Yukon University

SOP 601

Procedures: Human Research Ethics	SOP 601 Communication – Researcher
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 routine communication procedures between the Research Ethics Board's (REB) and the Researcher and with their research team.

2.0 SCOPE

This SOP pertains to the Yukon University (YukonU) REB that reviews human participant research in compliance with applicable policies and guidelines.

3.0 RESPONSIBILITIES

All REB members and the Research Ethics Coordinator are responsible for ensuring that the requirements of this SOP are met.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

For effective human research participant protection, it is important for the REB, Research Ethics Coordinator, Researcher and research team to maintain open communication. This applies not only to communication related to a specific research project, but also to communication related to questions, concerns, ethical issues and REB processes, policies and procedures. Feedback from Researchers should be encouraged and should be considered as an opportunity to review and to improve the function of the REB and of the Research Ethics Office procedures.

In order to facilitate clear and accurate communication with Researchers and research staff, the REB will follow standardized notification and documentation procedures. All REB decisions regarding specific research projects shall be documented in writing. Informal communications

between the Researcher or research team and REB Co-Chairs or Research Ethics Coordinator may occur through email, over the phone or in person. Documentation should be created to ensure accurate reflection of discussions for future reference. All Researchers participating in REB approved research shall be informed, in writing, of all determinations made by the REB regarding specific research.

5.1 Notification of REB Decisions

5.1.1 The REB will notify the Researcher and/or their research staff of the REB's decision within 2 weeks following the review (i.e., from the REB meeting or delegated review) date of new research, modifications, or amendments to currently approved research, applications for continuing review or unanticipated events;

5.1.2 The determinations of the REB will be summarized noting any concerns or requests for clarification including recommended changes to the consent form, and clarifying the reasons for the disapproval of the submission (when appropriate);

5.1.3 If the research does not receive initial approval or is denied re-approval (for continuing review), the REB Co-Chairs or designee will notify the Researcher of the REB's decision as soon as possible following the REB meeting. Formal written notification will follow;

5.1.4 The REB Co-Chairs or designee will review the draft REB review letter, make revisions as necessary, and will indicate their approval;

5.1.5 The REB review letter will be sent to the Researcher(s);

5.1.6 The Researcher may be asked to include the REB number or title to the research in all subsequent correspondence with the REB;

5.1.7 Upon receipt of the Researcher response to the REB review letter, the REB or Research Ethics Coordinator will follow-up with the Researcher and/or their staff to request any additional clarifications as needed, or as requested by the REB Co-Chairs or designee, or the reviewers;

5.1.8 Once all of the REB conditions are satisfied, the REB will issue a Certificate of Approval. Included in the Certificate of Approval is the study title and REB number, name of Principal Investigator and any co-investigator(s), and team members, funding agency, study sites and a list of approved documents with version numbers if applicable.

5.2 Researcher Consultation

5.2.1 A Researcher and/or research team may request advice, guidance or clarification with the REB Co-Chairs, designee or Research Ethics Coordinator for current for future research projects. Such consultations may involve communications through email, phone or in person.

5.2.2 REB Co-Chairs, designee or Research Ethics Coordinator will document such consultations in writing, including date, who was present and a brief description of what the concerns were and how they were addressed. Such documentation should be kept by the Research Ethics Coordinator for future reference if needed.

5.2.3 A Researcher may request a reconsideration or appeal the decision of the REB and/or any of the revisions to the research requested by the REB;

5.2.4 Appeals are conducted in accordance with established YukonU procedures (SOP 409) and the agreements that are established with other REBs for appeals review;

5.2.5 Only the REB may lift a restriction or re-review previously disapproved research. Delegated review procedures may not be used.

5.3 Communications Concerns Non-compliance

Researcher non-compliance may be the result of communication difficulties. The REB will attempt to resolve apparent instances of non-compliance without interrupting the conduct of the study, especially if the rights and welfare of participants may be jeopardized.

However, if it appears that a Researcher is intentionally non-compliant with the protocol, SOPs, TCPS2, REB, and/or other applicable requirements, the REB, through the REB Co-Chairs or designee, will notify the Researcher in writing, detailing the alleged non-compliance, specifying corrective action, and stating the consequences. Such actions may be the result of an onsite audit conducted by the Research Ethics Office. When appropriate, copies of such correspondence shall also be sent to the Researcher's supervisor and/or Department Head, study Sponsor/Funding Agency and the Associate Vice-President Research.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP 601	July 2022	YukonU version adapted from N2/CAREB SOP 601.003 (October 8, 2019) and CAREB 601.001 (2021)

Yukon University

SOP 602

Procedures: Human Research Ethics	**SOP 602 Communication – Research Participants and Members of the Public**
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	March 2022

1.0 PURPOSE

This standard operating procedure (SOP) describes the Research Ethics Board's (REB) communication with research participants and members of the public.

2.0 SCOPE

This SOP pertains to the Yukon University (YukonU) REB 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.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

Research participants and members of the public should be able to voice their concerns or questions and request information regarding participation or potential participation in research, in confidence, to an informed individual on the REB or in the REB office.

The REB is required to communicate certain items to those that may have an interest in the status of the research being done. Procedures should be established for prompt reporting

to the REB, institutional officials and where applicable, funding agencies and Sponsors. This includes reporting of:

- Serious adverse events or unanticipated problems
- Serious or continuing non-compliance with policies, protocols or REB requirements;
- Suspension or termination of research

Specific procedures for investigating and making determinations about these issues are addressed in SOPs 407 and 409.

5.1 Communication with Research Participants

Research participants should be able to communicate their concern, questions or request information regarding their participation or potential participation in research, in confidence to an informed individuals on the REB or to the Research Ethics office.

5.1.1 Research participants are encouraged to contact (by telephone or in writing) the Research Ethics office with questions and concerns, by using the contact information provided in the informed consent document(s) or recruitment materials, or through the YukonU website or directory. If requested to remain anonymous, the Research Ethics Coordinator will try to grant this request, or explain why this is not possible. If they are willing to share their identity then it will only be shared with the REB Co-Chairs and with the organization's appropriate representative, if applicable;

5.1.2 Each consent form approved by the REB must contain institutional contact information for participants who wish to discuss their rights as research participants and/or concern about the conduct of the study approved by the REB. Should the expressed concern require further consideration, the REB Co-chairs and/or the Research Ethics Coordinator may request an on-site review of the study;

5.1.3 The Research Ethics Coordinator will communicate participant concerns to the REB Co-Chairs or designee, where appropriate;

5.1.4 The REB Co-Chairs or designee works to answer or resolve participant issues or concerns, which may include a follow-up with the Researcher or the Researcher's supervisor or other organizational representative, or with appropriate federal agencies, as applicable;

5.1.5 The REB Co-Chairs or designee or Research Ethics Coordinator documents all communication with the research participant and a de-identified record of this communication is maintained securely and in the relevant research file in the Research Ethics Office.

5.1.6 If a study is suspended or discontinued for safety reasons or for non-compliance, the REB may require the Researcher to inform study participant in writing of the reasons for study suspension or discontinuation and any actions that should be taken by the participant to ensure safety and wellbeing.

5.2 Communication with Members of the Public

5.2.1 Members of the public may contact the Research Ethics Office with questions or concerns with respect to a research project, a Researcher or field of research they may become aware of through recruitment procedures, social networks or the media.

5.2.2 The Research Ethics Coordinator should actively listen and prompt the individual for sufficient information to understand the nature of the question or concern, who should be involved in answering or resolving it, and in the case of a complaint, what the person considers to be an acceptable answer or resolution;

5.2.3 The Research Ethics Coordinator will communicate the individual's questions or concerns to the REB Co-Chairs or designee, as appropriate;

5.2.4 The REB Co-Chairs or designee may consult with YukonU representatives on an appropriate response. The YukonU public relations department may be contacted if a formal response is required.

5.3 Communication with Others

5.3.1 Suspension of a study "for cause":
The REB will notify the Researcher's Department/Division Head and the Associate Vice-President Research.

If it is appropriate or required by contract, policy, or applicable regulations, the REB will also report the suspension to the study sponsor, the REBs at other institutions conducting the same study, and to applicable regulatory agencies;

5.3.2 Finding of a material conflict of interest:
If the REB determines that a material conflict of interest exists which is likely or may be perceived as compromising the safety, wellbeing or rights of study participants, and if the REB and the Researcher cannot reach agreement on how the conflict of interest will be managed the REB Co-Chairs will inform the Researcher's Department/Division Head and, if applicable, the Associate Vice-President Research;

5.3.3 Communication to Yukon University Official of REB Actions:

Minutes of all YukonU REB meetings will be prepared and maintained by the Research Ethics Coordinator Office and will be made available to appropriately authorized personnel if required;

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP 602	July 2022	YukonU version adapted from N2/CAREB SOP 602.003 (October 8, 2019) and CAREB 602.001 (2021)

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)

Yukon University

SOP 702

Procedures: Human Research Ethics	**SOP 702 Recruitment**
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 appropriate strategies for recruitment of prospective research participants.

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 recruitment methods and materials (if applicable) and ensuring that prospective participants and their rights to privacy are respected through the recruitment process.

The REB is responsible for verifying that the recruitment process is appropriate for the research and the prospective participant population.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

5.1 REB Review of Recruitment Process and Materials

5.1.1 The REB shall review the proposed recruitment process to ensure that the rights of prospective participants to privacy will be respected.

5.2 Recruitment Methods

5.2.1 **Indirect Recruitment:** Recruitment shall be done by indirect methods where the prospective participant is made aware of the research without interaction with the research team. Indirect methods may include:

- Posted written materials such as flyers, posters, advertisements
- Mass emails
- Postings on social media
- Presentations to groups;

5.2.2 **Direct Recruitment:** Recruitment shall be conducted by a member of the research team that does not have a conflict of interest or a power relationship with prospective participants. In some circumstances, this may be the Researcher;

5.2.3 **Databases:** The Researcher shall utilize contact information from prospective participants in the database in accordance with the conditions of consent to be contacted for research that they provided;

5.2.4 **Snowball Sampling:** Participants or informants shall provide information from the Researcher to individuals they know that may fit the inclusion criteria. These individuals may then contact the research team directly, if interested in participating;

5.2.5 **Participants known to the researcher**: If the potential participant has an academic, professional, social, or other connection to the Researcher, the Researcher may approach the potential participant directly, but in such a manner that the potential participant does not feel pressured or obligated in any way. In this instance, the participant's consent should be obtained by an individual other than the Researcher. Any exceptions to this procedure must be appropriately justified and submitted to the REB for review;

5.2.6 **In circumstances where the Researchers will obtain consent**: The Researcher must ensure that the consent has been obtained without undue coercion or influence and that there is no likelihood of social, professional or academic misconception, if applicable;

5.2.7 **Referrals:** The Researcher may send a letter to colleagues asking for referrals of potential participants (e.g. YukonU instructors or staff may be asked to refer students). The Researcher may provide colleagues with an REB approved consent form or research information sheet to give to their potential participants. The potential participant will then be asked to contact the Researcher directly, or, with

documented permission from the potential participant, the Researcher may initiate the contact;

5.2.8 **Yukon University Student Records**: The Researcher may ask the Yukon University to identity students who appear to meet the research's eligibility criteria. The Researcher should supply Yukon University with a standard letter describing the research and an invitation to participate that Yukon University may circulate to eligible students. It is NOT acceptable for the Researcher or their staff to contact students identified through Yukon University student records, or other databases independently by any means, unless the student has previously agreed;

5.3 Recruitment Materials

5.3.1 The REB shall review the recruitment materials or information to ensure there is no evidence of coercion or undue influence and that the materials are consistent with the proposed research and informed consent materials;

5.3.2 Advertisements, notices or media messages should be reviewed by the REB, as applicable, and according to REB requirements;

5.3.3 All recruitment materials must be approved by the REB and by each organization where the recruitment material will be displayed, as per local practice prior to their use.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP 702	July 2022	YukonU version adapted from N2/CAREB SOP 702.001 (April, 2019)

Yukon University

SOP 801

Procedures: Human Research Ethics	**SOP 801 Researcher Qualifications and Responsibilities**
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

The purpose of this standard operating procedure (SOP) is to describe the qualifications and responsibilities of the Researcher who engages in research involving human participants.

2.0 SCOPE

This SOP pertains to the YukonU Research Ethics Boards (REB) that review human participant research in compliance with applicable policies and guidelines.

3.0 RESPONSIBILITIES

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

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

Research involving human participants must be conducted by individuals with the appropriate education, training, and experience required to assume responsibility for the proper conduct of the research and for the protection of human research participants. The REB should have assurance that the qualifications of new Researchers, for the conduct of research, are appropriate.

Researchers are required to conduct the research in compliance with applicable policies and guidelines, and to comply with all REB requirements.

5.1 **Researcher Qualifications**

5.1.1 The Researcher must make available to the REB their current CV which should include their relevant training and experience, in sufficient detail for the REB to make an objective judgment regarding the Researcher's qualifications, if necessary;

5.1.2 The Researcher must have completed appropriate training regarding the requirements of conducting and overseeing research and should have sufficient expertise in the discipline and methods of the proposed research.

5.1.3 The Researcher and all team members named on an application are required to complete the TCPS2 CORE Tutorial.

5.1.4 If applicable, the Department Head or their designee must approve the application to the REB;

5.1.5 The organizational approver's signature attests that:

- They are aware of the proposal and supports its submission for REB review,
- The application is considered to be feasible and appropriate,
- Any internal requirements have been met,
- The Researcher is qualified and has the experience and expertise to conduct this research,
- The Researcher has sufficient space and resources to conduct this research;

5.1.6 Any concerns raised in the REB review of the Researcher's qualifications will be communicated to the Researcher and must be satisfied prior to REB approval of the application.

5.2 **Researcher Responsibilities**

5.2.1 The Researcher is responsible for complying with the decisions and responsibilities set out by the REB. In addition, it is the Researcher's responsibility to comply with all applicable requirements and ensure that (if applicable):

- They and their staff members are appropriately qualified by education, training and experience to assume responsibility for the proper conduct of the research and for protection of human research participants,
- They have adequate resources to properly conduct the research and conduct the research following acceptable practices,
- All real, potential, or perceived conflicts of interest are declared to the REB at the time of the initial application, and as they arise,
- The REB review and approval is obtained before engaging in research involving human participants,
- All necessary documentation is signed by the responsible Researcher, as applicable,

- Informed consent, when required, is obtained from participants in accordance with applicable regulations prior to their enrollment into the research, and using the most current informed consent document(s) approved by the REB (as applicable),
- They personally conduct or supervise the described research,
- The research is conducted in compliance with the approved protocol and applicable reporting criteria are reported to the REB, including deviations, unanticipated adverse events and privacy breaches,
- Any changes in the approved research are not initiated without REB review and approval, except where necessary to eliminate an immediate hazard(s) to the participant(s),
- Premature termination or suspension of the research is reported to the REB;
- Accurate and complete records are maintained according to applicable regulatory requirements,
- Written summaries of the research status are submitted to the REB at least annually, or more frequently if required by the REB, and an application for continuing review (renewal) is submitted to the REB prior to the expiration of REB approval,
- Any other unexpected finding or new research knowledge that could affect the risk/benefit ratio of the research is reported to the REB,
- The REB is notified if there is a change in Researcher or research team,
- The REB is notified when the research is complete (study closure form).

5.3 The researchers' primary Department/Division within YukonU is responsible for maintaining current CVs for each of its Researchers. The Researchers' Department/Division is also responsible for immediately advising the REB should it become aware of any information that would indicate that the qualifications of the Researcher may no longer be appropriate.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP 801	July 2022	YukonU version adapted from N2/CAREB SOP 801.003 (October 8, 2019) and CAREB SOP 801.001 (2021)

Yukon University

SOP 901

Procedures: Human Research Ethics	SOP 901 Quality Assurance Visits
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 processes for evaluating and improving the effectiveness of the human research protection program.

2.0 SCOPE

This SOP pertains to the YukonU Research Ethics Boards (REB) that review human participant research in compliance with applicable policies and guidelines.

3.0 RESPONSIBILITIES

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

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

Quality Assurance (QA) activities, such as periodic assessments of REB and research activities, allow for a continuous evaluation and subsequent assurance of the human research protection enterprise.

Findings are measured against established policies and procedures and all of the applicable ethical, legal, and regulatory requirements. When areas for improvement are identified, corrective action is taken including training, education, and the revision of SOPs.

5.1 Quality Assurance Assessments of the REB

5.1.1 The YukonU Quality Assurance (QA) officer or designee will develop a schedule for routine QA assessments of the REB and the Research Ethics Office in response to requests from the REB, Researcher or Organizational representatives;

5.1.2 QA assessments may be conducted by members of the Research Ethics Office, or by other YukonU personnel. REB members may be directly or indirectly involved;

5.1.3 When the QA Officer or designated individual conducts a QA assessment of the REB and the Research Ethics Office the evaluation may including the following:

- An assessment of the SOPs and compliance with applicable policies, guidelines and regulatory requirements,
- A review of research files, REB membership rosters, REB attendance records, and REB agendas and minutes,
- A review of workload, performance metrics and annual reports,
- A review of stakeholder satisfaction surveys,
- An assessment of quality control procedures for compliance with the SOPs,
- A review of checklists, forms, and templates,
- Interviews with REB members, REB Office Personnel and Researchers,
- A review of training/education records,
- A review of all continuous improvement activities,
- An assessment of whether any new requirements (ethical, legal, or regulatory) were incorporated into the policies and procedures,
- A review of the status of any corrective action items from previous reviews,
- A review of any deviations from ethical, legal, or regulatory requirements, or deviations from the Organization's policies, and whether the deviations require remediation,
- An assessment of compliance with all applicable requirements;

5.1.4 The QA Officer or designate, compares the findings against established policies, SOPs and applicable ethical, legal, and regulatory requirements;

5.1.5 The QA Officer or designate prepares a written summary of the assessment, including areas requiring improvement;

5.1.6 The QA Officer or designate reports the findings to the REB Co-Chairs or designee, and to the REB and/or to the appropriate YukonU Official as required;

5.1.7 The QA Officer or designee works with the REB Co-Chairs or designee to implement improvements (e.g. new or revised SOPs or forms, training, education, additional resources or modifications to existing resources).

5.2 Researcher Quality Assurance Visits

5.2.1 The QA Officer or designee will develop a schedule for routine QA visits and implement visits in response to Researcher requests;

5.2.2 The QA Officer or designee will work with the REB and the Organization at which the research is being conducted to determine if and when a for-cause visit of a Researcher is warranted;

5.2.3 The REB may direct the QA Officer /designee to conduct for-cause visits;

5.2.4 The QA Officer or designee may request that a pre-visit questionnaire is completed by the Researcher;

5.2.5 The criteria for selecting Researchers or research projects for visit may include:

- The results of a previous QA visit,
- Studies that involve a potentially high risk to participants,
- Studies that involve vulnerable populations,
- Studies in which Researchers are enrolling large numbers of participants,
- Suspected non-compliance,
- Unanticipated problems involving risks to participants or others,
- Suspected or reported protocol deviations,
- Research terminated by the REB due to failure by the investigator to submit the study for continuing review or failure to respond to a request for information from the REB,
- Studies reporting a large number of serious adverse events/unanticipated problems and/or protocol deviations,
- Participant complaints,
- Research Staff complaints,

- Any other situation that the REB deems appropriate;

5.2.6 The QA Officer or designee will notify the Researcher of the visit to review the research project and a mutually acceptable time will be scheduled. It may be necessary to schedule a visit without first obtaining the formal consent of a Researcher (e.g., participant safety or suspected non-compliance);

5.2.7 The QA Officer or designee will conduct a review of the research project using designated/appropriate evaluation tools;

5.2.8 When the QA Officer or designee conducts a review of the research project, the review may include some or all of the following (as applicable):

- An assessment of the SOPs and compliance with applicable policies and guidance,
- A review of REB approved documentation,
- Interviews with the Researcher and research team,
- A review of specimens and associated collection processes,
- A review of computer hardware and/or software associated with the research,
- A review of the consent documents and/or processes including eligibility requirements,
- A review of data collection mechanisms,
- A review of appropriate source material (e.g., participant medical records), and
- A review of other documentation, as relevant and available;

5.2.9 The REB or the QA Officer/designee may choose to have a qualified impartial observer to monitor the consent process or to interview research participants;

5.2.10 At the conclusion of the evaluation, the QA Officer or designee will discuss the findings with the Researcher;

5.2.11 The QA Officer or designee will draft a report or provide a summary of the inspection including positive findings, areas for improvement and recommendations for corrective action, and submit the report to the REB Co-Chairs or designee for review;

5.2.12 The Researcher will be given an opportunity to respond to the report with

responses and/or corrective action plans within a time specified by the REB;

5.2.13 The QA Officer or designee will send a copy of the final report to the Researcher and the REB Co-Chairs. When applicable, the REB Co-Chairs or designee will provide the findings to the Associate Vice-President Research (AVPR).

5.3 Corrective Action

5.3.1 The QA Officer or designee may recommend corrective action based on the findings;

5.3.2 Corrective action may include a recommendation for the provision of additional resources, training, or education, the development of, or revisions to the SOPs, and changes to forms, checklists or templates;

5.3.3 The QA Officer or designee will evaluate the effectiveness of the implemented improvements and adjust processes accordingly;

5.3.4 The QA Officer or designee will follow-up with the Researcher in a timely manner to determine if the corrective actions have been implemented by the Researcher following a research project quality assessment visit.

5.3.5 Upon completion of the review, the collected data will be analyzed and a written report generated. The report will specifically address all findings, itemizing and describing all of the observations of non-compliance (if any) made during the conduct of the inspection, along with the corresponding regulatory references and required remedial actions, if necessary. For directed audits, the report will include an assessment of whether the preponderance of evidence shows that any of the allegations of noncompliance are findings of non-compliance. If the audit results in findings of noncompliance, the Research Ethics Coordinator will recommend an appropriate course of action to the applicable REB Co-Chairs and, if appropriate, the AVPR;

5.4 Documentation

5.4.1 The QA Officer or designee files all reports and correspondence concerning QA visits in the appropriate QA Files.

6.0 6.0 REFERENCES

See References.

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP 901	July 2022	YukonU version adapted from N2/CAREB SOP 901.003 (October 8, 2019) and CAREB 901.001 (2021)

Yukon University

SOP 902

Procedures: Human Research Ethics	SOP 902 Non-Compliance
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 YukonU's Research Ethics Board (REB) process for responding to reports of non-compliance and the actions that the REB may take as a result of its review of reports of serious and/or continuing non-compliance. Non-compliance is defined as a failure to follow applicable guidelines and regulations governing human participant research and/or failure to follow the protocol approved by the Research Ethics Board (REB), or stipulations imposed by the REB as a condition of approval.

2.0 SCOPE

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

3.0 RESPONSIBILITIES

All REB members, the Research Ethics Coordinator and Researchers are responsible for ensuring that the requirements of this SOP are met.

Researchers are required to comply with all of the applicable policies. guidelines and other requirements governing the conduct of human research, as well as with the required conditions of approval of the REB.

The Research Ethics Coordinator and the REB members are responsible for acting on information or reports of non-compliance received from any source.

The REB Co-Chairs or designee is responsible for the initial review of allegations of non-compliance.

If intentional, serious or continuing non-compliance is established, the REB is responsible for determining the relevant corrective actions, as pertains to the ethical review of the research.

The REB is responsible for reporting any incidents of serious or continuing non- compliance to the Researcher and to the appropriate Department/Division Head, as well as the Associate Vice-President Research. The REB may direct the report to the YukonU Official as an allegation of breach of responsible conduct of research.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

Information of potential incidents of non-compliance may come from any source including the REB members, Researchers, research participants, organizational personnel, the media or the public. The rights and welfare of research participants could be at risk if there were serious or repeated non-compliance on the part of a Researcher or any member of the research team. It is, therefore, the duty of the REB to be receptive to these reports and to act on all credible allegations of non-compliance.

5.1 Reports of Non-compliance

5.1.1 Persons raising such concerns are encouraged to express them in writing. However, the Research Ethics Coordinator office will receive and document oral reports of non-compliance;

5.2 Evaluating Allegations of Non-compliance

5.2.1 When an allegation of non-compliance is referred to the REB, the Research Ethics Coordinator will document the information and the contact details of the person reporting the allegation, and immediately refer the incident to the REB Co-Chairs or designee;

5.2.2 The REB Co-Chairs or designee manages all allegations of non-compliance and reports of non-compliance that are determined to be more than minor;

5.2.3 The REB Co-Chairs or designee will conduct an initial review of all allegations to determine whether further investigation is necessary and may involve other Organizational personnel as required to make this determination;

5.2.4 The REB Co-Chairs or designee will obtain as much information as possible from the individual reporting the incident;

5.2.5 The REB Co-Chairs or designee will obtain as much information as possible, or verification from other sources by one or more of the following means:

- Contacting the Researcher,
- Consulting with other relevant organizational personnel,
- Collecting relevant documentation,
- Reviewing any written materials,
- Interviewing knowledgeable sources;

5.2.6 If the REB Co-Chairs or designee determines that there is evidence of non-compliance, they will then assess whether the non-compliance was intentional, serious and/or repeated;

5.2.7 If the REB Co-Chairs or designee determines that there is no or insufficient evidence to support the allegations, no further action will be required.

5.3 Managing Non-compliance

5.3.1 The REB will attempt to resolve apparent instances of non-compliance without interrupting the conduct of the research, especially if the rights and welfare of participants may be jeopardized by interrupting the research;

5.3.2 If the REB Co-Chairs or designee determines that the non-compliance was not serious or repeated, and the research staff recognized the non-compliance and took appropriate corrective actions, no further action may be required;

5.3.3 If the REB Co-Chairs or designee determines that the non-compliance was not serious or repeated, but the research staff did not recognize the non-compliance or take appropriate corrective actions, the REB Co-Chairs or designee may discuss the matter directly with the Researcher, recommend corrective action, request a Quality Assurance visit, and/or refer the matter to the REB at a Full Board meeting;

5.3.4 If it appears that a Researcher was intentionally non-compliant, the REB Co-Chairs or designee may suspend the conduct of the research immediately and refer the matter to the next Full Board meeting of the REB and inform the YukonU Official responsible for receiving allegations of breaches of responsible conduct of research;

5.3.5 The REB will review the information at the next Full Board meeting and determine the appropriate corrective actions that fall within its mandate;

5.3.6 Corrective actions are based upon the nature and the degree of the non-compliance. In evaluating the non-compliance, the REB may consider one or more of the following actions:

- Request modification of the protocol,
- Request modification of the informed consent documents,
- Require that additional information be provided to past participants,

- Require that current participants be notified,
- Require that current participants re-consent to participation,
- Modify the continuing review schedule,
- Require onsite observation of the consent process,
- Suspend the new enrollment of participants,
- Suspend REB approval of the research,
- Suspend Researcher involvement in the research,
- Terminate REB approval of the research,
- Require the Researcher and/or staff complete a training program,
- Notify organizational personnel (e.g., legal counsel, risk management),
- Ensure that all other regulatory reporting requirements are met, as required,
- Any other action deemed appropriate by the REB.

5.4 REB Response to Reports of Non-compliance

5.4.1 The REB Co-Chairs or designee will notify the Researcher in writing of the results of the REB review of incidents of non-compliance and any remedial actions required;

5.4.2 The REB Co-Chairs or designee will report any serious or continuing non-compliance to the Researcher as well as to the appropriate YukonU Official(s);

5.4.3 The REB may submit an allegation of research misconduct to the Department/Division Head and Associate Vice-President Research as appropriate;

5.4.4 The REB will request a time-sensitive response in writing from the Researcher, including the corrective action plan;

5.4.5 The Researcher's response may be reviewed using a delegated REB review procedure or the review may be referred to the REB, for a decision from the Full Board;

5.4.6 The REB Co-Chairs or designee will follow-up to assess any corrective measures implemented by the Researcher.

5.5 Documenting Non-compliance

5.5.1 The REB Co-Chairs or designee will document the findings of reports of non-compliance. The report will include the allegations, the information obtained during the initial assessment, whether allegations of non-compliance were verified, the REB's decision and actions taken, and the Researcher's response;

5.5.2 For those incidents of non-compliance referred to the Full Board, the Research Ethics Coordinator will document the following in the REB meeting minutes: a

description of the incident and findings, verification of the non-compliance, the REB's decision, the remedial action required by the REB, the Researcher's response and actions implemented and plans for further follow-up.

5.5.3 The REB Co-Chairs or designee will document cases where the non-compliance was referred to the Organizational Official responsible for allegations of breaches of responsible conduct of research and will follow-up with the official to ensure that they have received information on outcomes of an inquiry or investigation that could be relevant to the REB's decision-making on the Research.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP 902	July 2022	YukonU version adapted from N2/CAREB SOP 903.003 (October 8, 2019) and CAREB 902.001 (2021)