

## Procedures: Human Research Ethics

**SOP 101 Authority and Purpose**

<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>	July 2022

**1.0 PURPOSE**

The purpose of this standard operating procedure (SOP) is to:

- 1.1** State the organizational authority under which the Research Ethics Board (REB) is established and empowered;
- 1.2** Define the purpose of the REB;
- 1.3** State the principles governing the REB to assure that the rights and welfare of participants are protected;
- 1.4** State the authority of the REB.

**2.0 SCOPE**

This SOP pertains to Yukon University Research Ethics Board (REB) that reviews human participant research in compliance with applicable regulations and guidelines under the direct authority of Yukon University.

**3.0 RESPONSIBILITIES**

The Associate Vice-President Research (AVPR), 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**

The REB receives its mandate from the highest level of Yukon University (YukonU) and fulfills this mandate by following all written policies, standards, and procedures consistent with federal and provincial regulations, good clinical practice, and ethics guidelines when reviewing proposed research.

## 5.1 Statement of Institutional Authority

- 5.1.1** Yukon University (YukonU) has authorized the REB to review the ethical acceptability of all research involving human participants conducted under the auspices of the University;
- 5.1.2** The REB is established and empowered under the authority of the University. The University requires that all research involving human participants be reviewed and approved by the REB prior to initiation of any research related activities.

## 5.2 Purpose of the REB

- 5.2.1** The REB's purpose is to protect the rights and welfare of human participants participating in research;
- 5.2.2** The YukonU REB reviews and oversees the research to ensure that it meets ethical principles and that it complies with all applicable regulations and guidelines pertaining to human participant protection;
- 5.2.3** These include, but are not limited to the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, the US Federal Policy for the Protection of Human Subjects (Final Common Rule), YukonU Policy AR-03 and where applicable, US Federal Regulations.

## 5.3 Governing Principles

The REB is guided by the ethical principles regarding all research involving human participants including:

- Respect for Persons:
  - Recognize the intrinsic value of human beings and the respect and consideration they are due,
  - Incorporate moral obligations to respect autonomy and to protect those with developing, impaired or diminished autonomy.
- Concern for Welfare:
  - Aim to protect the welfare of participants, and, in some circumstances, to promote that welfare in view of any foreseeable risks,
  - Provide participants with enough information to be able to adequately assess risks and potential benefits associated with their participation,
  - Ensure that participants are not exposed to unnecessary risks.
- Justice:
  - Obligation to treat people fairly with equal respect and concern,
  - Vulnerable or marginalized people may need to be afforded special attention.

## 5.4 REB Authority

**5.4.1** YukonU's REB is established to review all research involving human participants within its established jurisdiction;

**5.4.2** The REB has the authority to ensure that all research conducted under its oversight is designed and conducted in such a manner that it protects the rights, welfare, and privacy of research participants.

**5.4.3** Specifically, the REB has the authority to:

- establish the ethics review processes, and provide research ethics oversight to ensure the ethical conduct of the research,
- approve, require modifications to, or disapprove, any research activity that falls within its jurisdiction,
- ensure that the researcher has policies and procedures to protect the rights, safety and welfare of research participants,
- request, receive and share any information involving the research that the REB considers necessary to fulfil its mandate, while maintaining confidentiality and respecting privacy,
- conduct continuing ethical review to protect the rights and welfare and privacy of research participants,
  - Review of regular progress reports;
  - Review of changes in the design or conduct of the study prior to implementation;
  - Review of unanticipated problems and serious adverse events;
  - Monitoring to determine that a study is being conducted as approved;
  - Observation of the informed consent process; and
  - Any other review procedure deemed to be necessary to protect the rights and welfare of human participants;
- suspend or terminate the ethics approval for the research,
- place restrictions on the research,
- take any actions considered reasonably necessary, and consistent with policies and procedures, to ensure the protection of the rights, safety, and well-being of participants in research conducted under the REB's jurisdiction.

## **5.5 Relationship of the REB to Institutional and other committees**

**5.5.1** Research that has been reviewed and approved by the REB may be subject review and disapproval by the officials or committees of the University. Those officials or committees may not approve research if it has been disapproved by the REB.

**5.5.2** The REB functions independently of the University. They are however, accountable to the University for their research ethics review processes.

## 5.6 Authorization

The Yukon University President has authorized the YukonU REB to review research involving human participants conducted by faculty, staff and students under the auspices of YukonU.

## 5.7 Federally Funded Research

If the study is part of a funded grant by a sponsoring agency, the human protocol must be reviewed by the REB prior to expenditure of any grant funds.

## 6.0 RESEARCH SUBJECT TO US REGULATIONS

The REB shall apply the requirements of the applicable US and International regulations to the extent that they vary from the protections set out in the applicable Canadian regulations and guidelines.

## 7.0 USE OF POLICIES AND PROCEDURES

The REB will maintain and follow all written policies and procedures consistent with federal and territorial regulations, good clinical practice and ethics guidelines when reviewing proposed research.

## 8.0 REFERENCES

See References.

## 9.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP 101	July, 2022	YukonU version adapted from the N2/CAREB SOP 101.003 (October 8, 2019)