MacEwan UNIVERSITY | RESEARCH ETHICS BOARD

SOP 701.01

Title	**Informed Consent Form: Requirements and Documentation**
SOP Code	701.01
Effective Date	September 2023

Site Approvals

Name and Title (typed or printed)	Signature	Date
Dr. Craig Kuziemsky Associate Vice-President, Research	*Original signed*	October 2020
Dr. Craig Kuziemsky, AVPR	*Original signed*	September 2023

1.0 PURPOSE

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

2.0 SCOPE

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

3.0 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 consent process, method for documenting consent, ensuring that prospective participants understand the voluntary nature of the request, 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 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.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

5.1 REB Review of Required Elements of Informed Consent

5.1.1 The REB 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) and documentation with a rationale if written documentation is not to be used. Documentation may include signed consent forms, field notes, audio or video recordings and other mechanisms as needed;

5.1.3 The REB will review the proposed consent form(s) or script(s) for general comprehension, appropriateness of the language and content and for the inclusion of the applicable elements as required. These may include:

- The individual is being invited to participate in a research study;
- The purpose of the study, researcher, funder (if applicable), duration and nature of the study, research procedures and responsibilities of participants;
- Foreseeable risks and benefits to participants and in general;
- Assurance that prospective participants are under no obligation to participate, are free to withdraw at any time without penalty or prejudice for services, will be given new information in a timely manner that may affect their decision to continue or withdraw, and information as to whether or up to what point they may withdraw data or samples;
- Possibility of commercialization of findings and the presence of any real, potential or perceived conflicts of interest;
- Measures for dissemination of research results and whether participants will be identified directly or indirectly;
- The name and contact information of a qualified designated representative who can explain the scientific or scholarly aspects of the research;
- The name and contact information of an individual outside of the research team who can be contacted regarding ethical issues that may arise;

- What information about participants will be collected and for what purposes, who will have access to information, how confidentiality will be protected, anticipated uses of information and in what situations may there be a duty to report confidential information;
- Payments to participants including incentives, reimbursement for out-of-pocket expenses and compensation in case of injury; and
- Statement that by providing consent the participant is not waiving any legal rights to recourse in case of harm;

5.1.4 The REB may require a separate consent form/script for optional procedures such as audio or video recording the research, notification of research results or material incidental findings, or for future uses of materials or data;

5.1.5 Following the review, the REB may approve the consent form(s) or script(s) as submitted or require changes;

5.1.6 When changes are required by the REB and are made by the Researcher, the REB or designee will review the consent form(s) or script(s) to confirm that the required changes have been made;

5.1.7 When the changes meet the criteria for delegated review, the revised consent will be provided to the REB Chair or designee for review and approval;

5.1.8 When changes do not meet the criteria for delegated review, the revised consent form(s) or script(s) will be reviewed at the next Full Board meeting.

5.2 Translation of Informed Consent Documents

5.2.1 The informed consent document should be in language understandable to the research participant (or acceptable representative);

5.2.2 When a research participant is non-English speaking, documentation of informed consent can be by one of two methods:

- **Written consent**: The REB approved English version of the informed consent document is translated into the research participant's native language. The REB may require that translated informed consents be accompanied by an attestation from a translator certifying that the translated informed consent accurately reflects the REB approved English informed consent. This method is preferred if it is anticipated that a significant percentage of a prospective research population is non-English speaking. A translated informed consent document does not replace the need for an interpreter to be present during the consent process and throughout the

research. The research participant will sign the translated version of the informed consent form document,

- **Oral consent**: If applicable/acceptable, a qualified interpreter fluent in both English and the research participant's native language orally interprets the REB approved English consent form to the research participant. The interpreter should be an impartial person. When the person obtaining consent is assisted by an interpreter, the interpreter must sign and date the consent form;

5.2.3 If a research participant is unable to read, an impartial witness must be present during the entire informed consent discussion. Verbal consent is obtained from the research participant after the informed consent document and any other written information is read and explained to the research participant. Signatures will be obtained from the research participant (if capable) and the impartial witness on the informed consent document, where applicable. The signature of the impartial witness attests that the information was accurately explained to, and apparently understood by, the research participant, and that informed consent was freely given by the research participant;

5.2.4 The REB requires that the translated informed consent materials be submitted for review and approval prior to use in enrolling non-English-speaking participants. The REB may require that the Researcher include a certificate or statement signed by the translator indicating that the translated materials are a true and accurate translation of the REB approved English materials;

5.2.5 The REB may follow delegated review procedures to review and approve translated informed consent materials if the English language materials have already been approved (particularly if a signed translation certificate or statement is on file);

5.2.6 An interpreter should be available to the research participant throughout the research;

5.2.7 The interpreter must sign and date the consent form attesting that the research was accurately explained to, and appeared to be understood by, the research participant.

5.3 Consent for Ongoing and Completed Research Participants

5.3.1 The Researcher must maintain ongoing consent throughout the research project. If the research extends over a long period of time, or involves multiple phases or procedures, the Researcher should periodically re-review the required information with participants and obtain verbal consent to continue;

5.3.2 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 (whether it be physical, emotional or mental health) even if they have completed their participation in the research;

5.3.3 The Researcher must obtain current participant's consent to continue to participate if there is a significant change to the research or risk;

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

5.3.5 If applicable, ongoing consent may be obtained verbally by contacting the research participant by phone or in person, providing the updated information, and documenting their agreement to continue;

5.3.6 The nature of the provision of the new information to current participants and the documentation required will be determined by the REB;

5.3.7 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.

5.4 Consent Must Precede Collection of, or Access to Data

5.4.1 Consent must be obtained from the participant or their authorized third party, before research may commence. This includes interaction, intervention or access to the participant's information.

5.5 Departures from General Consent

5.5.1 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;

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

- The alteration poses no greater than minimal risk;
- It is unlikely to adversely affect the welfare of participants;
- The research would be impossible or impracticable to be carried out if consent of participants was required;
- There is a described plan to debrief and an offer to participants to refuse consent and/or withdraw data, unless it is deemed impossible or impracticable to do so;

- That individuals in vulnerable circumstances will not be at greater risk of harm because of the alteration.

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;
- 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 to document verbal consent;
- Completion of a paper-based or online questionnaire;
- Audio-recording or video-recording prior to the recording of an interview;

5.7.2 Documentation should not be created in circumstances where evidence of participation in research may cause harm to participants;

5.7.3 A copy of the consent form, or an information sheet shall be provided to the research participant;

5.7.4 The REB may approve a short form written consent document, assent script, pictorial document or other mechanism in cases where the research participant may lack the capacity to consent. The assent process shall contain all required elements of informed consent that may be understood by the participant. Assent by the participant shall be documented through signed consent or fields notes. The assent process must be in addition to, not instead of, documentation of informed consent by the authorized third party;

5.7.5 The REB may approve a process that allows the informed consent document to be delivered by regular mail 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. All other applicable conditions for documentation of informed consent must also be met when using this procedure;

5.7.6 In some types of research, and for some groups or individuals where written signed consent may be felt by the participants as mistrust on the part of the Researcher, the REB may approve the process of verbal consent, a verbal agreement or a handshake;

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 is able to satisfy the following conditions:

- Identifiable information/materials is 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.

5.10 Broad Consent for the Storage of Data for Future Unspecified Research

5.10.1 Broad consent is used for future unspecified research. Unlike blanket consent, which is typically unrestricted, broad consent always includes specific restrictions (e.g., consent may be restricted to a particular field of study). Broad consent applies to the storage and secondary use of participants' data collected for research purpose, with no direct contact or intervention with participants at that time. While blanket consent is not permitted under the TCPS, broad consent is permitted.

5.10.2 To seek broad consent for the storage and future unspecified use of data, researchers shall provide prospective participants, or authorized third parties, with applicable information as set out in Articles 3.2 and 12.2, as well as the following details, as appropriate to the particular research project:

a. the type, identifiability, and amount of data and human biological materials being collected and stored for re-use, and for what potential purpose;
b. the voluntariness of the participant's consent, including any limitations on the feasibility of withdrawal;
c. a general description of the nature and types of future research that may be conducted, including whether the research might be conducted outside of Canada (if known);
d. the risks and potential benefits of storage of data and human biological materials, and of their use in future unspecified research, including areas of uncertainty where risks cannot be estimated;
e. access to a general description of the repository and its governance;
f. a statement regarding participants' preference to being re-contacted for additional future research;
g. whether the data or human biological materials could be shared with researchers who are not subject to the TCPS;
h. whether the research will (if known) or might include whole genome sequencing or similar technologies that may pose a substantial risk of re-identification of the participant or identification of material incidental findings (when appropriate);
i. whether linkage of data gathered in the research or derived from human biological materials with other data about participants – either contained in public or personal records – is anticipated (Article 5.3); and
j. separate options for consenting to participate in a specific research project and for consenting to the storage of data and human biological materials for future unspecified research.

5.11.3 It must be made clear to participants that they can choose to participate in the current study, but it is optional to consent to the storage, sharing and use of their data for future research.

5.11 Consent by Head of Family or Community

5.11.1 In cultures where consent to participate in research must be obtained by the participant's family head or community head, the Researcher should propose a consent process to the REB that will include free and informed consent of the family or community head as well as of the prospective participant;

5.11.2 The Researcher must ensure that the prospective participant is able to provide free and informed consent to participate without coercion or undue influence by the family or community head;

5.11.3 Consent by the family or community head alone is insufficient for the research to proceed.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
701.00	October 8 2020	Original version
701.01	September 2023	Removal of incidental findings, added new requirements for the broad consent for the storage of data for future unspecified research.