

Process for Review and Approval of Research

The Research Proposal Approval Committee (RPAC) requires that appropriate processes are in place for the use, disclosure, collection, protection, storage, retention and destruction of personal health information (PHI) and human biologic specimens used in the conduct of research. Additionally, RPAC assesses impact on NLHS resources and determines the requirement for compensation and/or management. The schedule for the biweekly RPAC meetings may be found on the Research and Innovation website.

RPAC utilizes a two-step research approval process:

1. All research proposals must have full approval of the Health Research Ethics Board (HREB) or other duly constituted research ethics board (REB) prior to submission to RPAC.
2. Following ethics approval, the researcher must apply to RPAC using the Organizational Approval for Research application form, found on the Research and Innovation website:

<https://ri.easternhealth.ca/rpac/>

Prior to receiving RPAC approval, all proposals will require:

- Approval by the applicable NLHS program (Clinical Chief, Director, or Manager)
- Completion of Departmental Agreement(s), if the proposal requires NLHS services including, but not limited to, Pharmacy, Laboratory, Diagnostic and/or Personnel or if the proposal impacts NLHS resources

Documents to be submitted with the application include:

- A scanned/faxed/or original copy of the 'Organizational Approval for Research' application form signed by the Applicant, Principal Investigator/Academic Advisor and the Clinical Chief/Department or Program Manager/Director of the respective area most affected by the research
- Pdf version of the completed and approved HREB (or other REB) application, accompanied by relevant supporting documentation, including:
 - Letter of approval from the HREB (or other REB)
 - 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* – your 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* – your 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* – please specify in your email that your submission is for an amendment (not the original study) and, in addition to any other relevant documentation, include the pdf of the approved 'HREB – Amendment Form' and the *tracked-change* version of the revised proposal.
 - Study Budget
- Departmental Agreements (as necessary)
- PHIA training records for all study team members who will (a) have contact with participants as part of the consent or data collection processes, or (b) have access to any identifiable study data including signed consent forms.

Please ensure the files names of each of all documents to RPAC include (1) the last name of the PI, (2) the date when they were prepared, and (3) some indication of their contents – e.g., 'Smith_Cancer Care research proposal_Oct 21 2024.' When you have everything ready, you can forward the application and required documents to RPAC@easternhealth.ca. For questions regarding RPAC, please call (709) 777-2214.

IMPORTANT INFORMATION

1. When filling out and sending your application, please use a formal workplace email address, such as an NLHS address.
2. Please refer to the information boxes throughout the application for guidance on answering the questions.
3. Several questions in the application are duplicated from your ethics application and require that you attest that this information has not changed.
4. If there has been a change in the information in your approved ethics application, please submit an amendment to the HREB/REB prior to applying for RPAC approval.
5. If PHI or biological specimens will be accessed/disclosed for the proposal, a Data Sharing Agreement (or Acknowledgment, as applicable) must be signed by the researcher (and supervisor, if researcher is a student), prior to RPAC approval.