Research Proposals Approval Committee

Terms of Reference

Mandate

The mandate of the Research Proposals Approval Committee (RPAC) is to review research proposals that propose to:

a) access data for which Newfoundland and Labrador Health Services (NLHS) is the data custodian;

b) impact NLHS resources in the conduct of research;

c) recruit participants or conduct research at an NLHS facility; and / or

d) engage NLHS personnel for the purpose of soliciting their assistance with recruitment or data collection.

Pending the outcome of its review, RPAC will decide whether to approve the proposed research, including associated data disclosures, that fall within in its mandate, as described above.

In fulfilling its legislative obligations under the Personal Health Information Act (PHIA) and the Access to Information and Protection of Privacy Act (ATIPPA), 2015, RPAC requires that appropriate processes are in place for the use, disclosure, collection, protection, storage, retention and destruction of personal health information and personal information. Additionally, RPAC assesses impact of research activities on NLHS resources and determines the requirement for compensation and/or management. Fulfillment of these obligations will normally entail ensuring that necessary agreements are in place, including departmental and data sharing agreements, as well as ensuring that appropriate program leadership has been engaged/informed.

All research reviewed by RPAC will have prior approval from the Health Research Ethics Board (HREB) or other duly constituted research ethics board. Additionally, researchers must submit to RPAC all required supporting documentation. This includes, but is not limited to, the following:

- Letter of approval from the HREB (or other REB);
- PDF of the approved HREB (or other REB) application;
- Research proposal (as distinct from the PDF of the completed HREB application)
- *For projects involving **secondary use** of health record data in NLHS's custody* – the RPAC submission should include, at minimum, the REB-approved 'Data Custodian Variable List' bearing a recently dated signature from a data custodian designated under the Personal Health Information Act (PHIA) section 4;
- *For projects involving **primary data collection** in NLHS facilities or from NLHS patients, clients, residents, staff, agents, volunteers, and/or visitors* – the submission should include any participant-facing documents like recruitment materials, consent forms/scripts, and/or data collection instruments (e.g., questionnaires);
- *For HREB-approved **amendments** to projects that were previously approved by RPAC* – communications with RPAC should specify that the submission is for an amendment (not the original study) and, in addition to any other relevant documentation, should include the PDF of the approved 'HREB – Amendment Form' and the tracked-change version of the revised proposal;
- Organizational Approval for Research Application form;
- Study budget, if available;
- PHIA training certificates for all study team members who will (a) have contact with NLHS patients/clients/residents as part of the consent or data collection processes, or (b) have access to any identifiable study data including signed consent forms; and
- Departmental agreements, data sharing agreements, and/or material transfer agreements, as necessary.

Applications that do not include the required supporting documentation will not proceed to committee review; rather, they will be returned to the applicant with a detailed list of the documents that are required for the application to advance.

Composition

The voting members of the Committee shall consist of:

- Chair - Director of Research and Innovation (or designate)
- Co-Chair - Chief Privacy Officer (or designate)
- Minimum of one physician representative
- Manager of the Clinical Trials division
- Manager of the Applied Heath Research division
- Manager of Privacy or Privacy Officer

- Minimum of two Epidemiologists and/or Clinical Research Scientists

- Data Access and Information Services representative

Other members:

- Other clinician and research membership as identified by the Chair and Co-chair to ensure effective committee operations and representation of required skill sets

Ad hoc representation (non-voting and in attendance for presentation of applicable application for which their expertise is required):

- Additional ad hoc representation may be invited from time to time to assist with the review of various proposals.

Voting

All committee members are eligible to vote. Decisions will be reached by consensus; however, in the event of a disagreement among members, a decision will be made by a majority vote. Ad hoc members are not eligible to vote.

A quorum shall be fifty percent or more of the voting members and must include a chair or co-chair; a clinical research scientist, epidemiologist *or* physician; and a privacy representative. An individual may serve dual roles on the committee. Members attending virtually shall be included in determining a quorum.

Operations/Processes

Assignment of reviewers:

- All applications must have a minimum of three reviewers. The reviewers will be nonsystematically assigned by the RPAC administrative assistant, with the exception of ensuring that a reviewer is not a member of the research team and, otherwise, has no conflict of interest. Reviewers shall thoroughly review their assigned applications prior to the meeting. Two of the three reviewers must be in attendance (virtually or in-person) for the review at the meeting to proceed. A third reviewer, if unable to attend the meeting, can submit feedback in writing prior to the meeting, though this is not a requirement for review to proceed.

Committee members will:

- render one of the following review decisions on each application:
    - Rejection

    - Approval, subject to changes and/or clarifying responses provided by the applicant and reviewed and approved by Chair and co-Chair.
    - Approval, subject to changes reviewed and approved by full committee
    - Full approval;

- consider whether the proposed research activities are compliant with PHIA, ATIPPA, 2015, or other applicable legislation;

- assess the impact on NLHS resources and determine the requirement for compensation for all uninsured services and/or resource impact;

- advise investigators of the results of the Committee's deliberations including clarifications required for approval;

- will be granted access to the formal communication (i.e., letter) sent to the applicants following review for the purpose of notifying Chair or Co-chair of any potential errors or omissions and to inform review and discussion of any resubmissions;

- develop and implement procedures for submissions of proposals including, but not limited to, submission deadlines, application forms and supporting documentation; and

- recommend changes on policies and procedures.

Meeting frequency:

- Committee meetings will take place bi-weekly with a minimum of eight meetings per year or at the call of the Chair or Co-chair.

Conflict of Interest

Members involved in the review must declare any perceived, potential, or actual conflicts of interest.

- An actual conflict of interest may arise when an employee is asked to make a decision as a public officer that directly affects or impacts their personal or private interests.

- Some conflicts may only be perceived—an employee's decision could be questioned based on a personal or private interest that may not actually have impacted any decision.

- A potential conflict of interest arises where a public officer has private interests that could conflict with their official duties in the future, or where a public officer has competing interests because they hold more than one official role or public duty.

- Management of a declared conflict of interest will be determined by the members present at the meeting. A record of the conflict of interest will be recorded in the minutes of the meeting. If a member is recused from voting on a review, they will be ineligible for approving the minutes of the meeting where the recusal occurred.