# GUIDANCE NOTES FOR

# VCH OPERATIONAL APPROVAL APPLICATION

Three requirements must be met before research may begin at VCHand **VCH Certificate of Approval** is issued. Note that all three may be initiated concurrently.

**1. Ethics Certificate of Full Board Approval
2. Submission of Application for Operational Approval to Conduct a Research Study**

**At Vancouver Coastal Health (VCH)1**

**3. Execution of a research agreement, if applicable** (i.e., clinical trial agreement, information sharing agreement, data transfer agreement)

*1Relevant forms: Community of Care (CoC) Signature Sheet and Research Impact Analysis (RIA) form*

Please review these guidance notes for additional information while completing the VCH Operational Application. Refer to the blue boxes for further clarification of what is expected in the questions.

# PART I: GENERAL RESEARCH INFORMATION

# 1. Research Identification

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| **a) Research study title (and short title)** | Enter the full title of the research study as written on the ethics application, and the short name (e.g., STARR Study) if applicable. |
| **b) REB # (Please also add the REB # to the footer of this document)**  | Add the REB# to the footer of the *VCH Research Approval Application*.  |
| **c) Type of Study (select all that apply)**  | Multiple selection can be applied in this section. |

# 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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| Enter the Principal Investigator’s information. State whether PI is a Co-Investigator like so “(Co-Investigator).” This only applies for studies that have multiple sites and VCH’s PI is listed as a Co-Investigator in the ethics application. |
| **Health Authority** Under which HA is the PI’s primary institution, i.e., VCH, PHSA, FH, PHC, IH, Island Health. |
| **Clinical Department** |
| **Clinical Division** |
| **Academic Institution** Enter the institution in which PI has an academic appointment (e.g., faculty appointments, clinical appointment, etc.) |
| Principal Investigator’s VCH Affiliation (one of the following **MUST** apply):  | Indicate PI’s VCH AffiliationThe following can help you determine the status of the Principal Investigator:**i) VCHRI Investigator**VCHRI Investigator is a researcher who leads or co-leads research at a VCH facility or a VCHRI research center, who is primarily located at a VCH, and has a medical or staff appointment at VCH or university facility appointment.**ii) VCHRI Affiliated Investigator Appointment**An Affiliated Investigator is a researcher who leads, co-leads, or is actively engaged in research at a VCH facility on a study-by-study basis. The Executive Director of VCHRI grants a VCHRI Affiliated Investigator Appointment. A Principal Investigator must apply for a VCHRI Affiliated Investigator Appointment under the following circumstances: (1) They do not have a VCH medical staff appointment,(2) Are not an employee of VCH, or(3) Are not a VCHRI Researcher.For more information regarding Affiliated Investigator, visit the ‘Membership with VCHRI’ [webpage](https://www.vchri.ca/services/new-vchri/membership-vchri). You can also find the membership application in the webpage. |

# 3. Research Team

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| [ ]  ***Principal Investigator is the Primary Contact (skip to 3b)***If the Primary Contact is also the Principal Investigator of the research study, indicate this by clicking the checkbox. Otherwise, fill out the boxes accordingly. |
| **b) VCH Collaborator**  | This section is ONLY applicable if PI is a VCHRI Affiliated Investigator. A collaborator MUST be listed when a project utilizes VCH resources such as accessing database, hospital services, etc., and the PI is non-VCH.A VCH Collaborator can be a physician, nurse educator, staff, etc. who is a VCH employee. An eligibility of the collaborator depends on the study – type of study, VCH resources required, etc.EXAMPLE SCENARIO:1) If the study is an Industry Sponsored clinical drug trial and PI is a VCHRI Affiliated Investigator, a VCH physician should be listed as the VCH collaborator.2) A retrospective review study that will be accessing CST Cerner only and whose PI is from SPH may have a VCH collaborator who is a resident at VCH.If you are unsure, you can reach out the Research Approvals Coordinator. |
| **c) Will research personnel not employed by/affiliated 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 | If a volunteer staff is partaking in the study, a *Volunteer Agreement* should be signed by the PI and Volunteer staff (e.g., volunteer research assistant). Please reach out to Privacy Advisor for guidance. |
| **d) Provide the name and roles of non-affiliated VCH research members** | List all the external staff who are non-VCH. |

# 4. Research Funding

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| **a) Type of Funding** | Specify the type of funding:InternalUnfundedGrant-in-AidContractIndustryGovernmentNon-profitOther |
|  **If other, please specify** |  |
| **b) Name of Funding Source(s)** | List **all** funding sources for the study. |
| **c) Funding Program (if applicable)**  | Funding that is awarded through peer-review competitions, government, and health research funding programs, etc. |
| **d) FAS # or Project #** | FAS # stands for Funding Account Summary that is provided through UBC RISe system. Project # is another term used by other institutions such as SFU.These number links the funding information of the project. |
| **e) Institution where funding is held** | **MANDATORY**Enter the institution where funding of the project will be held. For example, UBC, VGH, VCHRI, SFU, BCCA etc.  |

**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** | For clinical trial studies and Investigator initiated studies, researchers can utilize the provincial CTMS cloud-based platform that integrates all clinical trial activities into one place. This will be a requirement for VCH/VCHRI clinical trial studies (including Investigator initiated) as we will be aligning Provincial Health Services Authority (PHSA)’s strategy to expand the use of the provincial CTMS across all clinical trial sites. CTMS allows research teams to easily access regulatory documents, monitor and track study activities, and includes other features such as financial management.For more information about the CTMS, please refer to <https://www.vchri.ca/realtime-ctms-vchri>. To start utilizing the platform, contact andy.kim@vch.ca who can introduce the platform and user access. |
| **b) Please provide a reason CTMS will not be utilized.** | As VCH will start requiring the use of CTMS for clinical trial studies, please provide a justification as to why it will not be utilized. Consider using and familiarize yourself with CTMS as it will be mandatory at VCH for all clinical trial sites. |

# PART II: HEALTH AUTHORITY PRIORITIES

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| **a) Which of the following Health Authority Strategic Priorities from the Minister’s Mandate Letter to VCH does your study address? C:\Users\msaunders1\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\TS6NCJGO\purzen_Icon_with_question_mark[1].png** | To summarize, the mandate letter sets out overarching principles relevant to the entire public sector. Public sector organizations, including Health Authorities and Post-secondary Institution Boards, are expected to deliver on these priorities for the remainder of the government’s term. The mandate emphasizes advancing results that people can see and feel in key areas such as strengthened health care, safer communities, attainable and secure housing, and clean and fair economy delivering affordability and prosperity.Please refer to the mandate letter for more details of what the Minister’s strategic priorities are at <https://www.vch.ca/sites/default/files/2023-10/2023-24%20VCH%20Mandate%20Letter.pdf>  |

 **PART III: RESEARCH LOCATIONS**

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| **Approval from the appropriate VCH signatories must be obtained by signing the ‘Community of Care Signature Sheet’ and the ‘Research Impact Analysis’ form (if applicable).** |
| **a) Please indicate the VCH communities that will be impacted by this research [select all that apply]:** | Indicate which Communities of Care will be impacted in your research project.Multiple selection acceptable. |
| **b) Please list the specific facilities within the above-noted communities that will be impacted by your research** | Specify the locations of the clinic/unit/department/program that will be impacted in the Communities of Care and obtain the appropriate Manger signatures. Examples of location that requires Manager’s signature: BC Psychosis Program, Cardiac Cath Lab, ICU, VGH emergency department, Stroke Unit, Movement Disorder Clinic, etc.If you are unsure who the signatory is, contact Research Approval Coordinator. |
| **c) Select the research activities that will take place at these facilities [select all that apply]** | Ensure that all research activities that will take place in VCH have been selected. This information should match the information in the ethics application. |

 **PART IV: RESEARCH PARTICIPANTS**

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| **a) Select all the patients/participants that will be involved in this research**  | Select the appropriate patients/participants of the project. Ensure that the patient service manager of the clinic/unit/department has approved the project by providing the signature of approval in the “Communities of Care – Signature Sheet.” |

**PART V: RESEARCH WITH INDIGENOUS PEOPLES**

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| In alignment with the Truth and Reconciliation Commission Calls to Action and the United Nations Declaration on the Rights of Indigenous Peoples, the VCHRI Indigenous Health Research Unit provides support for research involving Indigenous Peoples and communities. If responses to any of these questions is **‘Yes’**, please reach out to VCHRIIndigenousHealthResearchUnit@vch.ca Resources:Please see the TCPS 2 Chapter 9 for more information: <https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter9-chapitre9.html>  |
| **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?**  | If your study will take place on First Nations, Inuit, or Métis lands, the IHRU will be engaged to provide support. For example, if you plan to conduct a study on a First Nations reserve, such as Musqueam or Squamish, then this is on First Nations lands. If you are unsure if your study meets these criteria, please see the resources below or contact the IHRU. * BC Treaty Commission: <https://bctreaty.ca/>
* Government of Canada: <https://www.rcaanc-cirnac.gc.ca/eng/1100100030285/1529354158736>
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| **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** | If your study will take place on First Nations, Inuit, or Métis lands, the IHRU will be engaged to provide support. For example, if you plan to conduct a study on a First Nations reserve, such as Musqueam or Squamish, then this is on First Nations lands. If you are unsure if your study meets these criteria, please see the resources below or contact the IHRU. |
| **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** |  Many studies can impact Indigenous populations even if they are not specifically designed to engage with Indigenous Peoples, including studies in areas with high Indigenous populations or studies exploring topics that disproportionately impact Indigenous Peoples. For example, the Downtown East Side (DTES) is home to many urban Indigenous Peoples, so any studies involving participants or topics from this area will likely impact Indigenous Peoples. In situations like this, the IHRU will assist in determining the degree of support required. |

 **PART VI: RECRUITMENT** ![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) Is the purpose of this application ONLY to seek permission for support from VCH in the recruitment of patients/participants** | If the research team is ONLY applying for recruitment materials to be posted/shared in VCH facility or services, 1) Ensure that the recruitment method/materials are mentioned in the ethics application 2) A UBC REB # is available. This # can be found when applying for ethics approval in UBC RISe system (e.g., H24-12345).*Note: If the study is out of province, researchers MUST submit an ethics application to UBC REB. Otherwise, VCH cannot share/post in VCH facilities.*3) PART VIII of the application will not be applicable in this case. |
| **b) Will patient/participant recruitment occur on a hospital ward/clinic/community site?** | The options selected will help VCHRI determine the impact that this research study will have on VCH resources. |
| **c) Will any notices for recruitment be posted in a VCH facility?** | If posting any notices for recruitment in a hospital ward/clinic/community site will be used, a signature of approval must be obtained on the applicable *Signature Sheet* from the applicable Clinic Manager or Patient Service Manager of the hospital ward/clinic/community site. If notices for recruitment are posted in a VCH facility, the following are required:1) Ensure that the poster is REB approved.2) VCH Corporate Communications must approve the poster*Note: VA Communications has a different approver to VCH-Coastal and Richmond.*3) If changes are required and has been made, submit the updated poster to REB for approval.Specify in d) where the posters will be put up.*Note: If a study has ethics approval from an institution with VCH/VCHRI research affiliation, recruitment materials can be shared/posted if all approvals are in place.* *A study that has ethics approval from an institution that has* ***NO research affiliation agreement*** *with VCH can utilize* [*REACH BC.*](https://reachbc.ca/)Contact Research Approval Coordinator to check. |
| **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** | VCHRI offers recruitment support services for research teams. See f) for available recruitment services.If you would like VCHRI to help promote your research study, please complete the [*Recruitment Support Form*,](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) and submit it to the Coordinator, Research Approvals. Please note that research studies involving the recruitment of VCH Staff do not qualify for VCHRI recruitment support. If you wish to recruit VCH Staff, the applicable Department Head/Operational Director/Manager must approve the recruitment method.Details of all methods of recruitment must be included in your ethics application. If the study is NOT registered on ClinicalTrial.gov, the VCHRI recruitment support form MUST be filled out and submitted to REB for approval (attach in section 9.5 of the ethics application). **MANDATORY** ALL VCHRI researchers’ studies must fill out the recruitment support form to be posted in the VCHRI website.Studies will be posted on the[**VCHRI Website**](https://www.vchri.ca/participate/search?keys=)**.** |
| **f) Select the recruitment support services from VCHRI** | [ ]  VCHRI Research Study Directory [ ]  Social Media (X/Twitter)[ ]  Newsletter (Research Insider)[ ]  Recruitment Poster  |
| **g) Have patients/participants previously consented to be contacted for research?** | Specify if patients/participants have previously consented. |
| **h) How will patients/participants be contacted?** | If VCH patients have not previously consented to be contacted for research purposes and VCH is providing the patient's contact information, the [VCHRI Letter of Initial Contact](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) must be used and approved by REB. **Ensure that you include and complete the checklist on page 1.**Contact the VCH Privacy advisor for questions. |
|  **If other, specify** |  |

 **PART VII: 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?** | Any research team member who requires access to a VCH clinical system must be listed on the ethics application as a co-investigator or research team member and must complete the ***Confidentiality Undertaking course in PHSA LearningHub – Course Code: 17110***If the Investigator already has access to the system/database for clinical purposes, an approval to access the system/obtain data for research purposes will still be required. |
| **b) Who will be retrieving/accessing VCH data?** | Provide the name of team members who will be accessing VCH data. Ensure that their name is listed in the ethics application. |
| **c) Does the person retrieving/accessing VCH data have a VCH account?** | If a VCH data is required to be accessed, there are certain requirements and consideration when obtaining approval. Some databases/clinical system require researchers to have a VCH account. |
| **c) Where/how will the VCH data be accessed?** | **DATABASES:*****IMPORTANT: List ALL DATABASES that will be accessed in c) below.*** Please specify the exact database that will be accessed if applicable. Otherwise, access may be delayed if the database name is not included in the VCH Certificate of Approval.For example, specify if you will require access to PaceArt, MUSE, PARIS, PACS, ORMIS, RIS, etc.Common Databases for research:**SUNSET –** Signature of approval from Joleen Wright is required if the researcher accessing SUNSET database has a VCH account and will only access VCH cohort. If the study requires access to multiple HA cohort, then a signature of approval from PHSA data steward must be obtained.**Co-Path** – Signature of approval from Department Head of Pathology is required.**VCH CERNER** – No signature required.**PACS –** Signature of approval from Radiology department is required.**CareConnect –** There is a strict policy in place by MoH when accessing CareConnect. This is only to be used for direct care purposes and no secondary use (e.g. research, QI, evaluation). Please reach out to Joleen Wright to obtain approval.*Note: VCH has extensive list of databases, therefore it is best to specify. Some databases have specific requirement/process when requesting for access.* *To be efficient with time, reach out to the clinical manager or patient service manager (clinical unit) to confirm what database you will require and the process to obtain signature of approval.***HEALTH RECORDS DEPARTMENT:**If the Investigator requires access to patient charts, which are stored in a VCH Health Records Department, the Health Records Department must sign the *Signature Sheet*. Please note that VGH, UBCH, GF Strong, Mary Pack Arthritis Centre, LGH and Richmond Hospital each have their own Health Records Departments and signatories.Health Records charges a $5 per patient chart retrieval fee.Approval is for access to the patient chart. Photocopying is **NOT** permitted.To receive timely access to patient charts located in the Health Records Department, please note the following:* Provide advance notice: The number of days or weeks of advance notice may vary. One or two weeks before a researcher requires access to patient charts, please email Health Records to advise of the need for access to patient charts. Please be aware that some patient charts are stored off site and require additional time to retrieve and deliver to VCH. You may wish to verify ahead of time with the site regarding the advance notice period.
* Request Batches of 25 records: Health Records has requested that research requests be made in batches of 25 patient charts. Once the researcher has worked through 25 charts, he/she may place another request for an additional 25 charts until all required charts have been reviewed.
* List of required charts: Where possible, prepare the lists of required patient charts with the records listed in terminal digit order (Decision Support may assist with this). When the researcher comes to the Health Records Department to review patient charts, the researchers will need to bring photo ID, and present a copy of the following documents to the Health Records Department:
	+ the valid VCHRI Certificate of Approval,
	+ the signed VCHRI VCH Operational Research Review Application, and
	+ the list of patient charts (include MRN, name, date of discharge).

Health Records Coordinator Contacts:VGH: 604-875-4066UBC and GFS: 604-822-7745Richmond: 604-244-5573LGH: 604-984-5910 |
| **d) Will sharing or transferring VCH data to outside institutions occur?** | This information must be mentioned in the ethics application. A data transfer agreement (DTA) or data sharing agreement (DSA) may be required. The agreement must be provided to the Research Approvals Coordinator. In some cases, a DTA/DSA must be executed for VCH Certificate of Approval to be issued. |
| **e) Will access to any diagnostic imaging be required for this study?** | Specify whether accessing diagnostic imaging will be required. |
| **f) Will de-identification of imaging data be required?** |  |
|  **Provide the system name for de-identification of imaging data.**  | If a system is required to de-identify images, ensure that you provide the system name used in the project. |
| **g) Will services of Data & Analytics (formerly known as Decision Support) be required?** | Data and Analytics is comprised of many areas but the area that is most relevant to research is the coding/abstracting and analysis area, which is called the Technical Section and includes VGH, UBC, GFS, LGH and Richmond Hospital. The Technical Section codes all inpatient and surgical day care hospital records using ICD-10 CA and CCI coding classification for reporting to The Canadian Institute for Health Information (CIHI) and the Ministry of Health (MOH). The analysts use the coded data to run lists and retrieve patient records listing specific conditions/treatments, as well as performing data reporting, statistical reviews for administration, clinical/medical services, etc.If the Investigator requires the services of Data and Analytics for the Research Study, Data & Analytics must sign the *Signature Sheet.*Please send the Data and Analytics requests to Chris Mah, Research Advisor, Data Governance – christopher.mah@vch.ca |

 **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?** | The options selected will help VCHRI determine the impact that this research study will have on VCH resources.If the answer to **Part VII b) to d)** is **YES**, obtain a signature of approval from the clinic manager/patient service manager. |
| **b) Where will informed consent be obtained?** | See a) *If applicable, obtain a signature of approval.* |
| **c) If a questionnaire will be administered, where will this occur?** | See a) *If applicable, obtain a signature of approval.* |
| **d) If a focus group will be held or interviewed, where will this occur?** | See a)*If applicable, obtain a signature of approval.* |

 **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?**  | **RADIOLOGY**If your research study involves the services or resources of the Radiology Department, the following documentation must be submitted to the Radiology Department for review:1. [The *Radiology – MI Research Study Requirement Form*](https://www.vchri.ca/services/operational-approval)
2. A copy of the research study protocol;
3. The *VCH Research Approval Application; AND*
4. Certificate of Ethics approval

Once the above-listed documents have been received and reviewed, along with the certificate of ethics approval, the Radiology Department will sign the applicable *Signature Sheet.* Please note that VGH Radiology now requires an approved ethics before review can be done. Submit all documents to Yiying Wu – Yiying.wu@vch.ca Please note that the Radiology Department charges a fee for the review of all industry sponsored clinical trials. This review fee will not be charged for grant-funded studies. |
| **b) Will the research study require access to PACS?**  | If your research study involves the use of **PACS**, the Radiology Department must sign the applicable Signature Sheet. If you already have access to PACS for clinical purposes, a signature of approval from the Radiology Department must be obtained. |

**2. Pharmacy**

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| **a) Will any investigational product be stored, handled, or administered to research participants?**  | If YES, VCH PHARMACY must review the research study protocol and sign the *Signature Sheet*. **IMPORTANT:** VCH pharmacies are not centralized, therefore if a research project is utilizing pharmacy in different VCH hospitals, this must be reviewed respectively. VGH Pharmacy approval does not extend to other VCH sites (i.e., RHS, LGH, etc.)Further detail of the policy of Lower Mainland Pharmacy Services’ (LMPS) participation in research can be found [here.](https://pulse/clinical/pharmacy/documentslowermainlandpharmacyservicesmanual/LMPS%20Pharmacy%20participation%20in%20research%20Nov%2021%202023.pdf)The VCH Pharmacy Department must review **all** research study protocols involving the administration of **any** drug (both investigational and marketed drugs) regardless of whether any drug is being stored and dispensed by the pharmacy or is the focus of the research study. After review, the VCH Pharmacy Department Manager will sign the *Signature Sheet* if they agree that VCH pharmacy is or is not involved.To complete its review, the VCH Pharmacy Department will require the following documentation at minimum:i. A cover letter detailing your request.ii. The research study protocol, andiii. The VCH Research Approval Application.Once the above-listed documents have been received and reviewed, the applicable *Signature Sheet* will be signed.**VCH Pharmacy is NOT involved:** If VCH Pharmacy Department is not requested to store and dispense any drug: the research study protocol will be reviewed by the pharmacy department only to determine if they agree that there is no VCH Pharmacy involvement and to determine that no drugs will need to be provided by the VCH Pharmacy.**VCH Pharmacy is involved:**If there is VCH Pharmacy Department involvement, the research study protocol and any related documents are reviewed to determine the level of involvement required. For example, in its review the VCH Pharmacy Department will:* Determine if pre-printed doctor’s orders, computerized order entry, medication administration records, and drug information sheets (for patients and/or Staff) are needed.
* Assess randomization and blinding procedures for potential problems and degree of VCH Pharmacy Department involvement if information is available.
* Ensure facilities are available to store and prepare research study drugs as directed by the protocol (i.e., monitored fridge or locked cupboard within the VCH Pharmacy Department).
* Ensure costs that will be incurred by the VCH Pharmacy Department for their participation in the research study are billed for.
* Determine the availability of any treatments. For example:
* Is the research study drug being compared to or given in addition to the standard of care at our institution?
* Are any additional drugs needed to comply with the protocol that are not on the hospital formulary? If so, will the cost to obtain them be reimbursed or will the sponsor supply them?
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| **b) Select all hospital sites where the investigational product will be administered** | As mentioned above:**IMPORTANT:** VCH pharmacies are not centralized, therefore if a research project is utilizing pharmacy in different VCH hospitals, this must be reviewed respectively. VGH Pharmacy approval does not extend to other VCH sites (i.e., RHS, LGH, etc.) |
| **c) Will the investigational product be administered at a VCH clinic/community site?** | Specify if an investigational product will be administered at a VCH facility. |
| **d) Who will administer the investigational product?** | Specify who will administer the investigational product.  |

**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)?** | If during your research study the VCH Laboratory Department will be processing samples collected for research study purposes only (e.g., whole blood, serum, plasma, urine, CSF), the VCH Laboratory Department must review the research study protocol, the *Laboratory Research Request Form*, and sign the applicable *Signature Sheet*. If a research study involves the services or resources of the VCH Laboratory Department, the following documentation must be submitted to the VCH Laboratory Department for review:1. A cover letter (include the number of Research Participants and tests that are applicable to your research study);
2. A copy of the research study protocol;
3. The *VCH Research Approval Application*
4. The *Laboratory Research Request Form (the department will provide this form when requested)*

Once the above-listed documents have been received and reviewed, the applicable *Signature Sheet* will be signed.Submit all documents to VGH Lab Research – vghlabresearch@vch.ca  |
| **b) Will the VCH laboratory process the samples and report the results?** | Specify if VCH laboratory will process the samples and report the results. |
| **c) Which laboratory will process the sample and report the results if not VCH?** | If the VCH Laboratory Department will not be processing the collected Biospecimens, please indicate which laboratory will be processing the samples and reporting the results. |
| **d) Will the research study utilize fresh and/or formalin fixed paraffin embedded tissue (FFPE)?** | **Diagnostic Tissue**Indicate if the research study is utilizing Fresh Tissue or Formalin Fixed Paraffin Embedded (FPPE) tissue.If the research study is utilizing Fresh Tissue, indicate the location where the tissue will be collected. Each department has their own review and approval process and must be contacted to discuss the impact prior to providing approval by signing the *Signature Sheet.*  **Note:** Tissue Specimens collected by the Operating Room may not be picked up from the Operating Room. All Tissue Specimens must be sent to the VCH Pathology Department. If a research study involves the services or resources of Anatomical Pathology (AP), the following documentation must be submitted to the Anatomical Pathology Department for review:*i.* VCH Application for Operational Approval to Conduct a Research Study; *ii.* A copy of the ethics application (pending or approved);*iii.* Anatomic Pathology Laboratory Resource Utilization Form; *iv.* Research Study protocol; and *v.* Specimen Collection for Research – Special Handling Instructions Form (as applicable, for studies involving the collection of tissue).VGH and UBCH: Documentation should be submitted via email to Anatomical Pathology - VGHAP.RESEARCH@vch.caPlease note that if Anatomical Pathology is processing tissue specimens for research purposes, the Pathologist who will be responsible for processing the tissue specimens must be named as a co-investigator on the Research Study (on certificate of ethical approval).  |

**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 | Indicate which hospital will be involved in the medical procedure of the participant.*Note: There is a separate guideline notes for* [Operating Room and Tissue Collection Guidelines](https://www.vchri.ca/services/operational-approval).If Research Participants will undergo any surgical procedure in the operating room, a signature of approval from the Operating Room Manager of Equipment and Supplies must be obtained on the applicable *Signature Sheet*. Prior to signing the applicable *Signature Sheet*, the Operating Room Manager of Equipment and Supplies must receive a completed *Operating Room Research Form*, a copy of the research study protocol, and the *Patient Informed Consent Form*.All research studies that take place in and/or impact the resources of the Operating Room must be reviewed and approved by the Operating Room Management prior to the start of the research study. You must submit the following documentation to the Operating Room for review:1. A copy of the research study protocol;
2. The *VCH Research Approval Application*;
3. The *Operating Room Research Form*;
4. A copy of the *Patient Informed Consent Form*; and
5. *The Specimen Collection for Research – Special Handling Instructions Form* (if applicable).

Upon receipt of the above documentation, the Operating Room will advise you if any additional documentation or information is required. The Operating Room will sign the applicable *Signature Sheet* once all Operating Room requirements have been met. If it is determined that the Operating Room will not be impacted by the research study, the Operating Room Manager will sign the applicable *Signature Sheet* and will indicate that there is no involvement of the Operating Room in your research study.Submit **ALL OR** documentation to the following:**VGH:** Debbie Hendricks, VA Manager Equipment & Supplies OR - Debbie.Hendricks@vch.ca **UBCH:** Amanda Jones, UBCH Manager, Clinical Operations, Surgical Suites - Amanda.Jones@vch.ca  |
| **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 | If Tissue Specimens will be collected for research purposes during a surgical procedure in the Operating Room (OR), Anatomical Pathology and the Operating Room must review and approve the research study.*Note: AP must sign and approve the Operational Application first, before OR.*Refer to the [Operating Room and Tissue Collection Guidelines](https://www.vchri.ca/services/operational-approval). |
| **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 | If blood specimens will be collected for research purposes during a surgical procedure in the Operating Room, the **Anesthesia Department** must review and approve the Research Study.  |

# 5. Reusable Medical Devices

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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?
* If NO, proceed to question 6.
 | Refer to the guidelines for medical devices used in research [**here.**](https://www.vchri.ca/sites/default/files/Guidance-for-Research-and-Project-Devices.pdf)All applicable forms for reprocessing of medical devices used in research can be found in the[**VCHRI Operational Approval page.**](https://www.vchri.ca/services/operational-approval) |
| 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)?
 | Refer to the guidelines for medical devices used in research [**here.**](https://www.vchri.ca/sites/default/files/Guidance-for-Research-and-Project-Devices.pdf)For reusable medical devices requiring reprocessing between use:If using a non-critical medical device (i.e., a device that will not be exposed to a sterile cavity or mucous membrane/non-intact skin), a reprocessing plan with instructions for cleaning and disinfection between patient uses needs to be provided to ensure infection prevention and control. Complete the *Application for Non-Critical Research Device Form* and send to the Reprocessing Practice Improvement Program (RPIP) at reprocessing@vch.ca to arrange review and approval of the application.  |
| 1. **If NO to 5b:**

The device is considered a non-critical device. To ensure safety between patient use, as 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. | Refer to the guidelines for medical devices used in research [**here.**](https://www.vchri.ca/sites/default/files/Guidance-for-Research-and-Project-Devices.pdf)If using a marketed Medical Device as intended, complete the *Application for Market Device in Research Form,* and send to RPIP at reprocessing@vch.ca. Provide RPIP with a copy of the Manufacturer’s Instructions for Use (MIFU) to ensure the validated sterilization instructions are compatible with the reprocessing capabilities of the facility in which the research study will be undertaken.If using a created or modified Medical Device, complete the *Application for Non-Market Research Device Form*. Provide a reprocessing plan with instructions for cleaning and disinfection or sterilization between patient uses, along with a copy of instructions for sterilization or high-level disinfection that have been validated by an independent certified lab (be sure to consider the costs of validation of reprocessing instructions by the independent lab in your funding proposal). Contact RPIP at reprocessing@vch.ca to ensure the validated sterilization instructions are compatible for the reprocessing equipment currently used in the facility in which the research will be undertaken.Relevant Forms can be found [**here.**](https://www.vchri.ca/services/operational-approval) |

# 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
 | Biomedical Engineering determines if a review is required for **electrically powered** medical devices used in research studies for treatment, diagnosis, and monitoring or data collection. The purpose of the biomedical engineering review is to determine the following:* Regulatory compliance with Federal requirements of Health Canada.
* Regulatory compliance with Provincial electrical code guidelines.
* Electrical safety test to confirm if the device is within the Canadian Standards Association (CSA) limits.
* Visual inspection to evaluate the condition of the device and ensure safety.
* Impact of device on other devices that are within the vicinity of use.
* In rare cases, operational impact on the biomedical engineering department.

***Note:*** *The scope of the biomedical engineering review may vary depending on whether the electrically powered device will be used in a clinical environment versus a non-clinical environment (refer to* [*Electrically-powered Medical Devices – Clinical Environment*](https://www.vchri.ca/sites/default/files/ExpectationsForResearchers-ClinicalEnvironment.pdf) *or* [*Electrically-powered Medical Devices – NON Clinical Environment*](https://www.vchri.ca/sites/default/files/ExpectationsForResearchers-NonClinicalEnvironment.pdf)*).*For planning purposes, researchers can use the following as a general guide for biomedical reviews: * Paper-based review: One Week
* Complex / Novel research devices: One to three Weeks
* Manual Inspection: Typically scheduled within a week after the paper-based review is completed.

***Note:*** *Significant delays may happen if the researcher needs to obtain additional information or regulatory approval*Important notes of clarification:1. *If a device is electrically powered but falls under the exclusion list (refer to* [*The Device Exclusions List*](https://www.vchri.ca/sites/default/files/DeviceExclusionsTable.pdf)*), biomedical review will not be required*.
2. *There is no cost associated with the paper-based review, on-site visit or hands-on inspection conducted by biomedical engineering****. Researchers are responsible for the costs associated with obtaining regulatory approvals in cases where the equipment lacks all necessary regulatory requirements.***

Please contact Lower Mainland Biomedical Engineering departments at BMEClerical@vch.ca Important notes of clarification:1. *If a device is electrically powered but falls under the exclusion list, biomedical review will not be required*.

*There is no cost associated with the paper-based review, on-site visit or hands-on inspection conducted by biomedical engineering****. Researchers are responsible for the costs associated with obtaining regulatory approvals in cases where the equipment lacks all necessary regulatory requirements.***For Biomedical Guidance Documents, visit [**here.**](https://www.vchri.ca/services/operational-approval) |
| 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
 | This list contains items that are exempt from biomedical engineering analysis. If you are unsure whether a device meets the criteria to be exempt, please contact biomedical engineering BMEClerical@vch.caThe Device Exclusions List can be found [**here.**](https://www.vchri.ca/sites/default/files/DeviceExclusionsTable.pdf) |

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

**All departmental approval signatures must be placed on the appropriate
Community of Care (CoC) Signature Sheet.**

# Community of Care (CoC) Signature Sheet

This document provides a space for appropriate VCH signatories to provide signature of approval when a research project has been reviewed and approved by departmental committees or VCH operational staff. Researchers can submit the CoC signature sheets that apply (e.g., if study requires VCH-Vancouver and GF Strong, then submit only those two CoC sheets).

This form is mandatory.

Research Impact Analysis (RIA) Form
This form is a tool made available for researchers and operational staff for convenience. If a clinical unit requests researchers to provide information about their study, researchers must fill out this form and submit to the appropriate VCH operational staff (e.g., patient service manager, operational director, etc.). Once reviewed and approved, the signed form must be submitted to the VCHRI Research Approval Coordinator.

This form is **not** mandatory.

# AMENDMENTS TO VCHRI APPROVED STUDIES

After VCHRI approval is granted, the Investigator may amend the research study protocol. The amendment may result in the research study having a greater impact on VCH resources, or it may result in a new department/clinic/ward or community site being impacted. If this is the case, the impacted department/clinic/ward/community site and VCHRI must be notified and must sign the **CoC signature sheet.**

The new department/clinic/ward or community site being impacted may sign the original **CoC signature sheet** – a new form does not need to be completed. Once all impacted departments have signed the form and any issues have been resolved, please provide the documentation to VCHRI. VCHRI will issue an amended Certificate of Approval.

# VCHRI RENEWALS

VCHRI is responsible for maintaining complete and accurate files on approved research projects and for ensuring that these projects are being conducted with valid ethical and VCH approvals in place.

A VCH Certificate of Approval is valid until the **expiry date of the UBC ethics application.** If the research study remains active after the expiry, please complete the “***Renewal of Operational Research Approval Form” and*** notify when the UBC ethics renewal has been approved. Once VCHRI receives this information, VCHRI will prepare a VCH Certificate of Renewal.