

Data Access for Research Project Application Form

This form has been developed with the guidance of the VCH Information Privacy Office. It is intended to inform applicants requesting access to or extraction of information from VCH databases (“VCH Database(s)”) for specific research projects about privacy compliance requirements.

If you are conducting research that does NOT involve patient/client identifiers or Personal Information as defined under the BC Freedom of Information and Protection of Privacy Act (FIPPA), then you do NOT have to complete this form.

However, if your research project involves patient/client identifiers or Personal Information (as defined below), then you need to complete this form and submit it together with your *Request for Approval to Conduct Research Form* to the Data Administrator of the VCH Database. Once it has been reviewed by the Data Administrator, it will be submitted to Vancouver Coastal Health Research Institute (“VCHRI”) for ‘sign off’. A copy of this Form will be provided to the applicable Data Administrator for their records.

“**Data Administrator**” means the data administrator or his/her delegate responsible for the applicable database(s).

“**Data Steward**” means the person or group of persons designated by VCH as data steward with responsibility and accountability for oversight of the database, including compliance with the VCH policies with respect to collection, use, access to and disclosure and disposal of data.

“**Personal Identifiers**” includes the following:

- Individual’s name
- All geographic subdivisions smaller than a Province, including street address, city, county, 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
- Any other unique identifying number, characteristic, or code, except a code to permit re-identification of the de-identified data.

“**Personal Information**” means recorded information about an identifiable individual, including electronic and printed records, and includes Patient Identifiers, but not business contact information.

“**VCH Database**” means a database that VCH has stewardship responsibilities and contains VCH patient, client, resident or staff information that will be used for an authorized research project, for example, databases such as PCIS, Sunset, PARIS, or Decision Support. These are examples only and do not constitute an exhaustive list.

I. RESEARCH PROJECT INFORMATION

Research Project Title:

Research Project Acronym:

Protocol Number (if applicable):

Brief Description/Summary of Research Project:

<p>A. Please name each VCH Database(s) that you will be accessing and/or from which you will be extracting information:</p>	
<p>B. Please confirm period of access and/or extraction from VCH Database:</p> <p><input type="checkbox"/> Ongoing basis: <input type="checkbox"/> Project, term of _____ (#) months</p> <p>If access/extraction is on an ongoing basis, please provide the reason for ongoing access or extraction:</p> <p>If access/extraction is for a term, please provide the following information: Start date: End date:</p>	
<p>C. Please specify how many research subjects you require? (sample size):</p>	
<p>D. Will you require data from another organization (outside of VCH) in order to meet the sample size?</p> <p>If YES, an Information Sharing Agreement will be required with the other organization. If an Information Sharing Agreement is already in place, please provide the name of the organization:</p> <p><i>Please consult with the VCH Information Privacy Office on any Information Sharing Agreements that involve bulk abstracts or highly sensitive information (ie. genetic) or have not been reviewed by an REB.</i></p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>

II. DATA REQUESTED

<p>A. Please indicate whether you will be accessing or extracting data using Personal Identifiers from a VCH Database.</p> <p><i>If NO, you do NOT have to continue to complete this form.</i></p> <p>IF YES, please indicate in the box below all Personal Identifiers that you will be accessing and/or extracting information for your project:</p> <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <tr> <td style="width: 33%; padding: 5px;"><input type="checkbox"/> PHN</td> <td style="width: 33%; padding: 5px;"><input type="checkbox"/> MRN</td> <td style="width: 33%; padding: 5px;"><input type="checkbox"/> Patient/Client Account Number</td> </tr> <tr> <td style="padding: 5px;"><input type="checkbox"/> Patient /Client Name</td> <td style="padding: 5px;"><input type="checkbox"/> Patient / Client DOB</td> <td style="padding: 5px;"><input type="checkbox"/> Patient / Client Address</td> </tr> <tr> <td style="padding: 5px;"><input type="checkbox"/> Postal Code</td> <td colspan="2" style="padding: 5px;"><input type="checkbox"/> Other (please describe or attach a list to the Request for Approval to Conduct Research Form):</td> </tr> </table>	<input type="checkbox"/> PHN	<input type="checkbox"/> MRN	<input type="checkbox"/> Patient/Client Account Number	<input type="checkbox"/> Patient /Client Name	<input type="checkbox"/> Patient / Client DOB	<input type="checkbox"/> Patient / Client Address	<input type="checkbox"/> Postal Code	<input type="checkbox"/> Other (please describe or attach a list to the Request for Approval to Conduct Research Form):		<input type="checkbox"/> Yes <input type="checkbox"/> No
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<p>B. If YES to Section II, A, what steps have been taken to eliminate the possibility of re-identification of study subjects (i.e., have steps been taken to filter data with Personal Identifiers?) Please explain:</p> <p><i>[For example, for "patient/client DOB", is an age range sufficient instead of the specific birth date and year? OR for "patient/client address", is geographic location sufficient (province), rather than the postal code?]</i></p> <p>NOTE: If reasonable measures have not been taken to satisfy this requirement, VCH recommends that appropriate expert advice be obtained to de-identify or reduce risk of re-identification.</p>										
<p>C. Can your research project be accomplished WITHOUT Personal Identifiers?</p> <p>Please explain:</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No									
<p>D. If the research project can only be accomplished with data containing Personal Identifiers, please confirm how the data will be accessed.</p> <p><input type="checkbox"/> Data will be directly accessed from Database by research team members</p> <p><input type="checkbox"/> Data will be extracted from Database by VCH database administrators and provided to research team members.</p>										
<p>E. If you indicated that data containing Personal Identifiers will be accessed directly from Database (in question D above):</p> <p style="margin-left: 20px;">i. Explain reasons why direct access is necessary rather than extracts:</p> <p style="margin-left: 20px;">ii. Provide the names of all research team members who will access the Database and advise which ones specifically require direct access to Personal Identifiers based on their job</p>	<input type="checkbox"/> N/A									

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function.								
Access to PI Required		Name of Research Team Member						
<input type="checkbox"/>								
<input type="checkbox"/>								
<i>Insert additional rows as needed.</i>								
<p>NOTE: Access must be on the basis of ‘need to know’ for each job function and only the minimum amount of information should be collected for the specific research project. The Research Ethics Board (REB) must approve all of the data fields that you will be collecting throughout the course of this project. Do not change the data collection during the study unless you have obtained REB approval and amended your initial project application document.</p>								
<p>F. If you indicated that data containing Personal Identifiers will be extracted from the Database (in Section II, D above), then please indicate how the data will be extracted from this Database.</p>								
<p>G. Will Personal Identifiers be used for data linkage* or matching data from the VCH Database?</p> <p>If YES, please advise which databases, data collections, or sources are being linked, and if so for what purpose:</p> <p>If YES, then the number of research team members who have access to the data with personal identifiers must be minimized. For example, the following process is suggested:</p> <ul style="list-style-type: none"> ▪ The Principal Investigator and/or Data Administrator and/or technical staff member should create a Linking Table by assigning an associated study ID # for each data with Personal Identifier; keep this data linkage or matching data record as a separate table; limit to only 1-2 team members; once the Linking table is created, the original data extract with Personal Identifiers should be destroyed. ▪ Create a separate table using only the study ID #. This table will be used by all other research team members. <p>NOTE: If you are linking identifiable information to a unique study code, see CIHR’s “Best Practices for Protecting Privacy in Health Research (Sept.2005)” for guidelines on identifiable data and strategies to safeguard your subjects’ privacy. *“data linkage” means that certain data elements containing personal identifiers are associated with other data elements.</p>		<input type="checkbox"/> Yes <input type="checkbox"/> No						
<p>H. If you plan to export data out of this Database into a secondary application or other database (e.g. MS Excel) for further analysis, where will the local electronic copy be stored? <i>Please check all that apply.</i></p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 33%;"><input type="checkbox"/> Local or personal drive</td> <td style="width: 33%;"><input type="checkbox"/> Departmental network</td> <td style="width: 33%;"><input type="checkbox"/> Database (provide details)</td> </tr> <tr> <td><input type="checkbox"/> N/A, no local copies</td> <td><input type="checkbox"/> Other (please specify below)</td> <td></td> </tr> </table> <p>Please explain how will it be safeguarded?</p>			<input type="checkbox"/> Local or personal drive	<input type="checkbox"/> Departmental network	<input type="checkbox"/> Database (provide details)	<input type="checkbox"/> N/A, no local copies	<input type="checkbox"/> Other (please specify below)	
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III. CHECKLIST for Access to or Extraction of Database(s) for Research Purposes that pertain to usage, storage and safeguarding of data with personal identifiers.

Please acknowledge the following reminders (if applicable):

- Research team members should only have access to personal information from the Database that pertains to their role and job function and which they “need to know” for the research project.
- There are risks that may arise from the use of patient/client identifiers so patient/client identifiers must be removed at the earliest opportunity.
- If you wish to access any data remotely, e.g. from home or offsite from a VCH location, you must consult with VCH IMIS Security Services regarding appropriate security and access requirements and policies.
- If you are contemplating any linkages or data matching or sharing of data with other individuals and/or organizations, you must discuss this with VCH Legal Services to determine whether a Privacy Impact Assessment (PIA) or an Information Sharing Agreement is necessary.
- To ensure that your team members on this research project are privacy compliant, you must ensure that those accessing a clinical system only collect the minimum amount of information needed for the project, ensure that everyone has proper ID when entering sites, and ensure that team members have read the VCH Information Privacy and Confidentiality Policy.
- Personal Identifiers should be removed before storing local electronic or paper copies. However, if this is not done, then any printed or otherwise paper copies of research data must be stored in locked filing cabinets in a locked room or in a locked office in a locked area. Any local electronic copies that contain personal identifiers are secured by password-protection and encryption.
- Any electronic data containing Personal Identifiers collected for the research project may not be kept on computers shared by multiple users ie. in shared fellows’ offices.
- Data containing Personal Identifiers should NOT be saved to a USB or Flash drive. Back up copies of this data is encrypted and password protected and kept in a locked office accessible only to the research team on a “need to know” basis.
- At the end of your research project, all paper printouts or electronic local copies of the research project must be permanently destroyed or deleted unless they are required to be retained in accordance with VCHRI, REB, VCH Records Retention Records Policy or applicable legislative or regulatory requirements.
- Any dissemination of the research project results at a professional conference or in a peer-reviewed journal must not contain any personal identifiers or be linked in any manner to an identifiable individual. All raw data materials that are retained or archived may only be retained for a period of time after publication in case the study results are questioned and in accordance with VCH’s records, retention and destruction policies.
- Any future changes to your research project must be approved by the REB before you implement them and submitted to the VCHRI and Data Administrator of the Database, as applicable. Common changes to research projects, for example, include:
 - Adding new co-investigators, trainees or staff to a project
 - Adding new sources of information (eg. reviewing PACs records in addition to paper health chart)
 - Adding new data collection fields
 - Increasing the sample size or number of charts reviewed
 - Extending the data collection period (eg. collecting data for an additional year or more)
 - Expiry date for research project
- All information sharing agreements related to the research project and applicable privacy policies must be complied with.

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