

Standard Operating Procedure

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| Document Number | REB.SOP.801 |
| Title | Researcher Qualifications and Responsibilities |
| Effective Date | September 23, 2021 |
| Next Review | 2026 |
| Next Administrative Review | 2023 |

1. Purpose

This standard operating procedure (SOP) describes the qualifications and responsibilities of the Researcher who engages in research involving human participants.

2. Definitions

See the MSVU **REB Glossary of Terms (REB.INFO.001)**

3. Scope

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

4. Responsibilities

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

5. Procedures and/or Specific Policies

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 must have assurance that the qualifications of 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 should 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. If applicable (i.e., is part of the institution's policy or procedures), all specified Organizational Officials must approve the application to the REB;
- 5.1.4. 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;
- 5.1.5. 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):
- Research study 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,
 - The researcher has 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),
 - The researcher personally conducts or supervises the execution of 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 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 immediately if the Researcher’s medical or dental license or hospital privileges are suspended, restricted, or revoked (if applicable) or should their qualifications otherwise no longer be appropriate,
- The REB is notified when the research is complete.

Note: (if applicable) the obligations of a Researcher holding a Clinical Trial Application (CTA) with Health Canada (i.e., sponsor-Researcher) include both those of a sponsor and those of a Researcher.

5.2.2. The organization is responsible for maintaining current CVs for each of its Researchers. The organization is 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. References

See References listed (if applicable)

7. Acknowledgements

The development of this document has benefited directly from similar documents made public by the Tri-Council, as well as several Canadian universities. In some instances, specific formulations drawn from these sources have been incorporated into this document. Specific iterations were drawn from the following:

- Standard Operating Procedures for Observational Health and Non-Clinical Trial Research Ethics Boards - [N2/CAREB-ACCER REB SOPs – Canadian Association of Research Ethics Boards](#) (retrieved July 2021)
- N2/CAREB-ACCER REB SOPs - N2 Network of Networks - [Resources - N2 Canada](#) (retrieved July 2021)

8. SOP History

| SOP Number | Key Changes | Effective Date |
|-------------|------------------|----------------|
| REB.SOP.801 | Original version | September 2021 |
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