Yukon University

SOP 701

Procedures: Human Research Ethics	SOP 701 Informed Consent Form Requirements and Documentation
Associated Policy	Human Research Ethics Policy AR-03
Procedure Holder	Associate Vice President Research
Executive Lead	Research Services
Approval Authority	President
Original Date	Replaces AR-03 procedures (May 2009, Oct. 2014)
Effective Date	July 2022

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 the YukonU REB that review human participant research in compliance with applicable policies and guidelines.

3.0 RESPONSIBILITIES

All REB members and Research Ethics Coordinator 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 a 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 also is responsible for providing a description of the recruitment methods and recruitment materials (if applicable).

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 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 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 form to ensure that it contains adequate information to safeguard the privacy and confidentiality of research participants;

5.1.6 The REB may require a separate consent form for optional procedures or sub-studies;

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

5.1.8 When changes are required by the REB and are made by the Researcher, the REB will review the consent form(s) to confirm that the required changes have been made and that the version date has been updated;

5.1.9 When the changes meet the criteria for delegated review, the revised consent will be provided to the REB Co-Chairs or designee for review and approval

5.1.10 When changes do not meet the criteria for delegated review, the revised consent form will be reviewed at the next Full Board meeting.

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 The REB may approve a consent procedure that does not include, or which alters, some or all of the elements of informed consent, or waive the requirements to obtain informed consent, provided that the REB finds and documents that:

- The research involves no more than minimal risk to the participants,
- The waiver or alteration is unlikely to adversely affect the rights and welfare of the participants,
- The research would be impossible or impracticable be carried out without the waiver or alteration,
- The precise nature and extent of any proposed alteration is defined,
- The information is used in a matter that will ensure its confidentiality,
- There is a described plan to debrief, and an offer to participants to refuse consent and/or withdraw data, 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 his/her 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 permanently or temporarily, the REB must 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 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. Assent from a participant is not sufficient to permit them to participate in a research project in the absence of consent by an authorized third party; however, their expression of dissent is respected;

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 capable substitute decision maker 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.

5.6.7 Other Individuals and Groups who may be Vulnerable in the Context of Research

- e REB will determine appropriate protections for individuals and groups who might be inappropriately excluded from research on the basis of attributes such as culture, language, sex, race, ethnicity, age and disability, and who require additional protections. For these individuals and groups the REB will take into account the risks and benefits of the research, and will consider protections afforded by organizational policies, and provincial and federal law. Other individuals or groups whose circumstances may make them vulnerable in the context of research should not be inappropriately included or automatically excluded from participation in research on the basis of their circumstances;
- In addition, when the REB regularly reviews research involving individuals, groups or populations who may be vulnerable in the context of research, consideration shall be given to the inclusion of one or more individuals who are knowledgeable and experienced in working with these participants. Participants may include, but are not limited to:
  - Children,

- The Elderly,
- Individuals with mental illness,
- Pregnant women,
- Individuals with limited language skills,
- Indigenous individuals and communities
- Prisoners;

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 the participant's authorized third party; and by the person obtaining consent;
- Field notes/notation in participant record to document verbal consent;
- Actions of the participant i.e., completion 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 documented;

5.7.3 A copy of the signed consent form shall 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 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, or their communities (e.g. geographical community, First Nation or other Indigenous group, or other identity group associated with the research)
- The Researchers will take appropriate measure to protect the privacy of individuals, and to safeguard the identifiable information/materials,
- The Researchers 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 Researchers have 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 Consent by Head of Family or Community

5.10.1 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;

5.10.2 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;

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

5.11 Consent Update for Ongoing and Completed Research Participants

5.11.1 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 wellbeing even if they have completed their participation in the research, including those who have withdrawn or been removed from the study;

5.11.2 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;

5.11.3 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;

5.11.4 If applicable, ongoing consent may be obtained orally by contacting the research participant by phone or web-conferencing software, providing the updated information, and documenting their agreement to continue;

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

5.11.6 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.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP 701	July 2022	YukonU version adapted from N2/CAREB SOP 701.003 (October 8, 2019) and CAREB 701.001 (2021)