APPLICATION FOR INITIAL ETHICAL REVIEW

The ethical review process is governed by the Fraser Health Policy: The Ethical Conduct of Research and Other Studies Involving Human Participants

Instructions:

1) Please complete the check list below and read the following information carefully before proceeding to the form:

Delegated Review	Full Board Review
• Submit for delegated review if study meets **all** of the following criteria: (double click to check) ☐ Minimal risk – refer to Guidance Notes for definition ☐ Does **not** have any corporate (i.e. industry/for profit) sponsorship ☐ Does **not** involve participants incapable of full consent unless for retrospective chart review or observational data collection only ☐ Does **not** deviate from standard clinical practices or from normal procurement of tissue/blood ☐ Includes only standard of care interventions	• Submit for full board review if study meets **any** of the following criteria: (double click to check) ☐ **Does** have any corporate (i.e. industry/for profit) sponsorship ☐ **Does** require a waiver of consent ☐ **Does** involve participants incapable of full consent unless for retrospective chart review or observational data collection only ☐ **Does** deviate from standard clinical practices or from normal procurement of tissue/blood ☐ **Does** involve linkage of personal information to non-Fraser Health databases/registries

2) Complete this form with reference to the current FHREB Guidance Notes (GN) for Initial Applications at: https://www.fraserhealth.ca/health-professionals/research-and-evaluation/find-resources/forms-guidance-notes-templates/

3) All consent form(s) and protocol templates are located at: https://www.fraserhealth.ca/health-professionals/research-and-evaluation/find-resources/forms-guidance-notes-templates/

4) Surveys do not require written consent as consent is implied with survey completion. Please ensure that the invitation to complete the survey meets standard requirements. Refer to the survey template at: http://www.fraserhealth.ca/health-professionals/research-and-evaluation/find-resources/forms-guidance-notes-templates/forms-guidance-notes-templates

5) Please note that ethical review is NOT conducted for evaluation/quality improvement studies

6) Email all documents to REB@fraserhealth.ca

7) Obtain electronic/digital signatures or email application's signature page to REB@fraserhealth.ca at same time as electronic submission

1. Title of Research Proposal

Is this proposal closely linked to any other proposal submitted to the FHREB? Yes ☐ No ☐

If Yes:

Provide the FHREB File Number of primary study:

Describe the relationship of this proposal to this primary study:

2. Main Contact Information

All correspondence including the Initial Certificate of Ethical Approval will be emailed to the address given here.

Title: **Email Address:**

Last Name: **Mailing Address:** **City/Province:**

First Name: **Postal Code:**

3. Fraser Health Principal Investigator

Must be Fraser Health employee or physician with privileges at the Fraser Health site(s) for this study, or an academic investigator who has been granted affiliated status with Fraser Health. Affiliated investigators must include a memo signed by their Fraser Health Co-Investigator describing their role in this study.

Title: **FH Department:**

First Name: **FH Site:**

Last Name: **Discipline:**
(e.g. medicine, nursing)

Email Address:

Mailing Address: **FH Program:**
(if applicable)

4. Key Words (key words may include the disease, the intervention, the topic/category of study, etc.)

1.	2.	3.	4.	5.
6.	7.	8.	9.	10.

5. Other REB Review: Has/will this study been/be submitted to/approved by another Research Ethics Board?

Yes ☐ - If yes, provide the name of the REB(s)

No ☐

6. Academic Program If this research is required for completion of an academic program, specify:

Name of university and type of degree:

☐ **Masters**

☐ **Doctorate**

☐ **Residency**

☐ **Other:**

7. Co-Investigators List all co-investigators (insert appendix if necessary)

FH Co-I: ☐	**Non-FH Co-I:** ☐	**Full Name:**	**Email:**
FH Co-I: ☐	**Non-FH Co-I:** ☐	**Full Name:**	**Email:**
FH Co-I: ☐	**Non-FH Co-I:** ☐	**Full Name:**	**Email:**
FH Co-I: ☐	**Non-FH Co-I:** ☐	**Full Name:**	**Email:**
FH Co-I: ☐	**Non-FH Co-I:** ☐	**Full Name:**	**Email:**
FH Co-I: ☐	**Non-FH Co-I:** ☐	**Full Name:**	**Email:**
FH Co-I: ☐	**Non-FH Co-I:** ☐	**Full Name:**	**Email:**

8. Type of Research

Please check the box which most closely describes the type of research for this study:

☐	**Biomedical**	Research on human participants that is not diagnostic or therapeutic
☐	**Clinical**	Research on or for the treatment of patients
☐	**Health Services**	Research on how to improve efficiency/effectiveness of the health care system
☐	**Population Health**	Research on factors affecting health status

Is this patient-oriented research (i.e., are patients or informal caregivers [family or friends] members of or advisors to the research team)? **Yes** ◯ **No** ◯

9. Sites Where Research Will Be Conducted

☐ ARHCC	☐ DH	☐ LMH	☐ RCH	☐ JPOCSC
☐ BH	☐ ERH	☐ MMH	☐ RMH	
☐ CGH	☐ FCH	☐ PAH	☐ SMH	

☐ Physician's Private Office

☐ Fraser Health Community Site(s) (e.g. Mental health clinics)
Please specify: _____

☐ Other: _____

10. Department Agreement for Providing Research-Related Services [DAR] Form

The DAR Form must be completed for any studies that require access to information or services required to complete the study and that are NOT standard of care. Submit by email a signed copy of the form to REB@fraserhealth.ca once available. For details, refer to https://www.fraserhealth.ca/health-professionals/research-and-evaluation/find-resources/forms-guidance-notes-templates/

10a. Is a DAR Form Required? Yes ◯ No ◯

If YES, indicate the department (s) providing service(s) for this study:

☐ Anatomical Pathology	☐ Diagnostic Imaging	☐ Health & Business Analytics
☐ Biomedical Engineering	☐ Health Records (Electronic)	☐ Information Management
☐ Patient Care (i.e. units)	☐ Health Records (Paper)	☐ Communicable Diseases/Public Health
☐ Pharmacy	☐ Laboratory	☐ Surgical Suites
	☐ Image Tech Lab	☐ Procurement

11. Funding Information: Please complete as applicable. Please only select and complete the proper funding source (industry sponsored, grant funded, unfunded, or other)

11a. ◯ **Industry Sponsored**
- ◯ Direct Sponsorship*
- ◯ Grant-In-Aid

***For Direct Sponsorship ONLY:** FHREB Fee of **$4,000.00** is required, payable to the 'Fraser Health Authority'. Please submit with the application, as payment is required to issue the Letter of Authorization to Conduct Research.

Name of Sponsor:

Please indicate the status of the Clinical Trial Agreement (CTA) for any study funded directly or indirectly by a grant-in-aid from an industry/for profit sponsor:
- ◯ CTA Submitted for Review
- ◯ CTA Submission Pending

Please indicate where the funds for the study will be held:
◯ Fraser Health Cost Centre ◯ Physician Held Account

11b. ◯ **Grant Funded**
- ◯ Awarded
- ◯ Pending

Name of Institution Administering Grant:
Is it Fraser Health? Yes ◯ No ◯ **Note: If yes, DERS will request FH Finance to create a cost centre**
If No, name other institution

Name of Granting Agency:

Name of Grant Awardee:

Notification of Award Letter attached*: ☐

** Fraser Health Grant Award Recipients must include the Notification of Award Letter with this application**

For studies funded by a grant held by a non-Fraser Health institution, is an agreement between Fraser Health and the institution/PI required? Yes ◯ No ◯
If Yes, ◯ Submitted for review ◯ Submission pending
If Yes, will funds be transferred to Fraser Health Yes ◯ No ◯

11c. ◯ **Unfunded**

11d. ◯ **Other** Please specify:

For Funded Research ONLY:

Is the researcher or research group paid by the funder for each participant enrolled? Yes ◯ No ◯
If Yes, state amount (Please refer to TCPS Article 7.3): $

Will any research-related costs be billed to the health care system? Yes ◯ No ◯
If yes, provide details:

12. Financial Conflict of Interest

If any of the following are true for the PI or the PI's close relatives please provide details in the space provided below:

☐	Has a financial interest in the research with value that cannot be readily determined (for example, stock that is not publicly traded);
☐	Has a financial interest in the research with value that exceeds $10,000 other than payments for conducting the trial as outlined in the clinical trials agreement;
☐	Has a financial interest in the research with value that exceeds 5% ownership;
☐	Has received or will receive compensation with value that may be affected by the outcome of the study;
☐	Has a proprietary interest in the research, such as a patent, trademark, copyright, or licensing agreement;
☐	Has received or will receive payments other than payment for the conduct of clinical research form the sponsor that exceeds $10,000 in the last 365 days;
☐	Is an employee of the agency or company sponsoring the research;
☐	Is on the board of directors of the sponsor;
☐	Has a financial interest that requires disclosure to the sponsor or funding source; or
☐	Has any other financial interest that may interfere with his or her ability to protect participants.

Provide details if any of the above are checked:

13. Clinical Trial Registration

All prospective clinical trials which include an intervention and comparison group MUST be registered at one of the following. Please check which applies: Not Applicable ☐

www.ClinicalTrials.gov ☐ Registration No.:

14. Regulated Research

Is this study a clinical trial regulated by Health Canada? Yes ○ No ○

If Yes, complete the following as applicable:

14a. Name the investigational drug(s) or natural health product(s):

14b. Name any marketed drugs or natural health products used outside of their approved indication:

14c. Name and describe any new investigational device(s):

14d. Name and describe any marketed devices to be used experimentally:

14e. Has the No Objection Letter (NOL) or Investigational Testing Authorization (ITA) been obtained from Health Canada for this study? Yes ○ No ○

If Yes, Date of Approval:

Letter attached? ○ Letter pending? ○

14f. If No, has the request for approval been submitted to Health Canada?
NOL/ITA must be submitted BEFORE the Letter of Approval to Conduct Research (LOA) is issued. Yes ○ No ○

14g. Is there a requirement for this research to comply with United States regulations under 45CFR46? (i.e. any U.S. government funded research) Yes ○ No ○

14h. Is there a requirement for this research to comply with United States regulations under 21CFR56? (i.e. any research regulated by the United States Food and Drug Administration) Yes ○ No ○

15. Peer Review

15a. Has this research proposal received independent scientific/methodological peer review? Yes ○ No ○

If Yes: ○ External Review
○ Internal Review

15b. Provide details: (i.e. include the names of committees or individuals involved in the review or explain why no independent review has taken place):

16. Participant Enrollment

16a. Is this a multi-centre study? (i.e. also being conducted outside of Fraser Health) Yes ○ No ○

16b. **For all studies**, what is the total number of expected research participants? This includes the use of individual record level data obtained for secondary research (e.g. how many charts).

16c. For multi-centre studies, what is the total number of expected research participants at Fraser Health sites?

16d. For studies that involve an experimental intervention, how many participants will be in the:

Experimental arm: Control/normal/placebo arm:

17. Procedures

17a. Please indicate which of the following procedures are involved in this study and if they are: **Standard Care [SC] or Investigational [I]**. Please check all that apply.

Procedure	SC	I
Drug administration	○	○
Surgical procedures	○	○
Experimental medical devices	○	○
Imaging procedures (e.g., X-ray, MRI)	○	○
Collection of blood	○	○
Analysis of tissue only	○	○
Analysis of data only	○	○
Questionnaires/surveys	○	○
Individual interview	○	○
Focus groups	○	○
Home visits	○	○
Video/audio recording	○	○
Database linkage	○	○
Prospective data collection	○	○
Collection of other tissue (use of identifiers must be in consent if sent off site)	○	○
Other Interventions (e.g. psychological, eHealth, rehabilitation)	○	○
Secondary use of previously collected data (e.g. Health records retrospective chart review)	○	○
Genetic Testing	○	○
Qualitative Data	○	○

Procedure	SC	I
Creation of biobank	○	○
Creation of databank	○	○
Natural health product administration	○	○
Psychotherapy	○	○
Manual therapy or exercise intervention	○	○

Other

18. Use of Study Results

18a. Describe any plans for using the results of the research:

18b. Are there plans to publish the results of the research?	Yes ☐	No ☐
18c. Are there plans to present the results of the research?	Yes ☐	No ☐
18d. Are there plans to implement the research results into practice at Fraser Health?	Yes ☐	No ☐

19. Retention of Research Records

19a. ☐ Research records will be maintained for 25 years for regulated clinical trials
☐ Research records will be maintained for 5 years

20. Research Harms ☐ Not Applicable

- Describe what is known about the risks of harm of the proposed research. Include any information about discomfort or incapacity that the participants are likely to endure as a result of the research procedure(s), along with the details of any known side effects/harms which may result from the research procedure(s).
- For clinical and non-clinical research, please attach a separate page using the table format as outlined below.
- For clinical research, ensure that all measurable side effects are quantified.
- For non-clinical research, use qualitative measures to assess severity, if quantitative measures do not apply.

Template for Completion of Risks of Proposed Research

Describe the Intervention	Prior Research including Exposure	Side effect Frequency	Severity Categories	Areas of Concern	Risk Mitigation	Consent Form Page
Clinical Pharmacology of the Investigational Agent Is the drug a new drug entity? Is there a novel mechanism of action? Is there a new receptor distribution? **Non-clinical** Research intervention Survey instruments assessing risk factors associated with violence	**Clinical** What type of clinical or pre-clinical trial, i.e. animal studies/Phase I, II, III, IV? How are results of different studies analysed? Is the prior research completed or ongoing? Exposure to Drug: How many participants exposed - dosage, duration? Were placebo or comparator drugs used? **Non-clinical** Site any studies wherein using the intervention did/did not result in harm if applicable e.g. Prior research conducted using survey instruments that ask questions of a sensitive nature.	**Clinical** List the type of harm; quantify/list frequency of risk for investigational drug & placebo, if applicable, using %'s where possible & in descending order Use absolute risk[1] - Frequencies MUST have range - Is study powered to detect all side effects? - Is drug dose different for this study compared to prior research? **Non-clinical** - Type of harm & frequency if known, e.g. less than 1% of all participants in prior research required counselling	**Clinical and Non-clinical** Mild Moderate Severe Life-threatening What are the short/long term effects? What is reversible/ non-reversible?	**Clinical** Bleeding, arrhythmias, PFT changes, immunology **Non-clinical** Emotional distress due to answering questions concerning abuse	**Clinical** Specific monitoring or procedures for risks and specific areas of concern, e.g. participant education, DSMB, enhanced participant monitoring **Non-clinical** Participant right to refuse to answer questions Provision of counselling	**Clinical** Ensure %'s in consent form match that of the study IB and protocol. **Non-clinical** Ensure risks match those in the study protocol.

[1] Kramer BS, et al. Getting it Right: Being Smarter about Clinical Trials. PloS Medicine. Vol 3, No. 6, June 2006, p. 004 and Ionnadis JPA et al for the CONSORT Group. Better Reporting of Harms in Randomized Trials: An Extension of the CONSORT Statement. Ann Intern Med 2004: 141, 781-788.

21. SITE-SPECIFIC INFORMATION

- All applicable information MUST be included in the Protocol/Proposal submitted for review
- If the information below is not part of your protocol/proposal, please attach as an appendix.
- Reference the Page # where the information is located in the protocol/proposal or indicate n/a.

☐ **Participant recruitment information**

☐ Describe how prospective participants will be identified and by whom.
Will contact information from a 'consent to contact database' be used? Yes ☐ No ☐

Describe the source of and the original purpose of the contact information.

Describe how initial contact with the study participants will be made and by whom.

Describe the selection and/or recruitment procedures for control/normal participants.

☐ **Informed Consent Form:** Informed consent must be obtained for all prospective research unless a waiver of consent is required for special circumstances which must be justified to the FHREB. Special conditions apply for the use of tissue previously collected from individuals who are now deceased or from whom consent was not previously obtained at the time of collection.

☐ **Consent Process:** Describe the exact steps used in the consent process, including:

- who will explain the consent form;
- who will obtain consent;
- where participants will be during the consent process;
- how long participants will have to decide whether or not to participate;
- how consent will be obtained, e.g. written, verbally, translation, and;
- any other special circumstances, e.g. emergency/telephone consent.

☐ **Competency:** Identify the competency level of the prospective participant as:

- legally able to give fully informed consent, or;
- unable to consent and without decision making capacity, or;
- unable to consent and with some decision making capacity, or;
- if legally able to consent but under the age of majority in BC (i.e. 19 years of age), describe if: i) mature minor, or ii) emancipated minor.

Describe how the PI proposes to determine each participant's ability to consent to participate in the study. If not competent, describe who will consent on the participant's behalf.

☐ If ASSENT will be used, please describe the exact steps used in the assent process, including:

- who will explain the consent or assent form;
- who will obtain assent;
- where the participant will be during the assent process;
- how long the participant will have to decide whether or not to participate;
- how assent will be obtained, e.g. written, verbally, translation, and;
- any other special circumstances, e.g. emergency/telephone consent.

☐ Describe if there are any provisions necessary for participants, or those consenting on their behalf, to have special assistance during the consenting process. (e.g. consents in Braille or consents in languages other than English)

☐ Provide details on any costs for the participant and any reimbursements.

Checklist of Submitted Documents:

The following page was developed for use as a guideline for what documents are to be submitted to the Fraser Health Research Ethics Board. Should you have any questions or concerns please contact the FHREB Coordinator at 604-587-4436 or email Sara O'Shaughnessy at Sara.OShaughnessy@fraserhealth.ca for additional information. **Please provide the title of the documents with version date in the boxes next to, or below, each item.**

☐ A completed and signed copy of the Initial Ethics Application Form

☐ The research protocol (clearly presented with a version date) including all supporting documentation and annexes.

☐ The consent form(s) (clearly presented with a version date on all pages)

☐ If the research involves products, such as medications, natural health products, or medical devices, the Investigator's Brochure(s) and/or product monograph(s) must be submitted.

☐ Questionnaires, Information sheets and/or Documentation to be used for the recruitment of participants (e.g. advertisements, social media announcements, telephone scripts).

☐ Electronic Case Report Forms (E-CRFs) or Data Capture Forms (including data variables for quantitative research and interview scripts for qualitiative research)

☐ Health Canada No Objection Letter, if applicable (please note this may be pending at the time of submission, however final approval will not be granted until this is submitted).

22. SIGNATURES

PRINCIPAL INVESTIGATOR [PI]: By signing this page, I certify that I have read this application and that the information provided is accurate and complete. I will conduct the proposed research in accordance with the Fraser Health Policy on the Ethical Conduct of Research and Other Studies Involving Human Participants, the Tri-Council Policy for Ethical Conduct for Research Involving Humans, and all other applicable laws, regulations and guidelines.	PI Signature _____ Date _____
ADMINISTRATIVE SUPERVISOR: *[this person cannot be a co-investigator]* I confirm that the Principal Investigator has the qualifications, experience and resources to carry out this research.	Supervisor Signature _____ Date _____ Supervisor Printed Name _____ Supervisor Title _____ Site _____

APPENDIX 1 – USE to append additional information if necessary.

APPENDIX 2 (Section 23: Privacy, Confidentiality and Data Security)

Please note that if the study requires access to patient personal information that is collected and maintained by Fraser Health, the information provided in Appendix 2 will be forwarded by the FHREB office to the Fraser Health Privacy Office for review and approval of the requirements for meeting the Fraser Health Privacy Office requirements as soon as the study has received ethical approval but before the Letter of Authorization to Conduct Research (LOA) is issued. The researcher/researcher contact person will be copied on this correspondence.

Please note that this will not delay the release of the LOA unless the Privacy Office determines that a Privacy Impact Assessment (PIA) is necessary. If so, the Privacy Office will contact the PI directly.

If a PIA is required, please notify the FHREB Office when it is approved by the Privacy Office as this is required before the Letter of Authorization to Conduct Research can be issued.

Personal information means recorded information about an identifiable individual other than contact information.

23.1 Access to Data

a. Will access to personal information about research participants that is currently held by Fraser Health and obtained for the original purpose of providing healthcare be required in order to carry out this research study? Please indicate all that apply.

Yes ☐ **No** ☐ Health Records
Yes ☐ **No** ☐ Administrative Databases, e.g. InterRai
Yes ☐ **No** ☐ Clinical Databases, e.g. Meditech, Paris, Pharmanet
Yes ☐ **No** ☐ Biological Tissues or Samples
Other: ☐

If no to all, NO FURTHER INFORMATION IS REQUIRED

b. **If Yes,** What type of access is required (check all options that apply)

☐ Paper copy report to be sent to Principal Investigator or designate
☐ Electronic data/report to be sent to Principal Investigator or designate. Specify file format: ☐
☐ Access to a Fraser Health information system. Please specify**:** ☐
☐ Other: ☐

c. Please indicate if this is one time access only or periodic.

☐ One time only
☐ Periodic

d. Is an interface to download personal information required? **Yes** ☐ **No** ☐

e. **If Yes,** please provide detailed specifications of the interface. ☐

f. **If Yes,** will participant consent be obtained for use of all data? **Yes** ☐ **No** ☐

g. **If No,** please complete the following as applicable.
Is this a retrospective study of previously collected data? **Yes** ☐ **No** ☐
If Yes, specify the date range. Month ☐ Year ☐ to Month ☐ Year ☐

OR

Is a waiver of consent requested for this research study? **Yes** ☐ **No** ☐

23.2 Data-linking

a. Will personal information from one database be linked or combined with personal information from another database(s)? **Yes** ☐ **No** ☐ **If No, proceed to 23.3.**

b. **If Yes,** will the data linking occur between two or more public bodies (including Fraser Health)? **Yes** ☐ **No** ☐ And/or will the data linking occur between one or more public bodies (including Fraser Health) and one or more non-public agencies? **Yes** ☐ **No** ☐

c. **If Yes,** specify the name of each database.

d. **If Yes**, specify the organization(s) that houses the database(s) and their location(s).

23.3 Data Elements

a. List all data elements that will be collected for this study and specify the date range if possible. For multiple pages of data elements (e.g. case report forms), please attach as an appendix and include a version number and date in the footer.

b. Will the data be identifiable such that the data could be directly linked to the participant's identity? **Yes** ☐ **No** ☐

c. **If Yes,** specify the identifier and please justify the use of this identifier. Note that date of birth, initials, reversed initials are all considered to be unique identifiers in addition to name, first and last 3 letters of the participant's name, hospital medical record number, PHN, SIN, address and phone #.

d. **If No**, specify the unique study code that will be used. Describe the process used for de-identifying the data. Describe where the master log that matches participant name to the unique study code will be kept and the security measures for safeguarding it.

23.4 Data Collection, Use and Storage (n.b. this does not apply to personal communications with research participants)

a. Please specify how the research-related data will be collected and used. Check all that apply.

- ☐ Paper
- ☐ Personal mobile devices with built in wireless, e.g. IPhone, tablet, smart phone, etc.
- ☐ Fraser Health mobile devices with built in wireless
- ☐ Personal computing devices, e.g. laptop, home PC
- ☐ Fraser Health computing devices, e.g. Fraser Health PC
- ☐ Other:

b. For any of the above modalities, please complete the following table. Scroll down for rows.
Please note that the Fraser Health standard for encryption is 256 Bit.

Device type	Device Name and MAC address(es)	Managed By	Owned By	Encryption?	Wireless?
E.g. Personal IPhone	N/A	John Doe	John Doe	Yes – enabled in OS; secure https connection	Yes – Rogers 3G
E.g. FH Corporate PC	PC12345-000406a5d3ff All FH computers have a PC # and an asset # on the hard drive.	FH computers are	IMIT FHA	Yes – Win 7 Bitlocker	Yes –Wifi

		managed by IBM/HSSBC			

It is expected that the PI will make available any devices used, upon request by the Health Authority, for review and confirmation of appropriate data handling and security controls as outlined above. *Mobile devices must support password protected locking and full disk encryption to be considered for use with Fraser Health data. If the device has a cellular wireless feature it should also support remote data wipe functionality.

c. Will the data be retained in/by Fraser Health? **Yes** ☐ **No** ☐ If No, Please skip to 23.5.

d. **If Yes**, Please specify how the data will be stored. Check all that apply.

☐ Storage space for paper files.
- ☐ All data will be kept in a locked storage unit/filing cabinet/desk.
- ☐ The locked storage unit will be maintained in a locked room when not in use.

FOR PAPER COPIES CONTAINING PERSONAL INFORMATION (I.E. If NOT De-Identified), will the copies be either shredded or returned to Fraser Health at the conclusion of the study? Yes ☐ No ☐

- ☐ Personal devices, e.g. phones, tablets, laptops
- ☐ Corporate devices. e.g. Fraser Health laptop
- ☐ USB Drive (i.e. removable storage device)
- ☐ CD/DVD
- ☐ Cloud storage services (i.e. external servers such as Google Drive)
- ☐ Web accessible applications (e.g. RedCap)
- ☐ Other:

FOR ELECTRONIC MEDIA: Electronic media can be recovered if erasure is not performed following strict guidelines. Will electronic files be erased using a deleted program other than the operating system?
Yes ☐ **No** ☐

e. For any of the above modalities with the exception of paper files, please complete the following table.

Storage type	Reason	Managed By	Owned By	Encryption?	Auditing?
E.g. USB Drive	Need mobility between devices	Research assistant	Research assistant	Kingston Data Traveller Vault Privacy Product	No
E.g. M Drive	Research study specific folder on M: drive	Research assistant	Principal Investigator	Password Protected	No

23.5 Authorization to Use Data

a. Please specify who will have access to the data once obtained from Fraser Health sources, i.e. name and position.

b. Please explain how information related to access to the data, e.g. user IDs, encryption keys, passwords, will be stored, and how study personnel will be made aware of their responsibilities concerning privacy and confidentiality at each stage of processing and analysis. Fraser Health employees must be updated on the following Fraser Health Policies and Procedures:

- Confidentiality and Security of Personal Information
- Managing Privacy Breaches
- Privacy and Security Requirements for Laptops, Notebooks, Blackberries and Other Mobile Technology

c. Who controls access and ensures it is updated and removed?

d. What access controls are in place?

e. If a vendor is required to have access to the software or system (for example for system support), indicate how this access will occur and confirm if there is a privacy schedule attached to their contract.

23.6 Transfer and Disclosure of Data/Samples Outside of Fraser Health

a. Once collected will any of the data or samples be transferred outside of Fraser Health?

Yes ☐ **No** ☐ If No, Appendix 2 is now complete.

b. If Yes, Please provide the name and address of the organization:

Please indicate the type of organization. Academic ☐ Industry ☐ Government ☐ Non-profit ☐

c. If Yes, please indicate how the data will be transferred outside of Fraser Health. **(n.b. This does not apply to correspondence with research participants)**

- ☐ Electronic messaging systems, e.g. email. Please specify the encryption method.
- ☐ Web form (electronic data capture)
- ☐ USB Drive (i.e. removable storage device)
- ☐ Secure file transfer service (SFTS)
- ☐ Secure socket layer (SSL)
- ☐ Other:

d. For any of the above modalities, please complete the following table.

Transfer Method	Reason	Managed By	Owned By	Security

e. Has this data transfer modality undergone a Privacy Impact Assessment (PIA) or Security Threat Risk Assessment (STRA) at another BC Health Authority or Institution? **Yes** ☐ **No** ☐

If yes, please provide the Institution's name and the REB number