the project at the time of debriefing or contest the limits imposed on withdrawing their data.

- Report to the REB any concerns expressed by participants related to the conduct of the project at the time of debriefing.

5.3 Waiver of Informed Consent Requirements for Emergency Research

5.3.1 The SickKids REB may approve research that will be performed in emergency settings without requiring informed consent from participants, under certain circumstances. These involve:

- Participants must be in a life-threatening situation for which available treatments are unsatisfactory/unproven,
- Need to collect valid scientific evidence to determine the safety and effectiveness of particular interventions,
- Obtaining informed consent is not feasible,
- Participants will not be able to provide their informed consent as a result of their medical condition,
- The interventions under investigation must be administered before consent from the participants Substitute Decision Maker (SDM) is feasible,
- There is no reasonable way to identify prospectively the individuals likely to become eligible for participation in the clinical investigation,
- Participation in the research must hold out the prospect of direct benefit to the participants in the study
- either the risk is not greater than that involved in standard efficacious care, or it is clearly justified by the prospect for direct benefits to the participant, and
- no relevant prior directive by the participant is known to exist.

5.4 FDA Regulated Research

5.4.1 The REB may not waive informed consent except under specific provision for emergency research per Code of Federal Regulations Title 21 part 50.24.

6.0 REFERENCES

See References