Yukon University

# SOP 404

| Procedures: Human Research Ethics | SOP 404 Ongoing REB Review Activities |
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| **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 procedures for REB review ongoing research activities that occur after the initial Research Ethics Board (REB) approval of a research project and prior to the formally scheduled continuing review of the research project.

## 2.0 SCOPE

This SOP pertains to the YukonU REB that review human participant research in compliance with applicable regulations and guidelines. It pertains to all research submitted to the YukonU REB.

## 3.0 RESPONSIBILITIES

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

The Researcher is responsible for reporting to the REB any unanticipated issues or events that may arise or proposed changes that are needed through the course of the research that might affect the rights, safety and well-being of research participants.

When action is taken to ensure the protection of the rights, safety, and well-being of participants (e.g., for an unanticipated problem involving risks to participants or others) the REB is responsible for reporting to the Researcher and the Organizational Official(s) and has the authority to notify the sponsor and/or the appropriate regulatory authorities of any events that meet the reporting criteria. The REB may delegate regulatory authority reporting (as applicable) to the organization.

The REB Co-Chairs or designee is responsible for reviewing all reportable events submitted to the REB as well as any proposed amendments to the research, and for determining the type of review (i.e., delegated or Full Board) or action required.

The REB members are responsible for reviewing any new information, reportable events or proposed amendments that are assigned to them or that are assigned to a Full Board meeting, and for recommending the appropriate course of action.

## 4.0 DEFINITIONS

See Glossary of Terms.

## 5.0 PROCEDURE

Circumstances may arise during the course of research that may need to be reported to the REB and/or require that changes be made to the project. It may be that the real risk/benefit ratio can be evaluated only after the research has begun; therefore, in addition to the formally scheduled continuing review, the REB must receive and review any new information generated throughout the course of the research that might affect the rights, safety and well-being of research participants. Such information may include:

- Proposed amendments to the previously approved research,
- Reports of unanticipated problems involving risks to participants or others,
- Reports of any serious or continuing non-compliance,
- Deviations to the previously approved research,
- Adverse events that meet the reporting criteria,
- Reports of any privacy breaches,
- Any other new information that my affect adversely the safety of the research participants or the conduct of the research

Modifications to the approved research may not be initiated without prior REB review and approval except where necessary to eliminate apparent immediate hazards to human participants. If changes are made to eliminate immediate hazards, the Researcher must notify the REB immediately.

### 5.1 Amendments to the Approved Research

**5.1.1** The Researcher is responsible for submitting to the REB any changes to the approved research in the form of an amendment request. Changes to the approved research include modifications including (for example) modifications to the research, to the consent form,), changes in participant materials (e.g., recruitment materials), a change in the Researcher or research team, etc.;

**5.1.2** When the amendment includes a change to the consent form, the Researcher must indicate their recommendation for the provision of the new information to current and/or past research participants;

**5.1.3** Amendments must clearly explain the following:

- What aspects of the protocol, consent form, information sheet and/or recruitment materials are affected. The revised documents must be highlighted on an attached, revised document,
- The nature of the proposed change,
- The reason for the proposed change,
- Any increase in risk or discomfort for study participants, and why it is required,
- Any need for a change in the consent process,
- Whether previously or currently enrolled study participants need to be re-consented,
- Whether or not the amendment meets minimal risk criteria;

**5.1.4** The Researcher must indicate the new level of risk the research poses by incorporating the changes. Supporting correspondence documentation and/or background information may be appended to the amendment submission;

**5.1.5** The REB Co-Chairs or designee reviews the amendment to determine the appropriate level of REB review required (i.e., Full Board or delegated review);

**5.1.6** The REB Co-Chairs or designee also may use delegated review procedures for review of amendments when the conditions are met (see SOP 401):

**5.1.7** If the proposed change represents more than minimal risk, it must be reviewed by the REB at a Full Board meeting.

**5.1.8** For amendments requiring Full Board review, the Research Ethics Coordinator assigns the amendment to the next available Full Board meeting. For amendments that meet the criteria for delegated review, the Research Ethics Coordinator will forward the amendment to the designated reviewer;

**5.1.9** When an amendment involves a revised consent, the REB will consider the recommendations of the Researcher in determining if, how and when the new information should be provided to the research participants and whether re-consent is required;

**5.1.10** The REB must find that the criteria for approval are still met in order to approve the amendment;

**5.1.11** The amended research may not be implemented prior to the REB review and approval, except when necessary to eliminate immediate hazards to participants.

## 5.2 Unanticipated Issues

**5.2.1** The Researcher is responsible for reporting any unanticipated issue or event that may increase the level of risk to participants or have other ethical implications for participants.

**5.2.2** Any unanticipated issue that may increase the level of risk to participants or may impact participants' welfare should be reported immediately.

**5.2.3** The researcher should indicate whether the unanticipated issue was directly related to the research and whether changes to the protocol are necessary to reduct the change of recurrence.

- The report submitted to the REB must include **all** of the following information:
  - The description of the serious and unexpected event(s),
  - All previous safety reports concerning similar adverse events,
  - An analysis of the significance of the current adverse event(s) in light of the previous reports, **and**
  - The proposed research changes, informed consent form changes or other corrective actions to be taken by the sponsor in response to the event(s),
- The individual AE reports or periodic safety updates or safety summary reports that meet the reporting criteria must be submitted to the REB in a timely manner;

**5.2.4** If changes are necessary, an amendment request should be submitted in addition to the unanticipated event report.

## 5.3 Deviations to Previously Approved Research

**5.3.1** The Deviations from the approved protocol that are necessary to eliminate an immediate risk(s) to the participants may be implemented immediately but must be reported to the REB at the earliest opportunity.

**5.3.2** Deviations that occur through the course of research may impact the risk assessment of the research or have other ethical implications must be reported to the REB. If a permanent change is required, an amendment request should be submitted.

**5.3.3** Minor deviations (e.g. typographical corrections of consent form, changes of wording on questionnaires) from the research that do not impact risk or have ethical implications may be summarized in annual status reports.

**5.3.4** **Privacy Breaches**: The Researcher must report to the REB any unauthorized

collection, use, or disclosure of personal information (PI) including, but not limited to:

- The collection, use and disclosure of PI that is not in compliance with the jurisdictional legislation or its regulation,
- Circumstances where PI is stolen, lost or subject to unauthorized use or disclosure or where records of PI are subjected to unauthorized copying, modifications or disposal,
- In the Researcher context, any unauthorized collection, use or disclosure of PI that was not authorized under the research and approved in the plan that was submitted to the REB,

The breach must be reported to the REB and to the appropriate Organizational Official as soon as the Researcher becomes aware of the breach;

**5.3.5** **Research Participant Complaint**: The Researcher must report to the REB, and to the University if required by the REB, a complaint from a participant when the participant reports concerns about their rights as a research participant or about ethical issues related to the research. Researchers are required to include the YukonU REB contact information on all consent forms given to participants.

### 5.4 Review of Unanticipated Event and Deviation Reports by the REB

**5.4.1** The Research Ethics Coordinator will screen the adverse event forms submission for completeness.

**5.4.2** Privacy breaches are reviewed by the REB Co-Chairs or designee, and any recommendations including remedial action are determined in consultation with the organization's privacy office. The privacy breach report is forwarded to the REB Co-Chairs or designee for review and final acknowledgement;

**5.4.3** The Research Ethics Coordinator may route the submission back to the Researcher to request clarifications, missing documents or additional information;

**5.4.4** The Research Ethics Coordinator will forward the submission to the designated REB reviewer(s);

**5.4.5** The assigned REB reviewer(s) will conduct a review of the report and determine if any action or follow-up is required;

**5.4.6** The assigned reviewer(s) may request further information from the Researcher;

**5.4.7** When reviewing a reportable event, the REB should:

- Assess the appropriateness of any proposed corrective or preventative measures by the sponsor and/or Researcher,
- Consider any additional appropriate measures that may or may not have been identified or proposed by the sponsor and/or Researcher,
- Consider whether the affected research still satisfies the requirements for REB approval; in particular whether risks to research participants are still minimized and reasonable in relation to the anticipated benefits, if any, to the research participants and the importance of the knowledge that may reasonably be expected to result,
- Consider whether some or all of the research participants should be notified of the events (i.e., if it may affect the participant's willingness to continue participation in the research), and
- Consider whether suspension or termination of the ethics approval of the research is warranted;

**5.4.8** If the event does not raise concerns and does not appear to involve risks to research participants or others, the REB Co-Chairs or designee acknowledges the report, and no further action is required;

**5.4.9** If the REB Co-Chairs or designee determines that the event meets the criteria for an unanticipated problem, and if immediate action is required to protect the safety of research participants, they may suspend ethics approval of the research pending review by the Full Board, providing the justification for such action is documented;

**5.4.10** If the event raises concerns or involves risk to research participants such that REB action may be required, the item is added to the agenda of the next Full Board meeting;

**5.4.11** For reports reviewed at a Full Board meeting, the REB determines whether further action is required. Possible actions that could be taken by the REB include, but are not limited to:

- Placing a hold on the research pending receipt of further information from the Researcher,
- Requesting modifications to the research,
- Requesting modifications to the consent form,
- Providing additional information to past participants,
- Notifying current participants when such information might affect the participants willingness to continue to take part in the research, and requiring that current participants re-consent for ongoing participation,
- Altering the frequency of continuing review,
- Observing the research or the consent process,

- Requiring additional training of the Researcher and research staff,
- Termination or suspension of the research,
- Allegation of non-compliance or break of responsible conduct of research in accordance with YukonU policy and procedures
- If the REB determines that the event does not raise concerns about risks to research participants, the REB may decide that no further action needs to be taken;

**5.4.12** When action is taken to ensure the protection of the rights, safety, and well- being of participants (e.g., for an unanticipated problem involving risks to participants or others) the REB Co-Chairs or designee is responsible for reporting to the Researcher and the University (as necessary) and has the authority to notify the sponsor and the appropriate regulatory authorities (as applicable).

## 5.5 Site Visits/Audits

**5.5.1** The REBs have the authority to observe, or have a third party observe, the consent process of research it has approved, and to verify that the study is being conducted as required by the REB and within University and site-specific Policies and Procedures as appropriate. Under the direction of the Office of Research Ethics, including but not limited to third parties not affiliated with the institution, may perform site visits to verify information in the initial study application or in any continuing review submissions;

**5.5.2** The REB will consider the following criteria to determine if a site visit is required:

- The research involves vulnerable populations or high-risk procedures,
- The Researcher has a history of serious or continuing non-compliance related to continuing review in the past three years,
- The REB has reason to doubt the veracity of the information provided by the Researcher,
- The information provided by the Researcher is inconsistent with other information known to the REB and the inconsistency cannot be resolved through communication with the Researcher,
- Any other reason where the REB believes verification should be required.

## 5.6 External Verification

**5.6.1** YukonUs REB may utilize sources other than the Researcher to identify information that may affect projects currently under their oversight. Those sources include but are not limited to the University, including the Researcher's supervisor, media reports, participant complaints, research staff informants, site visit reports and the Internet;

**5.6.2** The following avenues provide YukonUs REB with information that is supplemental to the information provided by the Researcher:

- YukonUs site visit/continuing review procedure,
- YukonU Office of Research Ethics is in direct contact with YukonU officials responsible for handling all allegations of research misconduct. Research Ethics Office is notified in the event that a Researcher has his or her privileges revoked, or has otherwise been disciplined or investigated by the Institution regarding the conduct of the research,
- YukonUs REB are often directly contacted by research sponsors who notify the Boards of relevant information when appropriate.

## 6.0 REFERENCES

See References.

## 7.0 REVISION HISTORY

| SOP Code | Effective Date | Summary of Changes |
|---|---|---|
| SOP 404 | August 2020 | YukonU version adapted from N2/CAREB SOP 404.003 (October 8, 2019) and CAREB SOP 401.001 (2021) |
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