Research Ethics Board

Standard Operating Procedure

Document Number	**REB.SOP.701**
Title	Free and Informed Consent
Effective Date	September 23, 2021
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Next Administrative Review	2023

1. **Purpose**
   This standard operating procedure (SOP) describes the necessary components for free and informed consent throughout the life cycle of the research project.

2. **Definitions**
   See the MSVU **REB Glossary of Terms (REB.INFO.001)**

3. **Scope**
   This SOP pertains to REBs that review human participant research in compliance with applicable policies and guidelines.

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

   The Researcher is responsible for providing the REB with a detailed description of the rationale for the consent documents or a consent waiver. The Researcher also is responsible for providing a description of the recruitment methods and recruitment materials.

   The Researcher is responsible for providing the REB with a detailed description of the consent process and method for documenting consent and ensuring that prospective participants have sufficient information to make a free and informed decision on whether to participate in the research and whether to remain through its duration.

   The Researcher, the research sponsor and the REB are jointly responsible for ensuring that the consent form contains all of the basic elements of consent and the applicable additional elements of consent. The REB is responsible for verifying that the consent form (if applicable) contains the required elements.

   The REB is responsible for determining whether informed consent exemptions or waivers are applicable and appropriate.

The REB is responsible for verifying that the consent process will provide sufficient information to enable individuals (and/or authorized third parties) to make a free and informed decision regarding their prospective participation and continued participation throughout the duration of the research.

The REB Chair or designee is responsible for reviewing consent forms or changes to consent forms if the changes meet the criteria for delegated review.

5. Procedures and/or Specific Policies

5.1. REB Review of Required Elements of Informed Consent

5.1.1. The REB members will review the proposed consent process to ensure that prospective participants shall be able to make a free and informed decision on whether to participate in the research;

5.1.2. The Researcher will propose the method for consent (written or verbal or implied (e.g., returning a questionnaire)) and documentation with a rationale if written informed consent (i.e., informed consent form signed by participant and/or authorized third party) is not to be used.

5.1.3. The REB may approve a process that allows the informed consent document to be delivered by regular mail, fax, or email to the potential participant, and to conduct a consent interview by telephone when the participant can read the consent document as it is discussed;

5.1.4. In some types of research, the REB may approve the process of verbal consent, a verbal agreement, or a handshake, e.g., where written consent is impossible to obtain or for some groups or individuals written signed consent may be felt by the participants as mistrust on the part of the Researcher;

5.1.5. The REB will review the proposed consent documents to ensure that they contain adequate information to safeguard the privacy and confidentiality of research participants;

5.1.6. The REB may require a separate consent document for optional procedures or sub-studies (e.g., tissue, blood, genetic testing, or specimen banking, recording);

5.1.7. Following the review, the REB may approve the consent document(s) as submitted or require changes.

5.2. Incidental Findings

5.2.1. Researchers have an obligation to disclose to the participant any material incidental findings discovered in the course of research, unless it is impracticable to do so;

5.2.2. The Researcher's plan to identify and to disclose incidental findings must be submitted to the REB and approved prior to implementation;

5.2.3. For Research where material incidental findings are likely, participants may be provided with the choice to opt out of being notified.

5.3 Consent Must Precede Collection of, or Access to Data

5.3.1 Consent must be obtained from the participant or their authorized third party, before research may commence, unless a departure from the general consent

requirements is approved by the REB. This includes interaction, intervention, or access to the participant's information.

5.4 Departures from General Consent

5.4.1 The Researcher may propose an alteration to the consent process for consideration by the REB. This may include:

- Partial disclosure or deception;
- Exception to the requirement for prior consent;

5.4.2 In considering these alterations, the REB shall ensure that:

- The research involves no more than minimal risk to participants;
- The alteration is unlikely to adversely affect the welfare of participants;
- The research would be impossible or impracticable to be carried out if prior consent of participants is required;
- The precise nature and extent of any proposed alteration is defined;
- There is a described plan to debrief, and an offer to participants to refuse consent and/or withdraw data and biological materials, unless it is deemed impossible, impracticable, or inappropriate to do so;

5.5 Consent for Research in Health Emergencies

5.5.1. The REB establishes the criteria for the conduct of research involving medical emergencies prior to approval of the research. The Researcher must justify to the REB the reasons why an exception to obtaining informed consent from participants is required;

5.5.2. The REB allows research that involves health emergencies to be carried out without the free and informed consent of the participant or of their authorized third party if ALL of the following apply:

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

5.5.3. When a previously incapacitated participant regains capacity, or when an authorized third party is found, free and informed consent is sought for continuation in the project and for subsequent research-related procedures.

5.6. Decision-making Capacity

5.6.1. For research involving individuals who lack capacity to provide consent, either temporarily or permanently, the REB shall ensure that:

- Participants will be involved as much as possible in the decision-making process;
- Consent will be sought and maintained from an authorized third party, who is

not the Researcher, nor a member of the research team;
- The research will be carried out for the participant's direct benefit or for the benefit of others in the same category;
- The research is being carried out for the participant's direct benefit or for the benefit of other persons in the same category. If the benefit is only for others in the same category, exposure to the individual must be minimal and the participant's welfare must be protected throughout;

5.6.2. If the participant lacking legal decision-making capacity has some ability to understand the significance of research, they shall be given the opportunity to provide assent or dissent to participation. Dissent shall preclude participation;

5.6.3. Prospective participants who may be capable of verbally or physically assenting to, or dissenting from, participation in research include:
- Those whose capacity is in the process of development, such as children, whose capacity for judgment and self-direction is maturing,
- Those who were once capable for making an autonomous decision regarding consent but whose capacity is diminishing or fluctuating, and
- Those whose capacity remains only partially developed, such as those living with permanent cognitive impairment;

5.6.4. If assent for research is required, the Researcher must submit to the REB the proposed procedures for obtaining consent from the authorized third party and assent from the research participant. The Researcher must submit an assent form or summary of the assent process to the REB for approval;

5.6.5. When authorization for participation was granted by an authorized third party, and the participant acquires or regains capacity during the research, the Researcher will seek the participant's consent as a condition of continuing participation;

5.6.6. If an individual signed a research directive indicating their preference for ongoing and/or future participation in research, in the event that the individual loses capacity or upon their death, an authorized third party may be guided by these directives during the consent process.

5.7. Documentation of Informed Consent

5.7.1. The REB typically requires documentation of informed consent which may include:
- A consent form signed and dated by the participant or their authorized third party;
- Field notes/notation in participant record to document verbal consent;
- Actions of the participant i.e., completion and submission of a paper-based or online questionnaire;
- Audio-recording or video-recording prior to the recording of an interview;
- Other strategies approved by the REB.

5.7.2. Where there are valid reasons for not recording consent in writing, the procedures used to seek consent must be well documented;

5.7.3. A copy of the consent form or an information sheet will typically be provided to the research participant, unless doing so may compromise participant safety or confidentiality or is inappropriate in the research setting;

5.8. Consent Monitoring

5.8.1. In considering the adequacy of informed consent procedures, the REB may require monitoring of the consent process by an impartial observer;

5.8.2. Such monitoring may be particularly warranted when the research presents significant risks to participants, or if participants are likely to have difficulty understanding the information to be provided;

5.8.3. Monitoring may also be appropriate as a corrective action when the REB has identified problems associated with a particular Researcher or a research project.

5.9. Consent and Secondary Use of Identifiable Information and/or Human Biological Materials for Research Purposes

5.9.1. The REB allows the secondary use of identifiable information and/or human biological materials for research purposes without obtaining consent from research participants if the Researcher can satisfy the following conditions:

- Identifiable information/materials are essential to the research,
- The use of identifiable information/materials without the participant's consent is unlikely to adversely affect the welfare of individuals to whom the information relates,
- The Researcher will take appropriate measure to protect the privacy of individuals, and to safeguard the identifiable information/materials,
- The Researcher will comply with any known preferences previously expressed by individuals about any use of their information/materials,
- It is impossible or impracticable to seek consent from individuals to whom the information relates/materials were collected, and
- The Researcher has obtained any other necessary permission for secondary use of information/materials for research purposes;

5.9.2. In cases where the secondary use of identifiable information/materials without the requirement to seek consent has been approved by the REB, if the Researcher proposes to contact individuals for additional information and/or materials, REB approval must be obtained prior to contact.

6. References

See MSVU SOPs:

- REB.SOP.702 – Translation of Informed Consent Documents
- REB.SOP.703 – Consent Updates and Ongoing Consent

Also see References listed (if applicable)

7. Acknowledgements

The development of this document has benefited directly from similar documents made public by the Tri-Council, as well as several Canadian universities. In some instances, specific formulations drawn from these sources have been incorporated into this document. Specific iterations were drawn from the following:

- Standard Operating Procedures for Observational Health and Non-Clinical Trial Research Ethics Boards - N2/CAREB-ACCER REB SOPs – Canadian Association of Research Ethics Boards (retrieved July 2021)

- N2/CAREB-ACCER REB SOPs - N2 Network of Networks - Resources - N2 Canada (retrieved July 2021)

8. SOP History

SOP Number	Key Changes	Effective Date
REB.SOP.701	Original Version	September 2021