

Title	Researcher Qualifications and Responsibilities
SOP Code	801.01
Effective Date	September 2023

Site Approvals

Name and Title (typed or printed)	Signature	Date
Dr. Craig Kuziemsky Associate Vice-President, Research	<i>Original signed</i>	October 2020
Dr. Craig Kuziemsky, AVPR	<i>Original signed</i>	September 2023

1.0 PURPOSE

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

2.0 SCOPE

This SOP pertains to 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 appropriately qualified by education, training, and experience 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 new Researchers, for the conduct of research, are appropriate.

Researchers are required to conduct the research in compliance with all REB policies and related guidelines.

5.1 Researcher Qualifications

- 5.1.1 The Researcher must make available to the REB 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 All MacEwan Researchers must have completed the Course on Research Ethics (CORE) tutorial prior to the approval of any proposed research;
- 5.1.3 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 policies and guidelines to 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,
 - 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,
 - Informed consent, when required, is obtained from participants prior to their enrollment into the research,
 - The research is conducted in compliance with the approved research and any unanticipated events or protocol deviations are reported to the REB,

- 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;
- An application for continuing review (ie. an annual 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,
- The REB is notified when the research is complete by submissions of a Closure form.

5.2.2 The institution 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.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
801.00	October 8 2020	Original version
801.01	September 2023	Reviewed, removed the Dean's signing authority process