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

**At Vancouver Coastal Health (VCH)**

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 in [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**

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| **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](file:///\\vch.ca\departments\VCHRI\Clinical%20Trials%20Administration\Operational%20Research%20Reviews,%20Approval,%20and%20Renewal\Forms%20and%20Guidelines\2022%20Operational%20Approval%20Application%20Update_JM\a)** | 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](file:///\\vch.ca\departments\VCHRI\Clinical%20Trials%20Administration\Operational%20Research%20Reviews,%20Approval,%20and%20Renewal\Forms%20and%20Guidelines\2022%20Operational%20Approval%20Application%20Update_JM\a)**  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](https://www.vchri.ca/sites/default/files/guidance-notes-vch-operational-approval-20240822.docx)**

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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](mailto:phoebe.luyun@vch.ca?subject=Request%20of%20VCH%20Operational%20approval%20for%20HXX-XXXXX%20)** 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](mailto:phoebe.luyun@vch.ca?subject=Request%20of%20VCH%20Operational%20approval%20for%20HXX-XXXXX)** 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](https://www.vchri.ca/services/new-vchri/membership-vchri) | Choose an item. |

**3. Research Team**

|  |  |
| --- | --- |
| ***Principal Investigator is the Primary Contact (proceed to 3b)*** | |
| **a) Primary Contact**  Click or tap here to enter text. | **Position title**  Click or tap here to enter text. |
| **Phone number**  Click or tap here to enter text. | **Email**  Click or tap here to enter text. |
| **Address**  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](https://www.vchri.ca/sites/default/files/guidance-notes-vch-operational-approval-20240927.docx)** | Enter the name of the collaborators. |
| **c) Will research personnel not employed by or not 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](mailto:phoebe.luyun@vch.ca?subject=Request%20of%20VCH%20Operational%20approval%20for%20HXX-XXXXX%20-%20Operational%20Impact%20Inquiry) | Choose an item. |
| **d) Provide the name and roles of the 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](mailto:phoebe.luyun@vch.ca?subject=Request%20of%20VCH%20Operational%20approval%20for%20HXX-XXXXX%20-%20Inquiry)** | 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](https://www.vchri.ca/realtime-ctms-vchri)** | 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](https://www.vchri.ca/realtime-ctms-vchri)** | Click or tap here to enter text. |

**6. Contract Agreement**

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| **What is the status of the agreement?** *(i.e. clinical trial agreement, data transfer agreement, material transfer agreement)* | Choose an item. |
| **Which office is handling the agreement?** | Choose an item. |

**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 [MANDATORY,** select all that apply**]? [C:\Users\msaunders1\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\TS6NCJGO\purzen_Icon_with_question_mark[1].png](https://www.vch.ca/sites/default/files/2023-10/2023-24%20VCH%20Mandate%20Letter.pdf)** | 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’ (mandatory) and the ‘Research Impact Analysis’ form (where applicable). | |
| **a) Please indicate the VCH communities that will be impacted by this research [MANDATORY,** select all that apply**]:** | Bella Bella (incl. ƛ̓uxválásu̓ilas Heiltsuk - formerly R.W. Large Memorial Hospital)  Bella Coola (including Bella Coola General Hospital)  North Shore (incl. Lions Gate Hospital)  Powell River (incl. qathet General Hospital)  Richmond (incl. Richmond Hospital)  Sea-to-Sky Corridor (incl. Squamish General Hospital)  Sunshine Coast (incl. Sechelt | Shíshálh Hospital)  Vancouver (incl. 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 (incl. the recruitment of VCH staff located across multiple service delivery area, and VCH leadership) |
| **b) Please specify the facilities within the above-noted VCH communities that will be impacted by your research** | Click or tap here to enter text. |

**Part IV: 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](https://www.vchri.ca/sites/default/files/guidance-notes-vch-operational-approval-20240927.docx)** | |
| **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](mailto:VCHRIIndigenousHealthResearchUnit@vch.ca?subject=Request%20of%20VCH%20Operational%20approval%20for%20HXX-XXXXX%20-%20Indigenous%20Peoples%20Inquiry)** | 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](mailto:VCHRIIndigenousHealthResearchUnit@vch.ca?subject=Request%20of%20VCH%20Operational%20approval%20for%20HXX-XXXXX%20-%20Indigenous%20Peoples%20Inquiry)** | Choose an item. |

**PART V: RECRUITMENT** [C:\Users\msaunders1\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\TS6NCJGO\purzen_Icon_with_question_mark[1].png](mailto:phoebe.luyun@vch.ca)

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| **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](https://www.vchri.ca/sites/default/files/guidance-notes-vch-operational-approval-20240927.docx) | 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?** | Choose an item. |
| **f) Select the recruitment support services from VCHRI** *(Submit the VCHRI Recruitment support form)* **[C:\Users\msaunders1\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\TS6NCJGO\purzen_Icon_with_question_mark[1].png](https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fwww.vchri.ca%2Fsites%2Fdefault%2Ffiles%2Fform-attachment-a-recruitmentsupportform-october2023.docx&wdOrigin=BROWSELINK)** | VCHRI Research Study Directory  Social Media (X/Twitter)  Newsletter (Research Insider)  Recruitment Poster |
| **g) How will patients/participants be contacted[C:\Users\msaunders1\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\TS6NCJGO\purzen_Icon_with_question_mark[1].png](https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fwww.vchri.ca%2Fsites%2Fdefault%2Ffiles%2Fletter-of-initial-contact-guidance-document.docx&wdOrigin=BROWSELINK)** | Choose an item. |
| **If other, specify** | Click or tap here to enter text. |

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

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| **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](mailto:phoebe.luyun@vch.ca) | 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](https://www.vchri.ca/sites/default/files/guidance-notes-vch-operational-approval-20240822.docx)  System access\* **[C:\Users\msaunders1\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\TS6NCJGO\purzen_Icon_with_question_mark[1].png](mailto:phoebe.luyun@vch.ca?subject=Request%20of%20VCH%20Operational%20Approval%20for%20HXX-XXXXX%20-%20System%20Access%20Inquiry)**  VCH - CST Cerner  Data extract service for a chart review  (section i will apply) **[C:\Users\msaunders1\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\TS6NCJGO\purzen_Icon_with_question_mark[1].png](mailto:christopher.mah@vch.ca?subject=Request%20of%20VCH%20Operational%20Approval%20for%20HXX-XXXXX%20-%20Data%20Extract%20Inquiry)**    \*Specify the locations and/or systems: Click or tap here to enter text. |
| **e) Will sharing or transferring VCH research data to or from outside institutions occur?** | Choose an item.  If yes, please provide the institution: Click or tap here to enter text. |
| **f) Will the sharing or transfer of personal identifiers to or from another health authority with VCH be required to match or link across data sets?** | Choose an item. |
| **g) Will access to any diagnostic imaging be required for this study?** | Choose an item. |
| **h) Will de-identification of imaging data be required?** | Choose an item. |
| **Provide the system name or process for de-identification of imaging data** | Click or tap here to enter text. |
| **i) Will data extract/services be required from VCH clinical systems (such as Cerner, de-identification/anonymization of personal identifiers, linking data pre and post Cerner, linking a cohort to a provincial data holdings)?** [C:\Users\msaunders1\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\TS6NCJGO\purzen_Icon_with_question_mark[1].png](https://www.vchri.ca/sites/default/files/guidance-notes-vch-operational-approval-20240927.docx) | Choose an item. |

**PART VII: RESEARCH IMPACT ON VCH CLINICAL DEPARTMENTAL SERVICES***This section corresponds to section 11 of the ethics application in RISe, with the following questions serving as additional inquiries.*

|  |  |
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| **a) Will the research study require access to PACS?** | Choose an item. |
| **b) If applicable, select all VCH hospital sites where the drug will be administered:** | VGH – Vancouver General Hospital   UBCH- UBC Hospital   RH – Richmond Hospital   LGH – Lions Gate Hospital   Other: Specify.   N/A |
| **c) Who will administer the drug?** | VCH Pharmacy   Hospital/clinic/community site medical or nursing staff   VCHRI CRU   Principal Investigator   Other: Specify. |
| **d) Will the VCH laboratory process the samples and report the results?** | Choose an item. |
| **e) Which laboratory will process the sample and report the results if not VCH?** | Click or tap here to enter text. |
| **f) Will the research study utilize fresh and/or formalin Fixed paraffin embedded tissue (FFPE)?** | Fresh   Fixed FFPE   Other: Specify.   N/A |
| **g) If applicable, select all sites where Operating Room (OR) will be impacted** | VGH – Vancouver General Hospital   UBCH – UBC Hospital   Other: Specify.   N/A |
| **h) Will tissue specimens be collected from patients/participants in the OR?** | Choose an item. |

**Reusable Medical Devices [C:\Users\msaunders1\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\TS6NCJGO\purzen_Icon_with_question_mark[1].png](https://www.vchri.ca/sites/default/files/guidance-notes-vch-operational-approval-20240822.docx)**

|  |  |
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| 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](mailto: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](mailto: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](mailto: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. |

**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](https://www.vchri.ca/services/operational-approval) | 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](https://www.vchri.ca/sites/default/files/DeviceExclusionsTable.pdf) | Choose an item. |

**General Comments**

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| Click or tap here to enter text. |

**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 | |
| 1. Principal Investigator’s VCH Division Head (if applicable)                 |  |  |  | | --- | --- | --- | | Full Name (printed) | Signature | Date | |
| 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](#_16._Additional_Required)                 |  |  |  | | --- | --- | --- | | Full Name (printed) | Signature | Date | |