Research Ethics Board

Standard Operating Procedure

Document Number	**REB.SOP.703**
Title	Consent Update and Ongoing Consent
Effective Date	September 23, 2021
Next Review	2026
Next Administrative Review	2023

1. Purpose

This standard operating procedure (SOP) describes the necessary procedures for free and informed consent documents 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, REB Office Personnel, and Researchers are responsible for ensuring that the requirements of this SOP are met.

5. Procedures and/or Specific Policies

5.1. Updated Consent

5.1.1. The Researcher must inform research participants of any new information that might affect their willingness to continue their participation in the research or that may affect their long-term health even if they have completed their participation in the research, including those who have withdrawn or been removed from the study;

5.1.2. The Researcher must obtain the currently enrolled participant's consent to continue to participate if there is a significant change to the research or risk;

5.1.3. If required, written documentation of ongoing consent for currently enrolled participants may be obtained by having the research participant sign an REB approved consent document containing the updated information;

5.1.4. If applicable, ongoing consent may be obtained orally by contacting the research participant by phone, providing the updated information, and documenting their agreement to continue;

5.1.5. The nature of the provision of the new information to currently enrolled participants and the documentation required will be determined by the REB;

5.1.6. The Researcher must inform former research participants of any new information that may be relevant to their long-term health by contacting them via phone or mail or in person, as applicable.

5.2. Ongoing Consent

5.2.1. Consent is a dynamic and ongoing process, researchers are expected to maintain informed consent throughout the research project.

5.2.2. Meaningful consent encompasses a process that begins with the initial contact (e.g., recruitment) and carries through to the end of participants' involvement in the project.

5.2.3. Researchers have a responsibility to respect the autonomy of their participants throughout all stages of the research as well as provide participants with all information relevant to their ongoing consent to participate in the research.

5.2.4. This entails that researchers not only obtain initial consent from their participants, but also that participants provide ongoing consent – or at least tacit consent – throughout the duration of their participation.

5.2.5. Where possible, researchers should incorporate various mechanisms into their research design to allow for participants to change their minds regarding their participation, or continued participations, and withdraw from the study.

5.2.6. In addition to items in Section 5.1 above, Researchers shall review the consent and obtain free and informed consent from participants for each separate interaction (e.g., multiple interviews).

5.2.7. Participant must sign a revised consent form is required for new safety or risk information, or revision to study requirements, but administrative items may be managed in other ways

5.2.8. For multi-session studies where there are no changes in the research design, risk or study requirements, the informed consent should be at a minimum, reviewed and discussed with the participant(s) at each interaction.

5.2.8.1. Re-consent or ongoing consent when there has been no change in risk or study requirements do not need to be signed again, but researchers must document re-consent or ongoing consent in their relevant field notes.

5.2.9. For long-term/longitudinal studies where there are no changes in the research design, risk or study requirements, the informed consent should be at a renewed at pre-determined points of the study.

5.2.10. Participants under the age of majority when they initially provided assent, and who have reached the age of majority during the research study and are determined to have capacity to consent for their own participation, and documenting their own consent, should they wish to continue to participate.

5.2.10.1. Therefore, the regular process of consent (not assent) should take place with the individual subject for ongoing participation once the participant reaches the age of majority.

6. References

See MSVU SOPs: REB.SOP.701 – Free and Informed 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:

- N2/CAREB-ACCER REB SOPs - N2 Network of Networks - Resources - N2 Canada (retrieved July 2021)
- Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans - Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS 2 (2018) – Chapter 3: The Consent Process (ethics.gc.ca) (Retrieved July 2021)
- Ryerson University - Guidelines for Obtaining Consent and Assent (ryerson.ca) (Retrieved July 2021)

8. SOP History

SOP Number	Key Changes	Effective Date
REB.SOP.703	Original version	September 2021

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