|  |  |  |  |
| --- | --- | --- | --- |
| **APPLICATION FOR INITIAL ETHICAL REVIEW FOR FH Sites on RisE ONLY**  **(i.e. the UBC RisE application is accepted for FH researchers who are the FH principal investigator for a UBC study)** | | | |
| The ethical review process is governed by the FH Policy: “The Ethical Conduct of Research and Other Studies Involving Human Subjects” | | | |
| **INSTRUCTIONS FOR COMPLETION** | | | |
| 1. Complete this form with reference to the current FHREB Guidance Notes (GN) for Initial Applications at <http://research.fraserhealth.ca/media/FHGN_Initial-Application-for-Ethical-Review.pdf> 2. All questions must be answered. Please indicate “Not Applicable” if necessary. | | | |
| **INSTRUCTIONS FOR SUBMISSION** | | | |
| **Delegated Review** | | **Full Board Review** | |
| * Submit for delegated review if project 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 (industry grants-in-aid are DR)  Does **not** involve subjects 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 | | * Submit for full board review if project 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 – refer to page 9.  **Does** involve subjects 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 subject personal information to non-FHA databases/registries | |
| Email all documents to [REB@fraserhealth.ca](mailto:REB@fraserhealth.ca)   * Obtain electronic/digital signatures or fax application’s signature page to 604-953-5137 at same time as electronic submission. * All approved consent form(s) will be stamped with approval date and returned with the initial ethics approval certificate. * List all documents submitted with this application; indicate n/a if not applicable. * **Incomplete submissions will be returned.** * **Use the attached Appendix 1, Page 10, for additional information or to complete the application boxes.** | | | |
| **Document Type: \* Always Required with Submission**  **Version # and/or Date MUST be included for applicable documents. INCLUDE DATE AS YYYY MM DD** | | | |
| Application Form-Principal Investigator Signature Date | | | Participant Consent Form  Version #      Date |
| Principal Investigator C.V.  Date | | | Normal/Control Consent Form  Version #      Date |
| Academic Research Ethics Board Approval Certificate Date | | | Optional Consent Form (e.g. biobanking, genetic, biomarker)  Version #      Date |
| Protocol  Version #      Date | | | Assent Form  Version #      Date |
| Signed Letter from Fraser Health Co-Investigator  **Submitted**  **Pending** Date  Questionnaires, Tests, Interview Scripts, Focus Group Guides, etc. Use Appendix 1 to append a separate list. | | | Other Consent Form  Version #      Date |
|  | | | Data Collection Tools/Case Report Form. A list of ALL variables to be collected must be submitted for quantitative studies.  Version #      Date |
| 1. **Title of Research Proposal** | | | |
|  | | | |
| |  |  |  | | --- | --- | --- | | **2. Main Contact Information**  All correspondence including the initial Certificate of Ethical Approval will be emailed to the address given here. | | | | **Surname** | **Title** | **Mailing Address** | |  |  |  | | **First Name** | **Email Address** | **City/Province** | |  |  |  | |  |  | **Postal Code** |   **3. Key Words** (key words may include the disease, the intervention, the topic/category of study etc.) | | | |
| **1.       2.       3.       4.       5.** | | | |
| **4. Has/will this study been/be submitted to/approved by another Research Ethics Board?**  Yes  No  If yes, provide the name of the REB(s) | | | |
| **5. Principal Investigator**  Must be a non-FHA researcher who has been granted ‘affiliated’ status with FHA or who is in process of obtaining it. **Granted**  **Pending** | | | |
| **Surname** | |  | | --- | | **Faculty/University** | | **Email**  **Address** | | **Mailing**  **Address** | | | |
| **First Name** |  | | |
| **Title** |  | | |
| **Discipline (e.g. medicine, nursing)** |  | | |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **6. Type of Research**  Please check the box which most closely describes the type of research for this study: | | | | | | |
| **Biomedical**  **Clinical**  **Health Services**  **Population Health** | Research on human subjects that is not diagnostic or therapeutic.  Research on or for the treatment of patients.  Research on how to improve efficiency/effectiveness of the health care system.  Research on factors affecting health status.  **Ethical review is NOT conducted for evaluation/quality improvement.** | | | | | |
| **7. FH Sites Where Research will be Conducted** | | | | | | |
| ARHCC  BH  CGH  DH  ERH FCH  LMH  PAH  RCH  RMH  SMH  JPOCSC  Physician’s Private Office  Community Site(s), please specify:  Other: | | | | | | |
| **8. 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 or fax as above. For details, refer to <http://research.fraserhealth.ca/approvals_%26_ethics/forms-and-guidance-notes/> | | | | | | |
| 8a. Is a DAR Form Required? If YES, indicate the department (s) providing  service(s) for this study. | | | | Yes | | No |
| Anatomical Pathology  Biomedical Engineering  Communicable Diseases/Public Health | | Diagnostic Imaging  Health Records (Electronic) Health Records (Paper) | Health &  Business Analytics  Information Management | | Laboratory  Pharmacy  Patient Care/Surgical Suites | |

|  |  |  |
| --- | --- | --- |
| **9. Funding Information:** Please complete as applicable. | | |
| 9a.  **Grant Funded** Awarded  Pending | | |
| Name of Granting Agency: | |  |
| Name of Grant Awardee: | | |
| Name of Institution Administering Grant: |  | |
| 9b.  **Other** | Please specify: | |
| 9c. **Unfunded** | | |

|  |  |  |
| --- | --- | --- |
| **10. Participant Enrollment** | | |
| Describe the FHA specific recruitment strategy and the process for obtaining informed consent if different from that described in the academic ethics application: | | |
| **11. Procedures** | | |
| 11a. 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. | | |
| SC or I  Drug administration  SC or I  Surgical procedures  SC or I  Experimental medical devices  SC or I  Imaging procedures (e.g., X-ray, MRI)  SC or I  Collection of blood  SC or I  Collection of other tissue – use of identifiers must be in consent if sent off site  SC or I  Other Interventions, e.g. psychological; eHealth, rehabilitation | SC or I  Questionnaires/surveys  SC or I  Analysis of tissue only  SC or I  Analysis of data only  SC or I  Individual interview  SC or I  Focus Groups  SC or I  Home visits | SC or I  Video/Audio Recording  SC or I  Secondary use of previously  collected data (i.e. health  records) (e.g. retrospective chart review)  SC or I  Database Linkage  SC or I  Prospective data collection  None of these Methods |
| **12. Privacy, Confidentiality and Data Security [Complete Appendix 2]**  ***\*Please note that if the study requires access to patient personal information that is collected and held by FH that the information provided in Appendix 2 will be forwarded to the FH Privacy Office for review and approval of the security requirements. The Privacy Office may determine that a Privacy Impact Assessment is necessary.***  This is a survey and does not require written consent as consent is implied with survey completion. **Yes**  **No**  If Yes, please ensure that the invitation to complete the survey meets standard requirements. Refer to the survey template at <http://research.fraserhealth.ca/approvals_%26_ethics/forms-and-guidance-notes/>  **N.B. This does not apply to Consent To Contact databases.** | | |

|  |
| --- |
| **APPENDIX 1 – USE to append additional information if necessary.** |
|  |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **APPENDIX 2 (Section 12: 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 that 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 security requirements for meeting the FHA 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 researcher 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.*  **12.1 Access to Data**   1. Will access to personal information about research participants that is currently held by the Fraser Health Authority and obtained for the original purpose of providing health care 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** ClinicalDatabases, e.g. Meditech, Paris, Pharmanet, clinic  **Other?**  **If No, NO FURTHER INFORMATION IS REQUIRED.**   1. **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. Please specify file format.  Access to a FHA information system. Please specify.   1. **Please indicate if this is one time access only or periodic.**   One time only  Periodic   1. Is an interface to download personal information required? **Yes**  **No** 2. **If Yes,** please provide detailed specifications of the interface. 3. **If Yes,** will participant consent be obtained for use of all data?  **Yes**  **No**   **If Yes,** please ensure that the consent form describes the data that will be collected in lay terms so that it is understandable to a research participant. Refer to the consent form templates at <http://research.fraserhealth.ca/approvals_%26_ethics/forms-and-guidance-notes/> or contact the REB Co-ordinator for assistance.   1. **If No,** please complete the following as applicable.   **Yes**  **No**  This is a retrospective study of previously collected data. **If Yes**, specify the date range. Month Year       to Month Year       (N.B. a waiver of consent is NOT required for retrospective studies).  **OR**  **Yes**  **No**  A waiver of consent is required in order to carry out this research study. If Yes, please submit the request for a waiver in a separate attachment and ensure that the **requirements of the Tri-council Policy 2014 Article 3.7A** [**http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter3-chapitre3/#toc03-1b**](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter3-chapitre3/#toc03-1b) **are addressed accordingly.**  **12.2 Data-linking**   1. Will personal information from one database be linked or combined with personal information from another database(s)? **Yes**  **No**  **If No, proceed to 12.3.** 2. **If Yes,** Will the data linking occur between two or more public bodies (including FHA)? **Yes**  **No** 3. And/or Will the data linking occur between one or more public bodies (including FHA) and one or more non-public agencies? **Yes**  **No** 4. **If Yes,** Specify the name each database. 5. **If Yes**, Specify the organization(s) that houses the databaseand their location.   **12.3 Data Elements**   1. 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**     1. **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 #. 2. **If No**, please 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.  **12.4 Data Collection, Use and Storage (n.b. this does not apply to personal communications with research participants)**   1. 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.  FHA mobile devices with built in wireless  Personal computing devices, e.g. lap top, home PC  FHA computing devices, e.g. FHA PC  Other? Clarify   1. For any of the above modalities, please complete the following table. Scroll down for rows.   **Please note that the FHA 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. FHA Corporate PC | PC12345-000406a5d3ff  All FHA computers have a PC # and an asset # on the hard drive. | FHA computers are managed by IBM/HSSBC | IMIT FHA | Yes – Win 7 Bitlocker | Yes –Wifi | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  |   It is expected that the Applicant 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 Health Authority data. If the device has a cellular wireless feature it should also support remote data wipe functionality.   1. Will the data be retained in/by FHA? **Yes**  **No**  If No, Please skip to 17.5. 2. **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 FHA at the conclusion of the study.  **Yes**  **No**  Personal devices, e.g. phones, tablets, laptops  Corporate devices. Specify the FHA Network Drive e.g. M drive  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? Please specify.  **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**   1. 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 | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  |   **12.5 Authorization to Use Data**   1. Please specify who will have access to the data once obtained from Fraser Health sources, i.e. name and position. 2. Please explain how information related to access to the data, e.g. user IDs, encryption keys, passwords, will be stored.   Please explain how study personnel will be made aware of their responsibilities concerning privacy and confidentiality at each stage of processing and analysis. FHA employees must be updated on the following FHA 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.    **12.6 Transfer and Disclosure of Data Outside of Fraser Health**   1. Once collected will any of the data be transferred outside of Fraser Health?   **Yes**  **No**  If No, Appendix 2 is now complete.   1. If Yes, Please provide the name and address of the organization: 2. Please indicate the type of organization. Academic Industry  Government  Non-profit   Please note that the FHREB requires that the following wording be included in the consent form template: Refer to the BC Common Clinical Informed Consent Template at <http://research.fraserhealth.ca/approvals_%26_ethics/forms-and-guidance-notes/>  Any study related data [and/or samples], sent outside of Canadian borders may increase the risk of disclosure of information because the laws in those countries, [insert (for e.g.) the Patriot Act in the United States] dealing with protection of information may not be as strict as in Canada. However, all study related data [and/or samples], that might be transferred outside of Canada will be coded (this means it will not contain your name or personal identifying information) before leaving the study site. By signing this consent form, you are consenting to the transfer of your information [and/or samples], to organizations located outside of Canada.   1. 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 Please specify.   1. For any of the above modality, please complete the following table.  |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Transfer Method** | **Reason** | **Managed By** | **Owned By** | **Security** | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  |  1. If the data is stored outside of Fraser Health, describe the security features of the service provider or enter “not applicable”.   **Fraser Health may require a full security review. Please indicate if one has been completed. For example:**  Security Threat Risk Assessment (STRA)  Not applicable  Software Assessment Form (SAF)  Not applicable  Alternate Service Provider (ASP) Questionnaire  Not applicable |