

## Research Data Request Form

### When to use this form

This form is used to request data from Ontario Health (Cancer Care Ontario) to support a research study. Requests for data for non-research purposes should be made using one of the appropriate forms located on the Cancer Care Ontario website:

<https://www.ccohealth.ca/en/request-data-for-research>. Requests for cost estimates should be directed to: [OH-CCO\\_Datarequest@ontariohealth.ca](mailto:OH-CCO_Datarequest@ontariohealth.ca)

**All sections of this form must be completed. Please ensure the appropriate signature is provided in section H.**

Append the following documents to complete the Application Package:	
1) Research Plan	
2) Copy of a Research Ethics Board (REB) application form, including relevant requests for amendments.	The REB must meet the requirements of s.44(2) of the Personal Health Information Protection Act, 2004 (PHIPA) and s.16 of Ontario Regulation 329/04 (see the FAQs for more information on PHIPA)
3) Approval letter from a REB	For new projects, please consider delaying submission of the REB application until the Data Disclosure Working Group has reviewed the request package to help mitigate the need for REB amendments
4) Evidence of funding approval to cover costs associated with the data request	
5) Components of the dataset creation plan (if applicable)	

Submit the completed Application Package to [OH-CCO\\_Datarequest@ontariohealth.ca](mailto:OH-CCO_Datarequest@ontariohealth.ca). Please ensure information provided is consistent across all documentation.

### Research Data Request Process

Ontario Health (Cancer Care Ontario)'s research data request process is comprised of 5 key steps:	
<b>Application</b>	<ul style="list-style-type: none"> <li>The application phase begins with submission of a complete data request Application Package to <a href="mailto:OH-CCO_Datarequest@ontariohealth.ca">OH-CCO_Datarequest@ontariohealth.ca</a>.</li> <li>During this phase, the Data Disclosure team will review the Application Package for completeness and will provide the Principal Investigator with a request number assigned to the project.</li> </ul>
<b>Review</b>	<ul style="list-style-type: none"> <li>The review phase involves a detailed review of the Application Package by CCO to determine data availability, limitations and request feasibility.</li> <li>During this phase, a group of CCO subject matter experts reviews the Application Package and makes a recommendation.</li> </ul>

	<ul style="list-style-type: none"> <li>The Principal Investigator may be contacted during the review to clarify any questions and to provide revisions or additional information for the application. A cost estimate will also be provided to the Principal Investigator.</li> </ul>
<b>Recommendation</b>	<ul style="list-style-type: none"> <li>Once all outstanding items have been addressed, the Data Disclosure Subcommittee reviews the updated Application Package.</li> <li>If approved, an approval letter and the Research Data Disclosure Agreement (RDDA) is shared with the Principal Investigator. Once the Cost Estimate is signed by the Principal Investigator, the administrative or amendment fee invoice is issued, and the work can begin.</li> </ul>
<b>Fulfilment</b>	<ul style="list-style-type: none"> <li>An analyst assigned to the project will work with the Principal Investigator to finalize the Dataset Creation Plan and begin data extraction.</li> </ul>
<b>Disclosure</b>	<p>Data is disclosed upon completion of the following:</p> <ul style="list-style-type: none"> <li>Requested data is fully prepared and undergoes quality assurance activities,</li> <li>The RDDA is fully executed, and</li> <li>The administrative fee or amendment fee (whichever is applicable) is paid.</li> </ul> <p>The data is disclosed using managed file transfer (MFT). The final invoice for analytical hours is then issued to the Principal Investigator.</p>

## Request Timeline

The length of the intake, review and approval for each data request varies based on the complexity of the data request and completeness of the Application Package. Please note, we will not review the request until the Application Package is complete.

## Cost Recovery

In advance of the fulfillment, a cost estimate is provided and the Principal Investigator must return a signed copy of it to CCO with her/his approval.

An administrative fee or amendment fee along with an hourly analytical fee are applied to all requests as follows:	
<b>Administrative Fee - \$3,000</b>	<ul style="list-style-type: none"> <li>for the time and effort required for an initial feasibility assessment, completing the dataset creation plan, and bringing research data requests through the review process</li> </ul>
<b>Amendment Fee - \$1,500</b>	<ul style="list-style-type: none"> <li>for the time and effort required for an initial feasibility assessment, completion of the dataset creation plan, and bringing <i>amended</i> research data requests through the approval process</li> <li>amendments are requests to update, refresh or add variables to an existing request where it was received and reviewed by CCO after September 1, 2015</li> </ul>
<b>Analytical Fee - \$75/hour</b>	<ul style="list-style-type: none"> <li>for the work of data analysts, which may include creating a cohort for the study, extracting the data or pathology reports required, linking multiple datasets and quality assurance steps</li> </ul>

# RESEARCH DATA REQUEST INFORMATION

A. CONTACT INFORMATION	
<b>Name of Principal Investigator</b>	Dr. Nikola Kage
<b>Role/Title</b>	Senior Scientist
<b>Name of Organization</b>	Breast Cancer Education Institution of Northeast Canada
<b>Address</b>	1234 Toronto Avenue, Toronto ON, M1M 3F3
<b>Phone</b>	416-000-0000
<b>Email</b>	Doctor_NikolaKage@BCEINC.ca
<b>Name of Alternate Contact</b>	Markie Marc
<b>Role/Title</b>	Project Coordinator
<b>Name of Organization</b>	Breast Cancer Education Institution of Northeast Canada
<b>Address</b>	1234 Toronto Avenue, Toronto ON, M1M 3F3
<b>Phone</b>	416-000-0000
<b>Email</b>	MarkieMarc@BCEINC.ca
<p><b>Please complete Section I: Additional Research Team Members at the end of this form with the names of all Co-Investigator(s) and person(s) who will have access to requested data.</b></p>	

B. PROJECT DESCRIPTION
<p><b>1. Project Title</b></p> <p>Breast Cancer Survival in the Greater Toronto Area: Does income matter?</p>
<p><b>2. Research Purpose and Clinical Relevance</b></p> <p><b>Briefly describe the purpose of the research project, stating the research question or hypothesis to be examined and the clinical relevance of the research findings.</b></p> <p>The aim of this study is to estimate the relative survival differences by income for patients diagnosed with breast cancer in the GTA. Breast surgery utilization will also be explored to investigate potential differences in treatment strategies. Important sociodemographic characteristics will also be examined to further understand the impact that the social determinants of health can have on patient outcomes and treatment strategies for breast cancer. This study will shed light on breast cancer survival in the GTA. The findings</p>

can help inform clinicians and public health workers on which populations may require targeted education and intervention.

### 3. Research Plan

**Append a full REB-approved research plan describing the research project. The research plan should include the objectives, methodology, and the anticipated public and/or scientific benefit.**

### 4. Analytical Plan

**Describe the proposed analysis using CCO data.**

Kaplan-Meier and Cox Proportional Hazards models will be used to examine longitudinal patient survival assessing the association of neighbourhood income and vitality status. Diagnostic and intervention codes from CIHI DAD and NACRS along with sociodemographic and clinical data from hospital database will be used to control for potential confounders.

Logistic regression will be used to estimate the odds ratio for neighbourhood income quintile and breast surgery occurrence. Diagnostic and intervention codes from CIHI DAD and NACRS along with sociodemographic and clinical data from hospital database will be used to control for potential confounders.

The impact of sociodemographic factors will also be assessed for their association with mortality and breast surgery occurrence.

## C. RESEARCH APPROVALS

### 1. Funding and Granting Information

**Does this research study have approved funding?** ☒ Yes ☐ No

**Funding Organization:** CIHR

**Period of Grant:** ☐ N/A

**From:** 4/1/2019

**To:** 3/31/2021

**Amount of Grant:** \$125,000 ☐ N/A

**Amount available for data request:** \$50,900

☒ Please acknowledge there are appropriate funds available to cover the administrative fee associated with the review and administrative duties associated with this request.

## 2. Ethics Approval Status

Identify all Research Ethics Boards (REBs) who reviewed the research proposal, the status of the application(s), and any decision from each.

REB	Current Status
University of Toronto, Health Sciences REB	Approved.
Click here to enter text.	Click here to enter text.
<b>NOTE: The REB(s) providing approval must demonstrate compliance with PHIPA under O.Regs 329/04 s.15</b>	

## D. DATASET CREATION PLAN

### 1. Access to Existing Data

Does some or all of this request include access to data from a previous data request for a new research purpose?

☐ Yes ☒ No

If yes, please complete the table below

CCO Data Disclosure Request #	PI Name	Study Title	Current Data Custodian
Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.

### 2. Data Required

List all requested datasets and data elements in the table below. Where required, reference the Frequently Asked Questions for details about available data elements.

**Note: The information listed in the table below (including the exact list of data elements, data sources, years and purpose of use) should also appear in the REB approved plan.**

Dataset	Variable(s) List all required variables	Year(s)	Rationale
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<b>Ontario Cancer Registry</b>	1. Last contact date 2. Vital status Date of birth	2006-present	Required for survival analysis.
<b>CIHI Discharge Abstract Database</b>	1. Main diagnosis 2. Secondary diagnosis 3. Main intervention 4. Secondary intervention Admission date	2006-present	Variables required for Cox Proportional Hazards model and logistic regression model to control for potential confounders.
<b>CIHI National Ambulatory Care Reporting System</b>	1. Main diagnosis 2. Secondary diagnosis 3. Main intervention 4. Secondary intervention 5. Registration date	2006-present	Variables required for Cox Proportional Hazards model and logistic regression model to control for potential confounders.
Choose an item.	Click here to enter text.	Click here to enter text.	Click here to enter text.
Choose an item.	Click here to enter text.	Click here to enter text.	Click here to enter text.

### 3. Data De-Identification/Minimization

Have any direct identifiers been requested (i.e. data elements that can directly identify an individual)?  
Examples of direct identifiers include: name, home address, telephone number, email address, health card number, and social insurance number.

☐ Yes      ☒ No

If yes, please provide rationale below as to why each direct identifier requested is required to meet the proposed research question(s): [Click here to enter text.](#)

*CCO strives to strike a balance between providing researchers with the level of data required to answer specific research question(s) while ensuring that we are following the highest standards to protect patient privacy. As a result, we do our best to disclose the minimum amount of identifiable information required to meet the question(s) when providing data for research purposes. The following series of questions are looking to see if we can perform some data minimization/generalization while ensuring that the study objectives can still be met:*

- a) If date of birth (DOB) has been requested, **could use** age or a generalized DOB be provided instead of full DOB?

☒ **Age**    ☐ **MM/YYYY**    ☐ **No**    ☐ **Not applicable** (DOB not requested)

If no, please provide rationale as to why exact date of birth is required to the proposed research question(s): [Click here to enter text.](#)

- b) If other specific date variables specific date variables have been requested (e.g. Date of Death, or Date of Diagnosis), would it be possible receive generalized or transformed dates in reference to an assigned reference (or index) date (e.g. diagnosis date is 01Jan0000 and death date is 11Jan0000. If diagnosis date is the assigned index date, this would be transformed to 'Index date=0', and death date would be transformed to 'Days to death=10')?

☐ **Generalized dates (MM/YY)**    ☐ **Transformed dates**    ☒ **No**

☐ **Not applicable** (no dates have been requested)

If yes, please list the applicable date variables: [Click here to enter text.](#)

If any exact dates are required, please provide rationale as to why they are required to meet the proposed research question(s): [Click here to enter text.](#)

- c) If postal code has been requested, would it be acceptable to provide a Forward Sortation Area (FSA), which is the first three characters, instead of full postal code?

☐ **Yes**    ☐ **No**    ☒ **Not applicable** (postal code not requested)

If no, please provide rationale as to why the full postal code is required to meet the proposed research question(s): [Click here to enter text.](#)

#### 4. Inclusion Criteria

Specify all inclusion criteria for data extraction. If subjects need to be identified by CCO, outline how they should be identified (e.g. index event [specific cancer, disease or procedure codes, timeframe for entering study, age restrictions, geographical location etc.).

☐ **Not Applicable**

1. Cohort provided to CCO will contain desired study population:
  - a. Female
  - b. Age 30-65 at diagnosis
  - c. Diagnosed with first and only breast cancer case between 2006-2010.
2. CCO will obtain data for patients residing in:
  - a. Central LHIN
  - b. Central East LHIN
  - c. Central West LHIN
  - d. Mississauga Halton LHIN
  - e. Toronto Central LHIN

## 5. Exclusion Criteria

Specify all exclusion criteria for data extract.

### ☐ Not Applicable

1. Exclude CIHI DAD and NACRS hospitalization records where the main diagnosis (ICD) are:
  - a. C70.0 – C70.9
  - b. C71.0 – C71.9
  - c. C72.0 – C72.9
2. Exclude patients who died within 30 days of breast cancer diagnosis.
3. Exclude patients where the LHIN of residence cannot be determined.
4. Exclude patients where the neighbourhood income quintile could not be determined.
5. Exclude patients where the last contact date is within 1 year of diagnosis.

## 6. Cohort Details

**What variables will be provided to CCO to perform the linkage?** *Please note for the most accurate linkage, CCO requests for the researcher to provide HIN, first and last name, and DOB for each patient in the cohort.*

### ☐ Not Applicable

Health card number, first name, last name, date of birth, postal code

## 7. Study Design

Please specify the study design for this request (e.g., cohort study, case-control, data-cut).

Longitudinal survival analysis, cohort study.

## 8. Study Size

Outline all groups involved in study (e.g. exposed, unexposed, cases, controls). If the number of study cases differs from the number of cases in the cohort applicable to this data request, please indicate.

### ☐ Not Applicable

1,978 patients provided. Number of exposed and unexposed unknown, to be determined by CCO.

## 9. Preferred Format and Output Variables



Specify the preferred format of the completed data (e.g., SAS file, Excel). Where possible, attach a template. If output should be formatted in a particular way, define how this should be done (e.g. age groups: 21-30, 31-40, 41-50, 51-54, 54+).

SAS file where the record granularity is at the hospitalization-level (i.e. do not transpose data to patient level).

Calculate and categorize age at hospitalization using patient birthdate and CIHI DAD admission date. Age variable: AGE (30-30, 40-49, 50-59, 60-65)

#### 10. Other Considerations

If there are other important considerations that need to be captured, indicate them here.

If there is a large range in the types of diagnostic or intervention codes in CIHI DAD or CIHI NACRS, codes may have to be categorized. This can be discussed as the data extraction process occurs.

### E. DATA LINKAGES, DATA FLOW AND FUTURE DATA REQUESTS

#### 1. Data Linkages

Complete table below if the research plan involves linking these CCO data to other datasets following disclosure. Add rows to the table as required.

Planned data linkages (list the databases that will be linked to CCO data)	What variables will be used for the linkage?
CCO data will be linked to hospital database containing sociodemographic data on cohort and other clinically relevant information from chart abstractions.	Health card number, first name, last name, date of birth, postal code.
Click here to enter text.	Click here to enter text.

If CCO data is to be linked to other data include an explanation of why such linkage is necessary:

Linkage of CCO data to hospital database is required as important sociodemographic and clinical information is present in the hospital database. After completion of the project, no information from CCO will be retained

## 2. Data Flow

Please describe:

1. How the data (cohort) will be collected and securely transferred to CCO (or alternatively how the cohort will be created by CCO)
2. How the data will be handled at CCO (e.g. linked to administrative databases)
3. Where the data will be securely disclosed to
4. How and where the data will be securely stored and accessed
5. How and when the data will be destroyed
  1. Breast Cancer Education Institution of Northeast Canada will transfer study cohort to CCO through MFT
  2. CCO will disclose the requested data to Breast Cancer Education Institution of Northeast Canada through MFT
  3. CCO data will be linked to hospital database containing sociodemographic data on cohort and other clinically relevant information from chart abstractions.

## 3. Permanent Linkages

Does the research plan include permanent linkages or data being kept indefinitely?

Yes ☐ No ☒

Click here to enter text.

## 4. Future data requests

Are there any plans to obtain additional CCO data for the purposes of this study in the future?

Yes ☒ No ☐

If yes, please include any relevant information about future data requests in the table below (e.g. include what data elements will be requested, the data sources, years and request timelines). With this information, CCO *may* be able to expedite the review and approval process.

We would like to request death clearance data in 3 years. The data would be used towards survival analysis.

Dataset	Variable(s)	Year(s)	Expected future request date
Ontario Cancer Registry	1. Last contact date. Vital status.	2006-2022	2022
Choose an item.	Click here to enter text.	Click here to enter text.	Click here to enter text.

## F. TIMELINE FOR DATA RETENTION AND DESTRUCTION

Date when access to PHI level data provided by CCO will no longer be required (i.e., when data destruction is planned for identifiable CCO data). Please note that CCO will only approve a maximum of a 5 year data retention period at a time. If the data needs to be retained beyond the 5 year mark, the researcher can submit an amendment to extend this date prior to the data retention period lapsing.

**3/31/2024**

Date when access to de-identified CCO data will no longer be required (i.e., when will all data be destroyed): **3/31/2024**

### NOTE:

- 1. Records of personal health information disclosed by CCO for research purposes must not be retained for a period longer than set out in the approved research plan. Researchers must destroy all data provided by CCO within 60 days of the dates listed above.**
- 2. Assertions of the destruction of data will require that researchers supply CCO with a Certificate of Destruction setting out the date, time and location of the secure destruction and the method of secure destruction employed as well as details of the items destroyed. The Certificate of Destruction will bear the signature of the persons who securely destroyed the information.**

Please contact [OH-CCO\\_Datarequest@ontariohealth.ca](mailto:OH-CCO_Datarequest@ontariohealth.ca) for a certificate of data destruction if required.

## G. PHIPA REB PLAN COMPLIANCE CHECKLIST

In order to disclose data for research purposes, CCO must meet all of the requirements of the *Personal Health Information Protection Privacy Act, 2004* (PHIPA). The table below helps CCO understand how the research project meets each privacy requirement and where it is reflected in the REB application(s).

**\*Please DO NOT add text to this table – only note the document and page numbers.**

	Requirement	Reference documents (e.g. REB Plan etc.)	Relevant section and page(s) where addressed
1.	REB approved Research Plan which includes: a. The affiliation of each person involved in the research b. The nature and the objectives of the research c. The anticipated public or scientific benefit of the research.		
2.	Description of the research proposed to be conducted		
3.	Duration of the research		
4.	Description of CCO data required and the sources (Note: please include a list of data elements and the source database(s) in the research plan)		
5.	Description of how PHI (including CCO's data) will be used in the research study, including <b>linkages</b> to other data (description and/or source) as well as <b>how</b> the linkage(s) will be conducted. Please provide a detailed data flow as part of this requirement.		
6.	Explanation as to why the research: a. Cannot reasonably be accomplished without PHI (including CCO's data) b. Requires linkages outlined		
7.	Explanation as to why consent to the disclosure of PHI is not being sought from the individuals to whom the information relates, if applicable (e.g. if it is impossible or impracticable to		

	address the research question if the prior consent of individuals is required) <sup>1</sup>		
8.	Description of the reasonably foreseeable harms and benefits that may arise from the use of PHI (including CCO's data) and how the researchers intend to address those harms.		
9.	Description of: <ul style="list-style-type: none"> <li>a. all persons who will have access to the information and</li> <li>b. why access is necessary</li> <li>c. Their roles in relation to the research and their related qualifications</li> </ul>		
10.	Safeguards that the researcher will impose to protect the confidentiality and security of CCO data, <b>including</b> an estimate of how long information will be retained in an identifiable form and why.		
11.	Information as to how and when the researcher will dispose of CCO data (please provide information for all copies including de-identified data if applicable)		
12.	Funding source of the research		
13.	Whether the researcher's interest in the disclosure of PHI or the performance of the research would likely result in an actual or perceived conflict of interest with other duties of the researcher		

#### H. Acknowledgements by Principal Investigator

The Researcher is requesting record level data from CCO. The Researcher understands and acknowledges that records requested may contain confidential personal health information (PHI) about individuals, including potentially identifiable information such as diagnoses dates, and names of physicians or hospitals, or may otherwise be in a form where individuals may be identifiable. If access to these records is approved, the Researcher must abide by the provisions of CCO's Research Data Disclosure Agreement (RDDA).

<sup>1</sup> Article 3.7- [http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter3-chapitre3/#ch3\\_en\\_a3.7a](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter3-chapitre3/#ch3_en_a3.7a)

The Principal Investigator (PI) acknowledges and understands that the records requested may contain identifiable, record-level personal health information (PHI). If this information is released to the PI, the PI must abide by the provisions of CCO's Research Data Disclosure Agreement (RDDA). If and when this request is approved by CCO, the PI and all those who will have access to the data will sign the required Research Data Disclosure Agreement before the data is provided by CCO. If and when this request is approved by CCO, CCO will also provide a Cost Estimate form which must be signed by the PI prior to any services being provided by CCO. In situations where the PI or others who will have access to data are students, the students' academic supervisor or advisor is also required to sign the Research Data Disclosure Agreement.

1. The PI agrees to ensure that cell sizes less than or equal to 5 will not be reported without prior written approval from CCO.
2. The PI agrees to only conduct data linkages in accordance with the approved Research Proposal.
3. The PI agrees that the retention period for data received from CCO indicated in section F is consistent with the retention period set out in the approved Research Proposal.
4. The PI agrees to ensure security and protection of identifiable record level data in accordance with best practices, including the Information & Privacy Commissioner's guidance with respect to secure storage and handling of PHI.
5. The PI agrees to ensure that data returned or destroyed be done in a secure manner in accordance with the Information & Privacy Commissioner, Ontario Fact Sheet # 10: Secure Destruction of Personal Information and Best Practices for the Secure Destruction of Personal Health Information.
6. The PI agrees to be invoiced for the administrative fee following review and approval of the request

**The Principal Investigator certifies that the information reported in this form and the appended Research Project Proposal, REB application and any other relevant supporting documents are accurate and agrees to comply with the terms and conditions contained in this form.**

<b>Name of Principal Investigator</b>	Dr. Nikola Kage
<b>Title</b>	Senior Scientist
<b>Signature</b>	
<b>Date</b>	Click here to enter a date.

## Additional Team Members

### I. CO-INVESTIGATOR(S) AND PERSONS WHO MAY HAVE ACCESS TO REQUESTED DATA

List all Co-Investigator(s) (CO-I) and other persons who may have access to the data. Please print additional copies of this page as required.

Name	Dr. Larrie Devid
Role/Title	Click here to enter text. Co-I <input checked="" type="checkbox"/>
Name of Organization	Toronto Central Hospital
Email	LarrieDevid@TCHospital.ca
Why is access required for this person?	If access to CCO data is not required, enter N/A Provide clinical insight to help guide analysis and interpretation of results
Name	Tamara Latford
Role/Title	Research Assistant Co-I <input type="checkbox"/>
Name of Organization	Breast Cancer Education Institution of Northeast Canada
Email	Tamara_Latford@BCEINC.ca
Why is access required for this person?	If access to CCO data is not required, enter N/A N/A