**Application for Operational Approval to Conduct a Research Study**

**At Vancouver Coastal Health (VCH)**

Hover over all **![C:\Users\msaunders1\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\TS6NCJGO\purzen_Icon_with_question_mark[1].png]()** icons as you complete this form for important supplementary information. We encourage you to utilize the [*Guidance Notes for VCH Operational Approval Application*](https://www.vchri.ca/sites/default/files/guidance-notes-vch-operational-approval-20240927.docx) while completing this form.

 All relevant forms can be found at [VCHRI – Operational Approval](https://www.vchri.ca/services/operational-approval)

**YOU MUST RECEIVE THE VCH CERTIFICATE OF APPROVAL BEFORE YOU BEGIN YOUR RESEARCH STUDY AT VCH.**

**PART I: GENERAL RESEARCH INFORMATION**

**1. Research Identification**

|  |  |
| --- | --- |
| **a) Research study title (and short title)** | Click or tap here to enter text. |
| **b) REB # (Please also add the REB # to the footer of this document) C:\Users\msaunders1\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\TS6NCJGO\purzen_Icon_with_question_mark[1].png** | Click or tap here to enter text. |
| **c) Type of Study (select all that apply)**  | [ ]  Interventional Study  [ ]  Medical Device  [ ]  Clinical Drug Trial **C:\Users\msaunders1\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\TS6NCJGO\purzen_Icon_with_question_mark[1].png**[ ]  Investigator-Initiated [ ]  Retrospective Chart Review[ ]  Behavioural Study [ ]  Surveys [ ]  Other: Specify  |

**2. Principal Investigator** **![C:\Users\msaunders1\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\TS6NCJGO\purzen_Icon_with_question_mark[1].png]()**

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| **Name** Click or tap here to enter text. | **Health Authority C:\Users\msaunders1\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\TS6NCJGO\purzen_Icon_with_question_mark[1].png** Click or tap here to enter text. |
| **Mailing/Billing Address**Click or tap here to enter text. | **Clinical Department**Click or tap here to enter text. |
| **Phone Number**Click or tap here to enter text. | **Clinical Division**Click or tap here to enter text. |
| **Email**Click or tap here to enter text. | **Academic Institution C:\Users\msaunders1\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\TS6NCJGO\purzen_Icon_with_question_mark[1].png**Click or tap here to enter text. |
| Principal Investigator’s VCH Affiliation (one of the following **MUST** apply): C:\Users\msaunders1\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\TS6NCJGO\purzen_Icon_with_question_mark[1].png | Choose an item. |

**3. Research Team**

|  |
| --- |
| [ ]  ***Principal Investigator is the Primary Contact (proceed to 3b)*** |
| **a) Primary Contact** **Name**  Click or tap here to enter text. |
| **Address**  Click or tap here to enter text. |
| **Phone number**  Click or tap here to enter text. |
| **Email**  Click or tap here to enter text. |
| **Position title**  Click or tap here to enter text. |
| **b) VCH Collaborator** **C:\Users\msaunders1\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\TS6NCJGO\purzen_Icon_with_question_mark[1].png** | Enter the name of the collaborators. |
| **c) Will research personnel not employed by/ affiliated with VCH participate in the conduct of this study?** C:\Users\msaunders1\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\TS6NCJGO\purzen_Icon_with_question_mark[1].png | Choose an item. |
| **d) Provide the name and roles of the above-mentioned non-affiliated VCH research members** |  Click or tap here to enter text.  |

**4. Research Funding**

|  |  |
| --- | --- |
| **a) Type of Funding** | Choose an item. |
|  **If other, please specify** | Click or tap here to enter text. |
| **b) Name of Funding Source(s)** | Click or tap here to enter text. |
| **c) Funding Program (if applicable) C:\Users\msaunders1\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\TS6NCJGO\purzen_Icon_with_question_mark[1].png**  | Click or tap here to enter text. |
| **d) FAS # or Project #** | Click or tap here to enter text. |
| **e) Institution where funding is held** | Click or tap here to enter text **[mandatory]**. |

**5. Clinical Trial Management System (CTMS)**

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| **a) Will the study be utilizing the provincial CTMS *(a platform designed to streamline the administrative process of clinical trials)*? C:\Users\msaunders1\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\TS6NCJGO\purzen_Icon_with_question_mark[1].png** | Choose an item. |
| **b) Please provide a reason why CTMS will not be utilized. C:\Users\msaunders1\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\TS6NCJGO\purzen_Icon_with_question_mark[1].png** | Click or tap here to enter text. |

 **PART II: HEALTH AUTHORITY PRIORITIES**

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| **a) Which of the following Health Authority Strategic Priorities from the Minister of Health’s Mandate Letter to VCH does your study address [select all that apply]? C:\Users\msaunders1\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\TS6NCJGO\purzen_Icon_with_question_mark[1].png** | [ ]  Indigenous Health & Wellness [ ]  Cancer Care [ ]  Digital Health & Technology[ ]  Financial Sustainability [ ]  Health & Safety in the Workplace [ ]  Health Human Resource Management [ ]  Mental Health & Substance Use [ ]  Population Health, Health Protection, Promotion and Prevention[ ]  Primary & Community Care [ ]  Quality & Patient Safety [ ]  Rural Health [ ]  Seniors Care[ ]  Aging Population & Prevention Strategies [ ]  Emergency Preparedness & Response [ ]  Chronic Disease Management [ ]  Health Equity [ ]  Others: Specify |

**PART III: RESEARCH LOCATIONS**

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| *Vancouver Coastal Health (VCH) serves residents in the communities of Richmond, Vancouver, North Shore, Sea-to-Sky Corridor, Sunshine Coast, Powell River, Bella Bella, and Bella Coola. These communities are located within the traditional territories of the Heiltsuk, Kitasoo-Xai’xais, Lil’wat, Musqueam, N’Quatqua, Nuxalk, Samahquam, shíshálh, Skatin, Squamish, Tla’amin, Tsleil-Waututh, Wuikinuxv, and Xa’xtsa First Nations.*Approval from the appropriate VCH signatories must be obtained by signing the ‘Community of Care Signature Sheet’ and the ‘Research Impact Analysis’ form. |
| **a) Please indicate the VCH communities that will be impacted by this research [select all that apply]:** | [ ]  Bella Bella (including ƛ̓uxválásu̓ilas Heiltsuk - formerly R.W. Large Memorial Hospital)[ ]  Bella Coola (including Bella Coola General Hospital)[ ]  North Shore (including Lions Gate Hospital)[ ]  Powell River (including qathet General Hospital)[ ]  Richmond (including Richmond Hospital)[ ]  Sea-to-Sky Corridor (including Squamish General Hospital)[ ]  Sunshine Coast (including Sechelt | Shíshálh Hospital)[ ]  Vancouver (including G.F. Strong Rehabilitation Centre, UBC Hospital, Vancouver General Hospital)[ ]  Vancouver Community (such as community health centres, mental health sites, long-term care facilities owned and operated by VCH)[ ]  VCH Corporate (includes the recruitment of VCH staff located across multiple service delivery area, and VCH leadership) |
| **b) Please list the specific facilities within the above-noted communities that will be impacted by your research** | Click or tap here to enter text. |
| **c) Select the research activities that will take place at these facilities [select all that apply]** | [ ]  Recruitment of patients/participants [ ]  Patient Medical record Access[ ]  Patient/Participant Visits[ ]  Space Utilization [ ]  Equipment utilization [ ]  Staff involvement/recruitment[ ]  Other: SpecifyComments: Click or tap here to enter text. |

 **PART IV: RESEARCH PARTICIPANTS**

|  |  |
| --- | --- |
| **a) Select all the patients/participants that will be involved in this research**  | [ ]  Inpatients [ ]  Outpatients[ ]  Long term care residents[ ]  VCH Staff[ ]  Healthy volunteers/controls[ ]  Not applicable[ ]  Other: Specify |

 **Part V: RESEARCH WITH INDIGENOUS PEOPLES**

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| The Indigenous Health Research Unit Provides Support for studies that may impact Indigenous Peoples. Please refer to the VCH Operational Approval Guidance Notes for further information. **C:\Users\msaunders1\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\TS6NCJGO\purzen_Icon_with_question_mark[1].png** |
| **a)** **Is the study taking place on First Nations reserves, Métis settlements, lands under Indigenous self-government, or lands with an Indigenous land claims agreement?**  | Choose an item. |
| **b) Will the study include participants who are part of an Indigenous community or organization, or who identify as Indigenous? C:\Users\msaunders1\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\TS6NCJGO\purzen_Icon_with_question_mark[1].png** | Choose an item. |
| **c) Will the study examine topics that may disproportionately impact Indigenous Peoples? C:\Users\msaunders1\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\TS6NCJGO\purzen_Icon_with_question_mark[1].png** | Choose an item. |

 **PART VI: RECRUITMENT** ![C:\Users\msaunders1\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\TS6NCJGO\purzen_Icon_with_question_mark[1].png]()

|  |  |
| --- | --- |
| **a) Is the purpose of this application ONLY to seek permission for support from VCH in the recruitment of patients/participants** C:\Users\msaunders1\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\TS6NCJGO\purzen_Icon_with_question_mark[1].png | Choose an item. |
| **b) Will patient/participant recruitment occur on a hospital ward/clinic/community site?** | Choose an item. |
| **c) Will any notices for recruitment be posted in a VCH facility?** | Choose an item. |
| **d) Select where recruitment information will be posted in a VCH facility** | [ ]  Hospital ward [ ]  Clinic[ ]  Community site[ ]  Public area [ ]  Common areas (e.q. elevators, cafeteria, bulletin boards) Specify the locations: Click or tap here to enter text.  |
| **e) Will recruitment support to promote the research be provided by VCHRI? C:\Users\msaunders1\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\TS6NCJGO\purzen_Icon_with_question_mark[1].png** | Choose an item. |
| **f) Select the recruitment support services from VCHRI** | [ ]  VCHRI Research Study Directory [ ]  Social Media (X/Twitter)[ ]  Newsletter (Research Insider)[ ]  Recruitment Poster  |
| **g) How will patients/participants be contactedC:\Users\msaunders1\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\TS6NCJGO\purzen_Icon_with_question_mark[1].png** | Choose an item. |
|  **If other, specify** | Click or tap here to enter text. |

 **PART VII: DATA PRIVACY AND PATIENT MEDICAL RECORD ACCESS**

|  |  |
| --- | --- |
| **a) Will the research team access VCH data, which includes identifiable information of VCH patients/residents/clients/staff?** | Choose an item. |
| **b) Who will be retrieving/accessing VCH data?** | Click or tap here to enter text. |
| **c) Does the person retrieving/accessing VCH data have a VCH account?** | Choose an item. |
| **d) Where/how will the VCH data be accessed?** C:\Users\msaunders1\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\TS6NCJGO\purzen_Icon_with_question_mark[1].png | [ ]  Health records chart review (physical copies) \* C:\Users\msaunders1\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\TS6NCJGO\purzen_Icon_with_question_mark[1].png [ ]  System access\* **C:\Users\msaunders1\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\TS6NCJGO\purzen_Icon_with_question_mark[1].png**[ ]  Data extract[ ]  VCH - CST Cerner [ ]  Other\* \*Specify the locations and/or systems: Click or tap here to enter text.  |
| **e) Will sharing or transferring VCH data to outside institutions occur?** | Choose an item. If yes, please provide the institution: Click or tap here to enter text. |
| **f) Will access to any diagnostic imaging be required for this study?**  | Choose an item. |
| **g) Will de-identification of imaging data be required?** | Choose an item. |
|  **Provide the system name for de-identification  of imaging data**  | Click or tap here to enter text. |
| **h) Will data extract/services from Data & Analytics (formerly known as Decision Support) be required?** C:\Users\msaunders1\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\TS6NCJGO\purzen_Icon_with_question_mark[1].png | Choose an item. |

 **PART VIII: PATIENT/PARTICIPANT VISITS ![C:\Users\msaunders1\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\TS6NCJGO\purzen_Icon_with_question_mark[1].png]()**

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| **a) Will any research study visits/assessments take place on a hospital ward/clinic/community site?** | Choose an item. |
| **b) Where will informed consent be obtained?** | Click or tap here to enter text. |
| **c) If a questionnaire will be administered, where will this occur?** | Click or tap here to enter text. |
| **d) If a focus group will be held or interviewed, where will this occur?** | Click or tap here to enter text. |

 **PART IX: RESEARCH IMPACT ON VCH CLINICAL DEPARTMENTAL SERVICES**

**1. Radiology/Medical Imaging**

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| **a) Will this research study involve the use of medical imaging?**  | Choose an item. |
| **b) Will the research study require access to PACS?** C:\Users\msaunders1\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\TS6NCJGO\purzen_Icon_with_question_mark[1].png | Choose an item. |

**2. Pharmacy**

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| **a) Will any investigational or marketed drug be stored, handled, or administered to research participants?** C:\Users\msaunders1\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\TS6NCJGO\purzen_Icon_with_question_mark[1].png | Choose an item. |
| **b) Select all hospital sites where the drug will be administered** | [ ]  VGH – Vancouver General Hospital [ ]  UBCH- UBC Hospital [ ]  RH – Richmond Hospital [ ]  LGH – Lions Gate Hospital [ ]  Other: Specify.  |
| **c) Will the drug be administered at a VCH clinic/community site?** | Choose an item.Specify location: Click or tap here to enter text. |
| **d) Who will administer the drug?** | [ ]  VCH Pharmacy [ ]  Hospital/clinic/community site medical or nursing staff [ ]  VCHRI CRU [ ]  Principal Investigator [ ]  Other: Specify.  |

**3. Laboratory Services**

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| --- | --- |
| **a) Will this research study involve the collection of specimens (e.g. whole blood, serum, plasma, urine, CSF)? C:\Users\msaunders1\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\TS6NCJGO\purzen_Icon_with_question_mark[1].png** | Choose an item. |
| **b) Will the VCH laboratory process the samples and report the results?** | Choose an item. |
| **c) Which laboratory will process the sample and report the results if not VCH?** | Click or tap here to enter text. |
| **d) Will the research study utilize fresh and/or formalin fixed paraffin embedded tissue (FFPE)? C:\Users\msaunders1\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\TS6NCJGO\purzen_Icon_with_question_mark[1].png** | [ ]  Fresh [ ]  Fixed FFPE [ ]  Other: Specify. [ ]  Not applicable  |

**4. Operating Room**

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| **a) Will patients/participants undergo any surgical procedures in the Operating Room (OR)?** **C:\Users\msaunders1\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\TS6NCJGO\purzen_Icon_with_question_mark[1].png** | Choose an item. |
| **b) Select all sites where OR will be impacted** | [ ]  VGH – Vancouver General Hospital [ ]  UBCH – UBC Hospital [ ]  RH – Richmond Hospital [ ]  LGH – Lions Gate Hospital [ ]  Other: Specify.  |
| **c) Will tissue specimens be collected from patients/participants in the OR?** C:\Users\msaunders1\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\TS6NCJGO\purzen_Icon_with_question_mark[1].png | Choose an item. |
| **d) Will blood specimens (not part of standard of care) be collected by Anesthesia during a surgical procedure?** C:\Users\msaunders1\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\TS6NCJGO\purzen_Icon_with_question_mark[1].png | Choose an item.  |

**5. Reusable Medical Devices ![C:\Users\msaunders1\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\TS6NCJGO\purzen_Icon_with_question_mark[1].png]()**

|  |  |
| --- | --- |
| 1. As part of your project, will you be using any device which contacts the patient directly or is used within the sterile field?
 | Choose an item. |
| 1. **If YES to 5a**: Will the device be exposed to a sterile cavity (i.e. critical device) or mucous membrane or non-intact skin (i.e., a semi-critical device)?
 | Choose an item. |
| 1. **If NO to 5b:**

The device is considered a non-critical device. To ensure safety between patient use, a reprocessing plan with instructions for cleaning and low-level disinfection needs to be provided. Complete **the Application for Approval, Non-Critical Device in Research** and send to the Reprocessing Practice Improvement Program (RPIP) via reprocessing@vch.ca to arrange for Infection Prevention and Control review and approval of the reprocessing plan.  **If YES to 5b (info below)**Which of the following does it fall under?a. A market device used as intended? Complete the *Application for Market Device in Research Form* and send to RPIP at reprocessing@vch.ca to arrange review and ensure the validated sterilization instructions are compatible with reprocessing equipment in the healthcare facility in which the research will be undertaken. Provide RPIP with a copy of the Manufacturer’s instructions for use (MIFU) which will include instructions for cleaning and sterilization for critical devices, or cleaning and High-Level Disinfection (HLD) instructions for semi-critical devices.b. A device created or modified for the research project? Complete the *Application for Non-Market Research Device* Form and provide a plan with instructions for cleaning and high-level disinfection or sterilization that have been validated by an independent certified lab\*. Send to RPIP at reprocessing@vch.ca to arrange review and ensure the validated sterilization instructions are compatible with reprocessing equipment in the healthcare facility in which the research will be undertaken.\*Be sure to consider the costs of validation of reprocessing instructions by the independent laboratory in your funding proposal. |  Add General comment.  |

**6. Biomedical Engineering**

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| --- | --- |
| 1. Is an electrically powered device used in the study? This includes any devices that are used for treatment, diagnosis, and monitoring or data collection. C:\Users\msaunders1\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\TS6NCJGO\purzen_Icon_with_question_mark[1].png
 | Choose an item. |
| 1. Are the electrically powered devices used in the study on the **device exclusions list**? C:\Users\msaunders1\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\TS6NCJGO\purzen_Icon_with_question_mark[1].png
 | Choose an item. |

**GENERAL COMMENTS**

Additional or general comments.

**Declaration by Principal Investigator**

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| --- |
| By signing below, I certify that:[ ]  All information provided in this form is accurate and complete.[ ]  The research study will be conducted in accordance with all applicable Vancouver Coastal Health policies and procedures pertaining to the conduct of research.[ ]  I have read and will comply with the [**VCH/PHC Data and Research Access Terms and Conditions**](https://www.vchri.ca/sites/default/files/VCH-PHC_Data_and_Research_Access_TermsandConditions_20210920.pdf).[ ]  All members of my research study team have completed the [VCH/PHC Privacy and Confidentiality Undertaking for Researchers Module.](https://learninghub.phsa.ca/Courses/17110/vch-phc-confidentiality-undertaking-for-researchers)[ ]  All fresh tissue collections must be sent to Pathology for accessioning prior to research pickup (if applicable). |
| Full Name of Principal Investigator (printed)      | Signature of Principal Investigator      | Date      |

# Additional Required Signatures

|  |  |  |  |
| --- | --- | --- | --- |
| 1. Principal Investigator’s VCH Department Head

|  |  |  |
| --- | --- | --- |
| Full Name (printed) | Signature | Date |

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| 1. Principal Investigator’s VCH Division Head (if applicable)

|  |  |  |
| --- | --- | --- |
| Full Name (printed) | Signature | Date |

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| 1. Principal Investigator’s Supervisor/Manager C:\Users\msaunders1\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\TS6NCJGO\purzen_Icon_with_question_mark[1].png

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| Full Name (printed) | Signature | Date |

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**All departmental approval signatures must be placed on the appropriate**[**Community of Care Signature Sheet**](https://www.vchri.ca/sites/default/files/signature-sheet-community-of-care-20240815-MASTER.docx)![C:\Users\msaunders1\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\TS6NCJGO\purzen_Icon_with_question_mark[1].png]()

*SIGNATURES OF APPROVAL WILL BE REQUIRED FROM EACH DEPARTMENT WITHIN VANCOUVER COASTAL HEALTH THAT WILL BE IMPACTED BY THIS RESEARCH STUDY.*