

VCH DATA APPLICATION

New Amendment

Please complete this form *electronically* and submit to Clinical Trials Administration,
Vancouver Coastal Health Research Institute c/o wylo.kayle@vch.ca. **Please note: Forms completed by hand will not be accepted.**

Research Ethics Board [REB] Application #

Application date

SECTION I: CONTACT INFORMATION AND STUDY TITLE

Principal Investigator

Phone Number

Email

Primary Contact

Phone Number

Email

Full Study Title

[FOR VCH & VCHRI USE ONLY]

VCHRI Approver

Signature

Date

Additional VCH Approver (if applicable)

Signature

Date

Additional VCH Approver (if applicable)

Signature

Date

SECTION II: SUBMISSION PROCESS

The *VCH Data Application* is required when researchers are requesting Data that is under the custody and control of VCH, and where VCH holds the legal authority for approving the disclosure of the Data for a specific research project. In addition to providing details about the Data that is being requested from VCH, researchers will be required to show VCH how they will meet, or already meet their responsibilities under the VCHRI Data and Research Access Terms and Conditions. The information entered onto this form should reflect the research project's data management policies, systems and procedures - which should be implemented and embedded into research procedures and regularly reviewed throughout the duration of the research project. Capitalized terms in the *VCH Data Application* will have the same meaning as defined in the VCHRI Data and Research Access Terms and Conditions.

Fill out the application to the best of your ability.

Submit a completed application electronically to VCHRI together with your VCH Operational Research Approval Application Form. The completeness of the application will be assessed by VCHRI; only completed applications will be submitted for VCH Information Privacy Office and/or the Applicable Data Steward ("VCH Departments") review.

If Decision Support will be providing data or other services in connection with the research project, it is recommended that the researcher consult with Decision Support before providing the completed documentation to VCHRI for review.

Please ensure the following information is consistent on ALL research project documentation including the *VCH Data Application*, VCH Operational Research Approval Application Form, ethics application and certificate, funding applications, external data applications and agreements, letters of support and any other project documentation:

Project Title
Research Team

Data Linkages
Research Objectives

All Dates and Date Ranges

SECTION III: RESEARCH PROJECT DESCRIPTION

Describe the research project, including how the Data will be collected, used, stored and shared.

SECTION IV: DATA REQUIRED FOR THE RESEARCH PROJECT

1. VCH Data

Chart Review

Not Applicable

Indicate the Data elements and years of Data to be accessed/requested. Researchers will [1] directly access the Data from a system or chart or [2] request a Data extract from VCH. In your description of data field/data source please include the **Personal Identifiers*** that you require.

**Personal Identifiers include the following: Individual's name; all geographic subdivisions smaller than a province, including street address, city, country, postal code; birth date; home telephone numbers; home fax numbers; electronic mail addresses; SIN; MRN; PHN; device identifiers and serial numbers; biometric identifiers; full face or identifiable photographic images and any comparable images; and any other unique identifying number, characteristic, or code, except a code to permit re-identification of the de-identified data.*

If you require additional space, please use page 6.

Source of VCH Data	Data Fields	How will data be accessed?	From Date (yyyy/mm/dd)	To Date (yyyy/mm/dd)
		<input type="checkbox"/> Direct Access <input type="checkbox"/> Data Extract		
		<input type="checkbox"/> Direct Access <input type="checkbox"/> Data Extract		
		<input type="checkbox"/> Direct Access <input type="checkbox"/> Data Extract		
		<input type="checkbox"/> Direct Access <input type="checkbox"/> Data Extract		
		<input type="checkbox"/> Direct Access <input type="checkbox"/> Data Extract		

2. NON-VCH Data

Not Applicable

External data is from other organizations (eg. source other than VCH). It is not held by VCH and not directly obtained from research subjects.

External Data Source/File	From Date (yyyy/mm/dd)	To Date (yyyy/mm/dd)

3. Researcher Collected Data

Not Applicable

Please include a description of the data the researcher plans on collecting (new data). Please include the data collection type (eg. survey/questionnaire/focus group/interview).

4. Can this research be done without personal identifiers?

Yes

No

5. If "Yes" to #4, when will de-identification of the Data occur?

At the conclusion of the research project

On or before date of receipt of Data

6. Who will de-identify the Data?

VCH Decision Support

Other (please explain below)

7. Provide details on how the de-identification will be done.

SECTION V: APPLICANT AND RESEARCH TEAM INFORMATION

The Research Ethics Board application should include the names of all research team members and should be updated when individuals are added or removed from the research team.

AUTHORIZED USERS - PERSONS WHO WILL HAVE ACCESS TO THE DATA [INCLUDING THOSE WITH WHOM DATA WILL BE SHARED]. Identify all individuals who will have access to the requested data at any time. Attach a separate sheet if necessary.

Name	Institution	Email Address	Access to Aggregate Data Only
			<input type="checkbox"/> Access to Aggregate Data
			<input type="checkbox"/> Access to Aggregate Data
			<input type="checkbox"/> Access to Aggregate Data
			<input type="checkbox"/> Access to Aggregate Data
			<input type="checkbox"/> Access to Aggregate Data
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			<input type="checkbox"/> Access to Aggregate Data

SECTION VI: LINKAGE BETWEEN VCH DATA AND EXTERNAL DATA Not applicable

Identify below all data sources and identifier fields that you propose to use for linkage [ie. Personal health Number (PHN, Medical Record Number (MRN) and/or Other]. A researcher may request some identified fields to be retained for analysis. Please identify and provide a detailed rationale for such a request in the space provided.

Data Source	Field Name	Retain for Analysis	Justification if Retaining for Analysis
		<input type="checkbox"/> Yes <input type="checkbox"/> No	
		<input type="checkbox"/> Yes <input type="checkbox"/> No	
		<input type="checkbox"/> Yes <input type="checkbox"/> No	
		<input type="checkbox"/> Yes <input type="checkbox"/> No	
		<input type="checkbox"/> Yes <input type="checkbox"/> No	
		<input type="checkbox"/> Yes <input type="checkbox"/> No	

If Data Linkage cannot be performed by VCH Decision Support, advise who will be responsible for linkage and the steps that have been taken, or will be taken to minimize the privacy risks of the proposed linkage at all stages. In particular, ensure the timeline for proposed removal and destruction of data used only for linkage is included.

SECTION VII: DATA SECURITY**1. PHYSICAL LOCATION AND SECURITY OF DATA**

Indicate the physical location(s) where the research data will be used or accessed including research sites, and storage sites (if different). Indicate all general physical security measures in place at each location. Include measures taken to protect workstations, hard copy and source media.

LOCATION 1:

Organization Name

Site (including Building Name and Room #)

Street Address City

Province Country

PHYSICAL SECURITY METHODS

Locked File Cabinet Door Keypad Other (please explain below)

LOCATION 2:

Organization Name

Site (including Building Name and Room #)

Street Address

City

Province

Postal Code

Country

PHYSICAL SECURITY METHODS

Locked File Cabinet

Door Keypad

Other (please explain below)

2. NETWORK SECURITY AND BACKUPS

If data will be stored on a network or system to which individuals other than identified project personnel have access, or on a system connected to a public network (the internet), indicate and describe the network security measures in place.

LOCATION 1 (specify):

Password rules (minimum length, complexity)

Password changed every

Firewall

Drives or folders with access restricted to specific research group

Access tracking

File encryption

Other (please explain below)

Security audit

LOCATION 2 (specify):

Password rules (minimum length, complexity)

Password changed every

Firewall

Drives or folders with access restricted to specific research group

Access tracking

File encryption

Other (please explain below)

Security audit

3. PERSONAL COMPUTER SECURITY AND BACKUPS

If data will be accessed or stored on the hard drive of a personal computer or removable drive, identify all security measures taken to protect data residing on the personal computer or removable drive.

- Electronic locking system
- Encryption
- Logon password
- Removable drives
- Individual file or folder attachments
- Physical attachment to floor or object
- Software firewall
- Antivirus
- Anti spyware or adware

Other (please explain)

4. DATA TRANSFER SECURITY

Data derived information, other than aggregated information such as statistical output, must be transferred by a secure file transfer. If this method is not possible, then an encrypted or password protected media must be used meeting the appropriate transfer protocols for the relevant public body, or transferred in person by someone named above as having access to the Data. Email, regular mail, fax and cloud storage (i.e., Drop Box) are not acceptable transfer methods at this time.

5. DATA RETENTION

Specify the timeline(s) for retention of the Data and plans for its disposal once such information is no longer required for purposes of the research project:

ADDITIONAL INFORMATION