

SOP 801.001

Title	Researcher Qualifications and Responsibilities
SOP Code	801.001
Effective Date	

Site Approvals

Name and Title	Signature	Date dd/mm/yyyy

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 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 his/her current CV which should include his/her 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:
 - He/she is 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):
 - He/she and his/her 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,
 - He/she 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),
- He/she 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 when the research is complete.

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.

6.0 REFERENCES

See References.

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7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP801.001		Original version