

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

<b>Associated Policy</b>	Human Research Ethics Policy AR-03
<b>Procedure Holder</b>	Associate Vice President Research
<b>Executive Lead</b>	Research Services
<b>Approval Authority</b>	President
<b>Original Date</b>	Replaces AR-03 procedures (May 2009, Oct. 2014)
<b>Effective Date</b>	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)