Organizational Approval for Research

Section 1: General Information

Project Title:

HREB Reference Number:

1. Reason for Request (select all that apply):
   - ☐ Secondary Use/Chart Review
   - ☐ General Research
   - ☐ Clinical Trial

2. Name of principal investigator/applicant and contact information:

3. Key contact name and contact information:

4. Names and email addresses of Co-investigators and other project team members:

5. Name and contact information of supervisor if the principal investigator/applicant is a student:

6. Please identify the data custodian(s) of the information you are requesting (select all that apply):

- ☐ Newfoundland and Labrador Centre for Health Information
- ☐ Eastern Health
- ☐ Central Health
- ☐ Western Health
- ☐ Labrador-Grenfell Health
- ☐ Other:

Section 2: Purpose of the proposed project

1. Purpose and study objectives:
    a. What is the goal or purpose of the project?

    b. Please confirm the list of your specific objectives.

    ☐ I attest that I have reviewed the approved HREB application for this project and that the information provided in Section 3.1 for Clinical Trials **or** 4.1 for General Research **or** 5.1 for Secondary Use is accurate and up-to-date.

2. Project Time Period:
    a. Range of years of data requested.
    ☐ I attest that I have reviewed the approved HREB application for this project and that the information provided in Section 1.14 for Clinical Trials **or** 3.5 for General Research **or** 3.4 for Secondary Use is accurate and up-to-date.

    b. If performing a chart review of paper or electronic records, please indicate the period of time during which you will be accessing the information.

3. Please describe your project methodology by answering the following questions:
    a. Describe the project population/groups of interest.
    ☐ I attest that I have reviewed the approved HREB application for this project and that the information provided in Sections 9.1 and 9.2 for Clinical Trials **or** 11.1 and 11.2 for General Research **or** 6.1 and 7.1 for Secondary Use is accurate and up-to-date.

    b. Describe how the study population/groups of interest will be identified for the project.
    ☐ I attest that I have reviewed the approved HREB application for this project and that the information provided in Section 13.1 for Clinical Trials **or** 12.1 for General Research **or** 3.5 for Secondary Use is accurate and up-to-date.

    c. Please state the outcomes of interest.
    ☐ I attest that I have reviewed the approved HREB application for this project and that the information provided in Section 8.1 for Clinical Trials **or** 9.1 for General Research **or** 7.1 for Secondary Use is accurate and up-to-date.

Section 3: Organizational Impact

1. Does this project require the provision of resources and/or personnel to perform activities or provide assistance that is outside their usual activities? Please review sections (i) to (iii) below and select all that apply.

(i) Resources (please select all that apply): ☐Not Applicable

☐A room ☐Health records
☐Office space ☐Clinic space
☐Equipment ☐Medication administration
☐Recruitment ☐Other:

If you selected any resources, please describe:

(ii) Personnel required to perform activities or provide assistance that is outside their usual activities (please select all that apply): ☐Not Applicable

☐Nursing staff
☐Allied health professionals
☐Clerical staff
☐Diagnostic Imaging
☐Laboratory
☐Other:

If you selected any personnel, please describe:

Please ensure that the appropriate departmental agreement(s) are appended.

(iii) Data services (Please consult with the data custodian to determine if they are able to provide the requested data services; please select all that apply): ☐Not Applicable

☐Data extraction ☐De-identification
☐Data Linkage ☐Retention of Study Key
☐Data Analysis ☐Other:

Please specify the desired format of the final dataset:

☐Excel
☐SPSS
☐SAS
☐Access
☐Other:

2. Does this project involve the use of study medication (including placebos) that will be dispensed by the hospital pharmacy?

   ☐Yes ☐No

   If yes, please describe:

   Also, if you answered 'yes', please ensure that the appropriate departmental agreement(s) are appended.

3. Does this project involve local laboratory tests, x-rays or other imaging techniques other than those that are part of standard patient care?

   ☐Yes ☐No

   If yes, please describe:

   Also, if you answered 'yes', please ensure that the appropriate departmental agreement(s) are appended.

4. Does this project request use of blood and/or other biological samples including archived or discarded samples?

   ☐Yes ☐No

   If yes, please specify:

   Also, if you answered 'yes', please ensure that the samples of interest are included on the data custodian variable list.

5. Will samples be sent to a laboratory outside of the Regional Health Authority?

   ☐Yes ☐No

   If yes, please ensure that the appropriate materials transfer agreement(s) are attached.

6. Does this project impact (directly or indirectly) use of inpatient or outpatient services of the Regional Health Authority other than those that are part of standard patient care?

   ☐Yes ☐No

   If yes, please describe:

   Also, if you answered 'yes', please ensure that the appropriate departmental agreement(s) are appended.

Section 4: Data Management Plan

1. Please attach your signed data custodian variable list to this application to identify the dataset(s) and variables required for this project.

2. Does this project require access to health records? ☐Yes ☐No
   If yes:
   a. How many records? _____
   b. Paper records, electronic records, or both? _____
   c. Do you have a data/chart extraction form? ☐Yes ☐No
      If yes, please attach a copy of the form.

3. What type of information is required from the organization? If requesting identifiable data, please provide a rationale.

   ☐I attest that I have reviewed the approved HREB application for this project and that the information provided in Section(s) 1.16 for Clinical Trials **or** 3.7 and 15.10 for General Research **or** 3.7 and 8.1-8.3 for Secondary Use is accurate and up-to-date.

4. Individuals accessing data for the project:
   a. List the individuals who will have access to the requested data for the purposes of the project. Please describe why their access is necessary and their role in relation to the project.
   b. How and where they will be accessing the data throughout the project.

   ☐I attest that I have reviewed the approved HREB application for this project and that the information provided in Section 15.3 for Clinical Trials **or** 14.3 for General Research **or** 10.3 for Secondary Use is accurate and up-to-date.

5. Data Management:
   (i.) Please identify who will be responsible for managing the project's data during and after the project ends.

   ☐I attest that I have reviewed the approved HREB application for this project and that the information provided in Section 16.5 for Clinical Trials **or** 15.8 for General Research **or** 11.8 for Secondary Use is accurate and up-to-date.

(ii.) Please provide specific details on the storage, retention and destruction of the data below:

a. Data storage:
   - **i.** How will the data be stored while the project is ongoing?
   - **ii.** Will there be any copies made of the data? If so, where will the copies be stored?
   - **iii.** Will the data be backed up? If so, where will the backed up files be stored?
   - **iv.** Please explain the process for ensuring secure storage for all paper and/or electronic files.
   - **v.** When the project is inactive, how and where will data be stored during the retention period?

   ☐I attest that I have reviewed the approved HREB application for this project and that the information provided in Section 16 for Clinical Trials **or** 15 for General Research **or** 11 for Secondary Use is accurate and up-to-date.

b. Retention & destruction:
   - **i.** For how long will the data be retained?
   - **ii.** How will the data be destroyed after the retention period?

   ☐I attest that I have reviewed the approved HREB application for this project and that the information provided in Section 16 for Clinical Trials **or** 15 for General Research **or** 11 for Secondary Use is accurate and up-to-date.

6. Please answer the questions below to provide a description of the proposed data flow.

a. Will any data be shared outside of your institution? ☐Yes ☐No
   - **i.** If yes, how do you plan on sharing data with the other institution(s) (e.g., secure file transfer, encrypted USB, etc.)?

   ☐I attest that I have reviewed the approved HREB application for this project and that the information provided in Section 16.2 for Clinical Trials **or** 15.2 for General Research **or** 11.2 for Secondary Use is accurate and up-to-date.

b. Will you be linking the data to other data sources? ☐Yes ☐No
   - **i.** If yes, how will the linkage occur?
   - **ii.** If yes, what organizations will be involved in the data linkage?

   ☐I attest that I have reviewed the approved HREB application for this project and that the information provided in Section 16.3 for Clinical Trials **or** 15.3 for General Research **or** 11.3 for Secondary Use is accurate and up-to-date.

Prior to submission of the Common Data Custodian Application Form please ensure that all required accompanying documentation is included:

☐HREB application, supporting documentation, and approval. These copies must also include any documentation pertaining to amendments. [Note: Please ensure you are submitting the final version of your HREB applications and/or amendments].

☐Signed data custodian variable list.

☐Valid PHIA online education course certificate.

☐Authorizing letters for use of additional data for the initiative have been attached (where appropriate). Note: This is only required for applications including the NL Centre for Health Information.

☐The application is signed and dated.

☐I have read and agree to the terms below:

- All applications must be completed electronically and kept in original format.
- Changes to a project cannot be implemented without prior approval by the Research Ethics Board (where appropriate) and/or the appropriate data custodian(s).
- An investigator wanting to have access to personal health information in records held by a data custodian must also have a data sharing agreement with the custodian.
- Data and/or materials obtained for the study cannot be used for any other or future purposes, without the explicit consent of the participant(s) and/or approval from the appropriate data custodian(s) (where appropriate).
- Reports, articles and conference presentations resulting from the project should acknowledge the support of the data custodian(s) involved.

Once completed, *this application and all accompanying documentation can be submitted to the appropriate data custodian(s) by email:*

Newfoundland and Labrador Centre for Health Information - InfoRequests@nlchi.nl.ca

Central Health - ethics@centralhealth.nl.ca

Eastern Health - rpac@easternhealth.ca

Western Health - marielparcon@westernhealth.nl.ca

Labrador-Grenfell Health - Nadine.calloway@lghealth.ca

By signing and submitting the application to request data, or access to data, I understand the content of the application and all submitted attachments will be used to evaluate the request. Any use of the data granted in response to this request is provided under the expectation of adherence to the representations made within the application and attachments. I further understand that additional conditions may be specified in relation to the use of this data.

Signature of Applicant:	Signature of Principal Investigator/ Academic Advisor:	Signature of Clinical Chief/Director/ Program Manager:
_____	_____	_____
Print/type name: _____	Print/type name:	Print/type name:
Date (yyyy/mm/dd): _____	Date (yyyy/mm/dd):	Date (yyyy/mm/dd):