

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)