Vancouver CoastalHealth Research Institute

Standard Operating Procedure
Confidentiality and Privacy

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Site Approval

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Document History

Version	Summary of Changes Made	Effective Date
1	Original document.	09-JUL-2010
2	This version has undergone extensive revision for: administrative, educational, regulatory, and clinical changes by individual content experts and the VCHRI SOP Committee. This document has also had substantial formatting, grammatical and glossary updates. It has been classed as a rewritten document.	10-JAN-2016
3	This version has undergone revision for administrative, education, regulatory and clinical changes by individual content experts and VCHRI SOP Committee. There have been changes made to 6.1, 6.2.6, 6.4. Definitions and References have been updated.	01-Jun-2021

1. PURPOSE

1.1. This Standard Operating Procedure (SOP) describes the procedure to ensure that integrity and confidentiality of data collected within the framework of a Clinical Trial/Study, and the privacy of Participants.

2. SCOPE

2.1. This SOP is applicable to Clinical Trials/Studies undertaken at the Institution, and to those Research Team Members responsible for ensuring the privacy, security and confidentiality of data, and Participant information.

3. RESPONSIBILITIES

3.1. The Principal Investigator or Sponsor-Investigator is responsible for ensuring that the confidentiality and privacy aspects of the Clinical Trial/Study meet the applicable regulatory, International Conference on Harmonisation (ICH) Good Clinical Practice (GCP), sponsor, privacy legislation, and Institutional requirements.

4. RELATED SOPS/DOCUMENTS

4.1. Confidentiality Undertaking for Vancouver Coastal Health (VCH) Research Projects
4.2. Vancouver Coastal Health Research Institute (VCHRI) Data and Research Terms and Conditions
4.3. VCH Information and Confidentiality Policy

5. DEFINITIONS

5.1. **Authorized Person**: A member of the Principal Investigator's or Sponsor-Investigator's research team who will be accessing data containing Personal Information, who has signed a Confidentiality Undertaking, who is qualified and has delegated authority, and is named as a Research Team Member in an approved Research Ethics Board application.

5.2. **Confidential Information**: All information, other than Personal Information, that is specifically identified as confidential or is reasonably understood to be of a confidential nature, that the Principal Investigator, Sponsor-Investigator and/or Research Team Members receive or have access through VCH or other parties, including vendor contracts, and other proprietary information that may have been received from a third party (including pharmaceutical companies and contract research organizations). Confidential Information may be written, verbal, electronic, photographic or stored in any other medium (i.e. tissue, diagnostic images).

5.3. **Personal Information**: Any recorded information about an identifiable individual (including but not limited to name, personal health number, medical record number, age, race, home address, personal telephone number, employee ID and other identity numbers). It does not include business contact information, and it does not include information with Personal Identifiers removed (provided you cannot identify the person the information is about from the remaining information). Personal Information might, for example, include a person's name, medical record number and personal health number, medical information, photograph, and health or employment records. Any information about patients, clients, co-workers or individual members of the public should generally be considered Personal Information.

5.4. See also VCHRI Glossary of Terms.

6. PROCEDURE

6.1. General

6.1.1. Information that is disclosed in the context of a professional or research relationship must be held confidential to the extent permissible within the applicable law. Confidential Information may be written, verbal, electronic, photographic or stored in any other medium (e.g. tissue, diagnostic images).

6.1.2. Protection of privacy and/or confidentiality in the context of clinical research includes prevention of disclosure, other than to Authorized Persons or as required by law, of any information which could identify a Participant, or result in disclosure of Sponsor's proprietary information.

6.1.3. Every Authorized Person with direct access to Clinical Trial/Study data must comply with the Declaration of Helsinki, the directives of the ICH-GCP, regulatory requirements and applicable privacy legislation for the maintenance of confidentiality, Participant identity and respect for the proprietary information of the Sponsor or Sponsor-Investigator. Clinical Trial/Study team roles will be delegated and have appropriate restricted access to Clinical Trial/Study records, as related to the role.

6.1.4. Where the research activity will be conducted on VCH premises or using VCH information technology, systems or data, the Principal Investigator, Sponsor-Investigator and Research Team Members will comply with the *Confidentiality Undertaking for VCH Research Projects*, the *VCHRI Data and Research Access Terms and Conditions,* and the applicable systems terms of use and any VCH policies.

6.1.5. Authentication of the person who has access to the data constitutes the most important aspect of security. It determines the overall level of protection and is linked to key elements of data security.

6.2. Data Security

6.2.1. Establish a mechanism for control of access to secure premises. Document the procedure. It is recommended that the control mechanism includes use of magnetic cards or a biometric recognition system that allows tracking of movement in and out of the premises, if applicable.

6.2.2. Retain a tracking document with the signatures and initials of all persons authorized to register data, or to make corrections to the Case Report Forms (CRFs), with the Essential Documents.

6.2.3. Physical security: concerns the premises where Clinical Trial/Study files containing Essential Documents and clinical data, as well as computer equipment used for data management, such as telecommunication servers, database servers and computers are located. These rooms should be located in an area protected from possible disasters (e.g., water or fire damage, etc.), and be protected by a secure access control system.

6.2.4. Logical security: concerns management of access to data, which includes identification, authentication, and authorization. In order to ensure logical security, the following measurements should be applied:

6.2.4.1. Limit authorized access to delegated and trained Research Team Members; those identified by the Protocol, Consent form and the delegation log.

6.2.4.2. Grant privileges for physical or electronic access to data to personnel according to the roles and responsibilities defined by the Sponsor-Investigator or Principal Investigator.

6.2.5. Where the Sponsor or Sponsor-Investigator is the designated person in charge of system management, they shall be considered a System Administrator.

6.2.6. System Administrator's responsibilities include:

6.2.6.1. Develop and enforce standardized procedures for logical security

6.2.6.2. Assign a different identification code to each user of the data management system

6.2.6.3. Ensure that users' passwords meet current standards, and are changed regularly, as defined by the System Administrator

6.2.6.4. Ensure the confidentiality of the authentication of system users, and document access tracking

6.2.6.5. Establish a disaster recovery plan for saving and recovering data, in the event of loss or disaster

6.2.6.6. Suspend the Authorized Access of a user after a given number of errors. Inform other users of this suspension. Update the delegation log accordingly. Retrain the user, if required, and document the training

6.2.6.7. Cancel access for Research Team Members who leave the Clinical Trial/Study. Update the delegation log.

6.2.6.8. Access codes must be kept in a secure location

6.3. Data Confidentiality

6.3.1. A Participant who authorizes access to his/her data must be reasonably assured that the Sponsor or Sponsor-Investigator, Principal Investigator, their authorized representatives, Research Ethics Board (REB), and Regulatory Authorities will take precautions to ensure that verified and collected data remain confidential.

6.3.2. Include a description of the provisions and limits of confidentiality within the context of the Clinical Trial/Study, in the Informed Consent Process and Form, as follows:

6.3.2.1. The Informed Consent form must describe to the Participant who will have access to their information and for what purposes (e.g., Health Canada, US Food and Drug Administration, Research Ethics Board, Sponsors, Monitors, etc.).

6.3.2.2. Information collected during the Clinical Trial/Study will not be shared by the Principal Investigator without the Participant's free and informed consent, unless required by law.

6.3.2.3. Information pertaining to the Participant must be recorded in the Case Report Forms (CRFs), and any other Clinical Trial/Study documents that will leave the research site, including electronically captured data, in such a way as to protect Participant identity. Participants will be identified with a unique identifier.

6.3.2.4. No Clinical Trial/Study materials sent to and/or retained by the Sponsor will contain any identifying information. This includes, but is not limited to, Investigational Drug returns, test results, medical histories, and Adverse Event reports.

6.3.2.5. Participant enrolment lists, copies of prescriptions and Informed Consent Forms, which include identifying information, will be retained at the Clinical Trial/Study site. All research documents with Participant identifiers should be kept separate from other Clinical Trial/Study documents.

6.3.2.6. Best practice dictates that reimbursements or stipends paid to the Participants will be paid from the research account specific to the Clinical Trial/Study, and not directly from the Sponsor. This will ensure the Sponsor does not have access to Participant names.

6.3.2.7. The Research Ethics Board review process and VCHRI operational research review process govern the secondary use of the information gathered (for purposes other than the original intent), in accordance with the applicable regulatory guidelines.

6.4. Institutional Safeguards

6.4.1. The Principal Investigator or Sponsor-Investigator and Research Team Members must take reasonable security precautions to protect Personal Information and Confidential Information against unauthorized access, collection, use, disclosure or disposal.

6.4.2. Physical Measures and Safeguards: The Principal Investigator or Sponsor-Investigator will comply with Institutional physical security requirements and will take all reasonable steps to protect Personal Information and Confidential Information against unauthorized access, collection, use, disclosure or disposal, including:

6.4.2.1. Keeping hard copies of files and records containing Personal Information or Confidential Information in a secure location, such as locked storage rooms or locked filing cabinets, with controls over distribution of keys or lock combinations;

6.4.2.2. Protecting mobile electronic devices and storage media containing Personal Information or Confidential Information against theft, loss or unauthorized access;

6.4.2.3. Refraining from disclosing or discussing Personal Information or Confidential Information in public areas where third parties may overhear or view records containing Personal Information or Confidential Information;

6.4.2.4. Following Institutional guidelines and procedures for the secure destruction or disposal of Personal Information or Confidential Information that is no longer required to ensure the Personal Information or Confidential Information is destroyed, erased or made anonymous;

6.4.2.5. Prohibiting removal of records containing Personal Information or Confidential Information from VCH premises except as necessary, and, in such cases, ensuring they are kept in a secure location and not exposed to risk of loss, theft or unauthorized access.

6.4.3. Technical Measures and Safeguard: The Principal Investigator or Sponsor-Investigator will comply with Institutional technical security requirements and will take reasonable steps to maintain the integrity of electronic systems, including:

6.4.3.1. Protecting the integrity of passwords, user IDs and other security access measures;

6.4.3.2. Logging-off computers when not in attendance;

6.4.3.3. Using encryption and password protection for mobile electronic devices and storage media.

7. REFERENCE(S)

BC Freedom of Information and Protection of Privacy Act, [RSBC 1996, c. 165], as amended from time to time.

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, TCPS 2 (2018), December 2018.

Department of Justice (Canada), Personal Information Protection and Electronic Documents Act (PIPEDA), last amended June 21, 2019, current to February 15, 2021.

Government of Canada, Medical Devices Regulations, Part 3 Medical Devices for Investigational Testing involving Human Subjects, SOR/98-282, May 7, 1998; last amended December 16, 2019, current to February 15, 2021.

Government of Canada, Natural Health Products Regulations, Part 4 Clinical Trials Involving Human Subjects, SOR/2003-196, June 5, 2003; last amended September 28, 2020, current to February 15, 2021.

Health Canada, Food and Drug Act, Part C, Division 5, Drugs for Clinical Trials Involving Human Subjects, (Schedule 1024), June 20, 2001.

Health Canada, Guidance Document: Part C, Division 5 of the Food and Drug Regulations “Drugs for Clinical Trials Involving Human Subjects”. GUI-0100. August 20, 2019.

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), ICH Harmonised Guideline, Integrated Addendum to ICH E6 (R1): Guideline for Good Clinical Practice, E6 (R2), November 9, 2016.

Network of Networks (N2) Confidentiality and Privacy SOP019_09, Effective 15 May 2021.

Pharmaceutical Inspection Convention, Pharmaceutical Inspection Co-operation Scheme, Annexe 11, Computerised Systems.

US Food and Drug Administration, Code of Federal Regulations, Title 21, Volume 1:

- Part 11, Electronic Records; Electronic Signatures, (21CFR11).
- Part 50, Protection of Human Subjects, (21CFR50).
- Part 54, Financial Disclosure by Clinical Investigators, (21CFR54).
- Part 56, Institutional Review Boards, (21CFR56).
- Part 312, Investigational New Drug Application (21CFR312).
- Part 314, Applications for FDA Approval to Market a New Drug (21CFR314).

US Department of Health and Human Services, Code of Federal Regulations, Title 45, Part 46, Protection of Human Subjects (45CFR46).

US Department of Health and Human Services, Guidance for Industry: Computerized Systems Used in Clinical Investigations, May 2007.

8. ATTACHMENT(S)

None.