Queen's UNIVERSITY RESEARCH

N2 NETWORK OF NETWORKS RÉSEAU DES RÉSEAUX

SOP 102.004

Title	**Research Requiring REB Review**
SOP Code	102.004
Effective Date	15-May-2023

Site Approvals

Name and Title (typed or printed)	Signature	Date MM/DD/YYYY
Meera Sidhu, Research Ethics Manager	MSidhu	12/01/2023
Steven Smith, Deputy Vice-Principal Research		12/04/2023
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1.0 PURPOSE

The purpose of this standard operating procedure (SOP) is to describe research **studies ~~activities~~** that require Research Ethics Board (REB) review and research activities that do not.

2.0 SCOPE

This SOP pertains to REBs that review human participant research in compliance with applicable regulations and guidelines.

3.0 RESPONSIBILITIES

All 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

All research involving human participants must be reviewed and approved by an REB. **Queen's University has two REBs: the Health Science and Affiliated Teaching Hospitals Research Ethics Board (HSREB) and the General Research Ethics Board (GREB).** No intervention or interaction with human participants in research, including recruitment, may begin until **the appropriate** REB has reviewed and approved the research protocol, consent documents and recruitment materials. **All changes that occur to the protocol, consent documents, recruitment material or information listed in the original research ethics application must be approved by the appropriate REB before implementation of the change. Refer to SOP 404.004 for exceptions.**

5.1 Research that Requires REB Review

5.1.1 The following requires ethics review and approval by an REB before the research commences:

(a) Research involving living human participants,

(b) Research involving human biological materials, as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells. This applies to materials derived from living and deceased individuals.

NOTE: Research-Based Case Study or Series. If the case study or series has a research objective and questions of 'what', 'how' or 'why', this is considered research and requires REB approval. A case study can be as little as one file. REB approval cannot be obtained, retrospectively.

5.2 Research Exempt from REB Review

5.2.1 Research that relies exclusively on publicly available information does not require REB review when:

(a) The information is legally accessible to the public and appropriately protected by law.

(b) The information is publicly accessible and there is no reasonable expectation of privacy.

5.2.2 REB review is not required for research involving the observation of people in public places where:

(a) It does not involve any intervention staged by the Researcher or direct interaction with the individuals or groups.

(b) Individuals or groups targeted for observation have no reasonable expectation of privacy.

(c) Any dissemination of research results does not allow the identification of specific individuals.

(d)

5.2.3 REB review is not required for research that relies exclusively on the secondary use of anonymous information or anonymous human biological materials, so long as the process of data linkage or recording or dissemination of results does not generate identifiable information.

5.2.4 The opinion of the REB **or Research Ethics Office (REO)** should be sought whenever there is any doubt about the applicability of the guidelines and regulations.

5.3 Activities Not Requiring REB Review

5.3.1 Activities outside the scope of research subject to REB review may still raise ethical issues that would benefit from careful consideration by an individual or a body capable of providing some independent guidance other than an REB.

5.3.2 Quality assurance and quality improvement studies, program evaluation activities, performance reviews, or testing within normal educational requirements, when used exclusively for assessment, management or improvement purposes, do not constitute research for this SOP and do not fall within the scope of REB review.

To determine whether a study qualifies as Quality Assurance/Quality Improvement/Program Evaluation (QA/QI/PE) refer to the AREECI (Alberta Research Ethics Community Consensus Initiative) guidelines and screening tool. The ARECCI Screening tool helps to determine the

level of risk of your project, the types of ethical risks and the appropriate type of ethics review. You will be given a score: Yellow (score 0-7), Orange (score 8-46) and Red (score greater than 47).

Queen's HSREB and GREB recommend the submission of all QA/QI/PE studies regardless of the ARECCI score. However, if a score of:

- **<u>Yellow is achieved</u>, and a formal exemption from the REB is not required, no further follow-up is required. Reminder: some publications require a formal REB exemption letter. REB approval and exemption cannot be obtained retrospectively.**
- **<u>Orange is achieved</u>. Submit a Quality Initiative Screening Tool application in TRAQ. The REB will review the application and determine if the study meets the requirements for REB exemption. The REB will issue a formal exemption letter. However, if the study has been determined not to meet the REB exemption criteria the application will be withdrawn, and the researcher will be asked to submit the appropriate GREB or HSREB application form in TRAQ.**
- **<u>Red is achieved</u>. Submit the appropriate GREB and HSREB application form in TRAQ, as this study has not been deemed as a QA/QI project and is in fact, research that requires REB review.**

5.3.3 Creative practice activities, in and of themselves, do not require REB review. However, research that employs creative practice to obtain responses from participants that will be analyzed to answer a research question is subject to REB review.

5.4 Oversight of Research Activities Requiring Ethical Review from HSREB and GREB

5.4.1 If a research study includes one or more of the following elements, a review from the HSREB must be sought:

• Participants from any of the Affiliated Teaching Hospitals or in other health care clinics or medical settings at any point during the research.
• Conducting research or recruiting participants from any of the Affiliated Teaching Hospitals (Kingston Health Sciences Centre (KGH and HDH Sites), Kingston General Health Research Institute (KGHRI), Hotel Dieu Hospital Research Institute (HDHRI), Providence Care Centre (PCC) and Ongwanada) or in other healthcare, clinic, or medical settings.
• Pharmaceutical device, drug, or natural product(s) clinical trials.
• Medical or physical interventions, treatments, therapies, or surgeries.
• New medical techniques or technologies, deviations from standard of care.
• Use of human biological material from living or deceased participants; physical exertion (beyond walking/normal daily activities).
• Medical or dental patients, doctors, nurses, dentists, or any other health care professionals, and rehabilitation therapy.
• Accessing health or medical records.
• Using X-rays, CT scan, PET Scan, MRIs, ultrasounds, EKG or other medical tests or scans.
• Administering or ingesting any substance.
• Biobanks and large databases.

If none from the list above are applicable to the research study, review from the GREB must be sought.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP102.001	15-Sept-2014	Original version
SOP102.002	08-Mar-2016	No revisions needed
SOP102.003	08-Oct-2019	No revisions needed
SOP102.004	15-May-2023	No revisions needed
SOP 102.004	1-Dec-2023	Queen's Specific Revisions/Clarifications added to the N2 SOPs with modifications in bolded text