Queen's University RESEARCH

N2 Network of Networks Réseau des réseaux

SOP 801.004

Title	Researcher Qualifications and Responsibilities
SOP Code	801.004
Effective Date	15-May-2023

Site Approvals

Name and Title (typed or printed)	Signature	Date MM/DD/YYYY
Meera Sidhu, Research Ethics Manager		01/25/2024
Steven Smith, Deputy Vice-Principal Research		01/25/2024
Dean Tripp, Chair HSREB		May 7 2024
Jacob Brower, Chair GREB		May 8 2024

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 regulations 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 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 applicable regulations and guidelines and all REB policies.

5.1 Researcher Qualifications

5.1.1 The Researcher must make available to the REB their current CV, their medical license number (if applicable), and 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 If applicable, the Researcher must be a physician with a specialty qualification in their field and current professional qualifications entitling them to provide health care under the applicable laws.

5.1.3 The Researcher must have completed appropriate training regarding the requirements of conducting and overseeing research. **Training on the current version of TCPS 2 is mandatory for all Queen's University and affiliated hospital researchers conducting research involving human participants, including their data and/or biological materials.**

Clinical trials involving human participants must comply with GCP. Further, clinical trials that are conducted under a Clinical Trial Application and/or Investigational Testing Authorization in Canada must follow Division 5 of the Health Canada Food and Drug Regulations, and/or Part 3 of the Medical Device Regulations, and/or Part 4 of the Natural Health Product Regulations.

Therefore, in addition to TCPS2 training, all researchers and research team members must have documented training on GCP and applicable regulations. At a minimum, retraining or refresher training will be required upon any updates to GCP or the regulations or for GCP, every 5 years. Note, GCP retraining or refresher training may be required more frequently by

affiliated hospitals, sponsors, funding agencies or at the discretion of the Principal Investigator.

Formal training is provided online for TCPS2 through TCPS2 Core, and for GCP and HC Division 5 through CITI Canada Online.

The lead researcher is responsible for ensuring the applicable study team members have the appropriate training to perform their respective study tasks.

5.1.4 If applicable, all specified Organizational Officials must approve the application to the REB.

5.1.5 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.

5.1.6 Any concerns raised in the REB review of the Researcher's qualifications will be communicated to the Researcher and must be satisfied before 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 regulations and ensure that (if applicable):

- He/she and their staff members are 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,
- He/she has adequate resources to properly conduct the research and conducts the research following written SOPs,
- 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 before 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 described investigation(s),
- The research is conducted in compliance with the approved research, and applicable reporting criteria are reported to the REB, including deviations, serious, unexpected 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,
- The REB is notified immediately if their 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.

Documents must be obtained and retained on file by the PI but <u>not required for ethical submission</u> include:

- **Legal agreements (Data Transfer Agreements/Material Transfer Agreements)**
- **Cover Letters/Resumes**
- **Medical Licenses**

- **TCPS 2 CORE training certificates (for the PI and the whole study team)**
- **CITI training certificates**
- **NOL from Health Canada (HC)**
- **Notifications from HC**
- **Grant information**
- **Financial Accounts**
- **Pharmacy agreement(s)**

NOTE: Although the REB will not retain these documents in the ethical file, these documents should be readily available for a compliance audit by Queen's University's compliance team or any regulatory body. The REB or REB Office Personnel may ask to see documents. These requests will be conducted at the REB or REB Office Personnel's discretion.

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 and medical licenses (if appropriate) 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.

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP801.001	15-Sept-2014	Original version
SOP801.002	08-Mar-2016	No revisions needed
SOP801.003	08-Oct-2019	No revisions needed
SOP801.004	15-May-2023	Replaced his/her with their

SOP801.004	19-Jan-2024	Queen's Specific Revisions/Clarifications added to the N2 SOPs with modifications in bolded text