Vancouver Coastal Health Research Institute (VCHRI)
Data and Research Access Terms and Conditions

These Terms and Conditions govern access by a principal investigator to Vancouver Coastal Health ("**VCH**") data, patients/clients/residents/staff and/or facilities for the purpose of conducting a Research Project described in a "VCH Operational Research Review Application" (the "**Application**"). The principal investigator must sign an Application agreeing to be bound by these Terms and Conditions, and understands and agrees that these Terms and Conditions will apply to the principal investigator for each and every subsequent Research Project that is the subject of an approved Application.

For clarity, the principal investigator will be referred to in these Terms and Conditions as "**you**" and "**your**" as the context requires.

1.0 DEFINITIONS

"**Authorized Person**" is a member of the principal investigator's research team who will be accessing Data containing Personal Information, who has signed a Confidentiality Undertaking and is named in an approved Research Ethics Board application.

"**Confidentiality Undertaking**" means the "Confidentiality Undertaking for VCH Research Projects" form.

"**Data**" means information in the custody and control of VCH, which may contain Personal Information, which you have requested through an Application.

"**Data Linking**" means the linking or combining of Personal Information in one database with Personal Information in one or more other databases for a different purpose than for which the data was originally collected.

"**Data Management Plan**" means an addendum to the Application outlining how the Data shall be collected, stored, shared and disposed of during and after the Research Project is completed.

"**FIPPA**" means the *Freedom of Information and Protection of Privacy Act* (British Columbia), and regulations thereto, as amended from time to time.

"Personal Identifiers" means any recorded information that could, either by itself or in combination with other information, be used to link or associate Personal Information to a particular individual (including but not limited to name, birth date, photograph, PHN, MRN, home address, six character postal code, personal telephone number, social insurance number (SIN), driver's license number, employee ID and other identity numbers).

"**Personal Information**" means any recorded information about an identifiable individual (including but not limited to name, PHN, MRN, age, race, home address, personal telephone number, employee ID and other identity numbers).

"**Research Ethics Board**" means a committee recognized by VCH that is composed in accordance with the TCPS-2 and that is responsible for assuring that a Research Project conducted by you meets current ethical, regulatory and scientific standards for the protection of human research participants.

"**Research Project**" means a project described in an Application that has been approved by a Research Ethics Board and that must be conducted in accordance with these Terms and Conditions.

"**TCPS-2**" means the Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2010.

2.0 CORE RESEARCH PRINCIPLES

2.1 You acknowledge that your primary responsibility as a principal investigator is to safeguard the rights and welfare of each research participant involved in a Research Project.

2.2 You recognize that research participants include persons directly involved in a Research Project such as a participant in a clinical trial, as well as persons whose data or human biological materials are used to conduct research.

2.3 You shall conduct your Research Project in accordance with the research principles set out in the TCPS-2, and comply with any other relevant federal or provincial laws or guidelines for the protection of human research participants.

3.0 ACCESS, USE, DISCLOSURE, RETENTION AND DESTRUCTION OF DATA

You are responsible for accessing, using, retaining and destroying any Data provided to you by VCH in accordance with the following terms:

3.1 You shall ensure that Data disclosed by VCH to you will only be used in connection with the Research Project(s) as described in your Application(s), and as approved by a Research Ethics Board.

3.2 You agree to submit a new Application form for each Research Project for which Data is requested by you.

3.3 You are responsible for ensuring that every Authorized Person completes a Confidentiality Undertaking, including new research team members not listed on the original Research Ethics Board application, and you shall inform VCHRI annually about changes to your research team for the duration of the Research Project.

3.4 You shall not disclose any Data other than as de-identified data, to anyone other than an Authorized Person, unless VCH provides written consent.

3.5 You shall not use or attempt to use the Data to contact the individuals to whom the Data is about in order to participate in any research, including research related to the Research Project, unless the individuals have provided written consent or the VCH privacy office has provided written approval.

3.6 You shall not perform Data Linking using the Data, except if approved by a Research Ethics Board and VCH.

3.7 Where Data has been provided to you in de-identified form, you shall not use the Data to re-identify any patients/clients/residents/staff, except if approved by VCH.

3.8 You agree to destroy the Data immediately after your Research Project has been completed, subject to any applicable data retention policies or laws or written approval from VCH to do otherwise, unless you have been requested by VCH to destroy or return the data at an earlier date. You shall provide VCH with confirmation of the destruction or return of the Data upon request.

3.9 You shall either remove or destroy all Personal Identifiers within the Data at the earliest possible time or limit access to the Personal Identifiers to only those of the Authorized Persons whose role in the Research Project requires access to those Personal Identifiers.

3.10 You acknowledge that as between VCH and you, the Data remains at all times the property of and within the control of VCH, unless VCH agrees otherwise under a separate contract or agreement that applies to the Data.

3.11 If a request is made to you for access to the Data, for example by law enforcement, court order or subpoena, you shall not respond to the request. You shall immediately advise the VCH Information Privacy Office of the request and you will collaborate and assist VCH in responding to the request.

3.12 You shall ensure that Data is utilized, transferred or stored in accordance with the approved Application, including the terms of a Data Management Plan if it is appended to the Application.

3.13 You shall ensure that no Data containing Personal Information is accessed from or stored outside of Canada, except in accordance with the exemptions described in section 33.1 of FIPPA.

4.0 DATA SECURITY AND PROTECTION OF PRIVACY

4.1 You shall be responsible for the confidentiality and security of the Data while it is in your or your research team's possession, and you will use reasonable measures to maintain the confidentiality and security of the Data in your custody against such risks as unauthorized access, collection, use, modification of use, disclosure or disposal.

4.2 Where the research activity will be conducted on VCH premises or using VCH information technology or systems, you shall comply with these Terms and Conditions, the Confidentiality Undertaking, applicable systems terms of use and any VCH policies.

4.3 You are required to immediately notify VCH about, and provide a detailed written report of the circumstances of any unauthorized access, use, disclosure or modification of the Data, or breach of confidentiality or security breach of a computer or network (the "**Breach**") and any remedial actions taken.

4.4 In the case of a Breach, as defined above, if VCH considers the remedial actions taken by you are not sufficient, VCH may suspend the provision of Data to you or require the return or destruction of any Data provided to you, in addition to other measures.

5.0 ACCURACY AND USE OF INFORMATION

5.1 The Data is provided on an "as is" and "as available" basis and VCH makes no warranties or representations regarding the accuracy, completeness, reliability or fitness for use of the Data.

5.2 VCH assumes no liability for any losses or damages arising out of your use, misuse or inability to use the Data.

6.0 PUBLICATIONS

6.1 If you intend to publish findings or reports based on research conducted using Data or involving VCH patients/clients/residents/staff, you agree to only use de-identified data in a publication.

6.2 You agree to acknowledge the contribution of VCH in all reports or publications resulting from your use of the Data or research conducted at VCH.

7.0 CONDUCT FOR CLINICAL TRIALS

7.1 You acknowledge that your access to VCH Data, patients/clients/residents and/or facilities, in order to conduct your clinical trial, is subject to your adherence to the research protocol approved by the applicable Research Ethics Board.

7.2 You shall ensure that all members of your research team, and all others directly involved in the conduct of the Research Project, have the required education, training and experience to perform their research duties.

7.3 You shall ensure that consent in writing is obtained from each clinical trial staff member allowing the sponsor to collect, use and disclose that member's personal information for the following purposes: (i) the conduct of the Research Project; (ii) verification by governmental or regulatory agencies across the world; (iii) compliance with legal and regulatory requirements; (iv) publication on www.clinicaltrials.gov and websites and databases that serve a comparable purpose; and (v) storage in databases to facilitate the selection of investigators for future clinical trials.

7.4 You shall collect, document and maintain records of informed consent from each research participant, or the participant's legally authorized representative, as required under applicable laws and by the Research Ethics Board.

7.5 You shall not enroll participants in research prior to receiving final approval from VCHRI.

7.6 You shall not deviate from your research protocol without approval from the Research Ethics Board, except if necessary to eliminate immediate danger or risk to a research participant.

8.0 GENERAL

8.1 You agree to explain the requirements described herein to all members of your research team.

8.2 You acknowledge and agree that your obligation to maintain the privacy, security and confidentiality of the Data provided to you will survive these Terms and Conditions.

8.3 You acknowledge and understand that you are responsible for your conduct and that of your research team while performing research using VCH Data or at a VCH facility, and that you may be legally liable for harms or expenses caused by you or your research team's negligence, omissions or failure to comply with these Terms and Conditions.

8.4 You accept that it may be necessary for VCH to amend these Terms and Conditions from time to time. You understand that you may not be personally notified of any changes and that you are expected to review the most current Terms and Conditions periodically and each time you submit a new Application.

9.0 VCHRI CONTACT INFORMATION

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