## GUIDELINE FOR OBTAINING OPERATIONAL APPROVAL OF RESEARCH AT VANCOUVER COASTAL HEALTH

These notes are offered as guidance to investigators. If you have questions or circumstances that are not addressed in this document, please contact the Director, Clinical Trials Administration at 604-675-2567 or stephania.manusha@vch.ca.

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## INTRODUCTION

This document is intended to guide researchers in the preparation of their VCHRI research study application. The guidance notes in this document correspond with the sections of the “VCH Application for Operational Approval to Conduct a Research Study”. All research forms referred to in this guidance document are located on the VCHRI website: <http://www.vchri.ca/services/operational-approval>.

## DEFINITION

BCIT – British Columbia Institute of Technology

LGH – Lions Gate Hospital

LMPS – Lower Mainland Pharmacy Services

SFU – Simon Fraser University

UBC – University of British Columbia

UBCH – University of British Columbia Hospital

VCH – Vancouver Coastal Health Authority

VCHRI – Vancouver Coastal Health Research Institute

VGH – Vancouver General Hospital

## OVERVIEW

All research studies involving human subjects that utilize VCH property, resources, facilities, patients or staff, must receive VCH approval to conduct research in addition to ethical approval. The VCH research approval process ensures that the research is reviewed from a resource use framework.

Researchers will be required to download the VCH Application for Operational Approval to Conduct a Research Study” from the VCHRI website: <http://www.vchri.ca/services/operational-approval>. This form must be completed and submitted to VCHRI together with the applicable operational approvals. Researchers must obtain operational approval from each area within VCH that will be impacted by the research study. The VCH individual responsible for approving the request will determine whether their area is able to support the research.

Research may begin when the researcher receives the VCH Certificate of Approval issued by VCHRI. This certificate confirms that all of the applicable operational approvals have been obtained by the researcher. A copy of the VCH Certificate of Approval must be kept with the researcher’s study files.

## DEFINITION OF RESEARCH

A research study, regardless of how it is funded, will be considered under the terms of VCH and UBC policy, as being research involving human subjects if:

* A human is subjected to procedures, the purpose of which go beyond the subject’s need for prophylaxis, diagnosis or therapy; or
* A human is subjected to procedures which are experimental but which do not necessarily go beyond the subject’s need for prophylaxis, diagnosis, or therapy; or
* Procedures are used in which an invasion of privacy may be involved, for example, by examination of records, by interviews, by observations, by administration of a questionnaire or test, or by audio or video recording; or
* Human tissue, biological fluids, embryos or fetuses are being studied.

## VCHRI SUBMISSION CRITERIA

Research studies meeting the above definition, that utilize VCH property, resources, facilities, patients or staff, must receive VCH approval to conduct research in addition to ethical approval.

For detailed information on departmental approvals, expand the ‘GUIDANCE NOTE’ below.

## OBTAINING APPROVAL TO CONDUCT RESEARCH AT VCH

Three processes must occur before research is approved by VCHRI and may begin at VCH:

1. Submission to a UBC (or affiliate institution) REB for review and approval;
2. Submission to the VCHRI office for review and approval (forms and guidelines for the research approval process are located at <http://www.vchri.ca/services/operational-approval> and
3. Execution of a research agreement (if applicable).

**Submission for VCHRI review, REB review and research agreement review may be initiated in parallel.**

## VCHRI Research Study Application:VCH Operational Research Review Application

In the shaded area at the top of the ***“VCH Application for Operational Approval to Conduct a Research Study”*,** indicate which VCH sites will be impacted.

## GUIDANCE NOTE #1: RESEARCH STUDY TITLE AND PROTOCOL NUMBER

Include the complete title of the research study. Enter the protocol number and short name (e.g. STARR Study), if applicable. Enter the REB # (Research Ethics Board #)

## GUIDANCE NOTE #2: INVESTIGATOR

The Investigator takes on the responsibility of the overall conduct of the research study within VCH.

Include the name, address, telephone number, fax number, and the email address of the Investigator for this research study. The Investigator named on this form must:

1. Have a medical appointment at VCH,
2. Be a VCH employee (e.g., nurse, respiratory therapist, manager),
3. Be a VCHRI Investigator, or
4. Be a VCHRI Affiliated Investigator (See **Section 2.2** below for additional information on this appointment.

**2.1 VCHRI Investigator**

VCHRI investigator is a researcher who leads or co-leads research at a Vancouver Coastal Health (VCH) facility or a VCHRI research centre, who’s primarily located at a VCH or VCHRI facility, and has a medical or staff appointment at VCH or university faculty appointment.

**2.2 VCHRI Affiliated Investigator Appointment**

This appointment is granted by the Executive Director, VCHRI. If an Investigator does not have a VCH medical staff appointment, or is not an employee of VCH; but, does have a faculty appointment at a VCHRI affiliated post-secondary institution (UBC, SFU, BCIT, Royal Roads), the Investigator must apply for a VCHRI Affiliated Investigator appointment.

An Affiliated Investigator is a researcher who leads, co-leads, or is actively engaged in research at a VCH facility or a VCHRI research centre on a study-by-study basis.

To obtain a VCHRI Affiliated Investigator appointment, the following documentation should be submitted to Dr. Teresa Tsang, VCHRI’s Executive Director, for review:

1. A letter describing the Investigator’s research program and requesting this appointment.
2. A letter of support from the Investigator’s Head of School.
3. The “Application for an Affiliated Investigator Appointment at Vancouver Coastal Health Authority”; and
4. A copy of the Investigator’s academic CV.

Please submit the above documents to Dr. Tsang’s Executive Assistant, Melissa BonaNascimento melissa.bonanascimento@vch.ca

If the Investigator named on the ***“VCH Application for Operational Approval to Conduct a Research Study”*** is a VCHRI Affiliated Investigator, a VCH Collaborator must be appointed and named in Section 4 of the***“VCH Application for Operational Approval to Conduct a Research Study”***. The VCH Collaborator must have a VCH medical staff appointment or be employed by VCH. The VCH Collaborator must also be listed as a co-investigator or study team member on the ethics application.

Please contact Phoebe Luyun at phoebe.luyun@vch.ca and copy vchrioperationalapproval@vch.ca for further information.

## GUIDANCE NOTE #3: INVESTIGATOR’S DEPARTMENT AND DIVISION

Include the Investigator’s clinical department and division (as applicable).

Include the Investigator’s Academic institution and department (e.g. UBC – Faculty of Applied Science, SFU, etc.)

## GUIDANCE NOTE #4: VCH COLLABORATOR

This ONLY applies if the Investigator is a *VCHRI Affiliated Investigator*, the name of the VCH Collaborator must be included in this section.

## GUIDANCE NOTE #5: PRIMARY CONTACT PERSON

Include the name of the person VCHRI should contact regarding the VCHRI research study application for administrative purposes. Enter the person’s telephone number, fax number, and email address.

## GUIDANCE NOTE #6: INTERNAL MAILING INSTRUCTIONS/ADDRESS

Include the mailing address where all correspondence regarding the VCHRI research study application should be sent.

## GUIDANCE NOTE #7: TYPE OF FUNDING SOURCE

Include the type of funding the Investigator has received to conduct the research study.

* Internal – these type of funding is from health authorities or academic institution (i.e. no overhead)
* Unfunded
* Grant
* Contract

## GUIDANCE NOTE #8: FUNDING SOURCE

Include the name of the funding source(s) and information such as the institution where funding is held.

## GUIDANCE NOTE #9: TYPE OF RESEARCH STUDY

Indicate the type of research study.

## GUIDANCE NOTE #10: DEPARTMENT HEAD SIGNATURE

Obtain the signature of the Investigator’s VCH Department Head. Please print the name of the individual who is signing the form.

The signature of the Investigator’s Department, School or Program Head indicates that the Investigator at VCH has the qualifications experience, and facilities to carry out the research study.

If the Investigator is the Department Head, the person who the Investigator reports to, must sign the form.

For VCHRI affiliated investigators, the VCH Department Head will be VCHRI’s Executive Director – Dr. Teresa Tsang.

## GUIDANCE NOTE #11: DIVISION HEAD SIGNATURE

Obtain the signature of the Investigator’s VCH Division Head. Please print the name of the individual who is signing the form.

If the Investigator does not have a Division Head (e.g., research nurse, patient service manager, respiratory therapist), a signature is not required.

## GUIDANCE NOTE #12: SUPERVISOR/MANAGER SIGNATURE

If the Investigator is a VCH employee (e.g., research nurse, patient service manager, respiratory therapist) the Investigator must obtain his or her supervisor’s/manager’s/director’s signature. Please print the name of the individual who is signing the form.

## GUIDANCE NOTE #13: PRINCIPAL INVESTIGATOR SIGNATURE

The Investigator must sign the form.

## GUIDANCE NOTE #14: VCH SERVICES OR RESOURCES REQUIRED FOR THE RESEARCH STUDY

Section 14 includes signature tables for each of the VCH Health Service Delivery Areas (HSDAs): Vancouver Acute, Vancouver Community, Coastal and Richmond Health Services.

Note that signature requirements vary among the different HSDAs.

### A. Department Approvals

If a research study impacts VCH services or resources, the appropriate hospital clinic/ward/department or community site approval must be obtained. Hospital clinics/wards/departments and community sites require information about the study and services that are required (clinic staff nursing time, clinic space, access to clinic patients for recruitment, lab technician time, etc.). It is the responsibility of the hospital clinics/wards/departments and community sites to determine if such services will have sufficient impact, as to require recovery from the research study budget, to offset VCH operating costs. It is the responsibility of the hospital clinics/wards/departments and community sites to provide investigators with the cost of those services.

The hospital clinic’s/ward’s/department’s and community sites signature on the ***“VCH Application for Operational Approval to Conduct a Research Study”*** indicates a willingness to participate and support the Research Study.

In this section, the Investigator must indicate all VCH sites the research study will be conducted, and which VCH hospital wards/clinics/departments and community sites the research study will impact. Enter the name of the hospital ward/clinic/department or community site that will be impacted.

Information regarding the research review processes of key VCH departments is provided below:

### PHARMACY

The Pharmacy Department must review all research study protocols involving the administration of any drug (this includes both investigational and marketed drugs) regardless if the drug is the focus of the research study.

Pharmacy Department involvement is necessary for research studies that involve administration of a drug to in-patients within VCH and may be necessary for out-patients in VCH clinics. Research study protocols are reviewed for the level of Pharmacy Department involvement required. For example, the Pharmacy Department in its review will:

* Determine if pre-printed Dr’s orders, computerized order entry, medication administration need records and drug information sheets (for patients and/or staff) are needed.
* Assess randomization and blinding procedures for potential problems and degree of Pharmacy Department involvement.
* Ensure facilities are available to store and prepare study drugs as directed by the protocol (i.e. monitored fridge or locked cupboard within the Pharmacy Department).
* Ensure research study medications intended for outpatient use are labeled appropriately and meet regulatory requirements.
* The appropriateness of the comparator treatment. For example:
	+ Is the research study drug being compared to the “standard of care” at our institution?
	+ Are any “extra” drugs needed to comply with the protocol that Pharmacy Department normally would not use, and if so, are they appropriate and will the sponsor supply them?
* Ensure the sponsor will cover any costs incurred by the pharmacy for the research study.

 The Pharmacy Department requires the following documentation for review:

* Cover letter;
* A copy of the research study protocol; and
* A copy of the ***“VCH Application for Operational Approval to Conduct a Research Study”***.

Once the above-listed documents have been received, reviewed and the “***VCH Application for Operational Approval to Conduct a Research Study”*** has been signed, the Pharmacy Department will contact the person listed on the cover letter to obtain the signed form.

IMPORTANT NOTE: 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).

### RADIOLOGY

Radiology department now requires an ethics approval prior to review. If a Research Study involves the services or resources of the Radiology Department, the following documentation must be submitted to the Radiology Department for review:

* Radiology Department Research Study Requirements Form;
* Copy of the Research Study protocol;
* VCH Operational Research Review Application.
* Certificate of Ethics Approval

VGH: The above documentation should be emailed to the Radiology Department Research Coordinator, Yiying Wu at yiying.wu@vch.ca . Please note that the Radiology Department at VGH charges a setup/review fee of $300 plus $100 per additional modality for the review of all industry sponsored clinical trials. This review fee will not be charged on grant-funded studies.

UBCH: The above documentation should be sent to the attention of the MRI supervisors, Karen Smith or Leslie Costley, MRI Supervisor.

If a research study involves the use of PACS (Picture Archive Communication System), the Radiology Department (Dr. Savvas Nicolaou) must sign the **VCH Application for Operational Approval.**

If the Investigator already has access to PACS for clinical purposes, a signature of approval from the Radiology Department must still be obtained.

### CARDIOLOGY

If your research study involves the services or resources of the Cardiology Department (ex. ECG, ECHO, cardiac catheterization, etc), the following documentation must be submitted to the Cardiology Department for review:

NEW - Contact e-mail: heartservicesforresearch@vch.ca

1. *VCH Research Approval Application*
2. Completed *Heart Service for Research* Study *Information* form.  Key information needed includes:
	1. Study short name – needed for any test requisitions
	2. Number of Participants AND the number of tests needed per Participant
	3. Study Payer -  Person/entity who is legally responsible for paying the invoice.  This is NOT the same as the person who remits the invoice for payment or the person who forwards the payment.  It should be the name of the entity that is cutting the cheque to the organization (In other words, if it were to go to collections, who would the collection agency contact?).
	4. Activities you will require from the Cardiology Department
3. A copy of the Study protocol (If costing is required for tests that are not standard of care)
4. For requests involving echocardiograms, will a Core lab be involved in test analysis
5. [Heart Service Study Information Checklist](https://www.vchri.ca/sites/default/files/checklist-heart-services-study-information-20221021.pdf) – found on the VCHRI Operational Approval website.

### CLINICAL LABORATORY

If a Research Study involves the services or resources of the Clinical Laboratory, the following documentation must be submitted to the Clinical Laboratory Department for review:

* Cover Letter (include the number of subjects and tests that are applicable to research);
* Copy of the Research Study protocol;
* VCH Operational Research Review Application.

Vancouver (Acute): The above documentation should be sent to via email to: VGH Lab Research – vghlabresearch@vch.ca

### OPERATING ROOM

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 prior to the start of the Research Study. The Investigator must submit the following documentation to the Operating Room for review:

* Copy of the study protocol;
* Application for Operational Review to Conduct a Research Study
* OR Research Form; and
* Specimen Collection for Research – Special Handling Instructions Form, as applicable.

VGH: The above documentation should be sent via email to the OR Manager.

UBCH: The above documentation should be submitted via email to the Patient Service Manager Surgical Suites & Surgical Clinic.

Upon receipt of the above documentation, Operating Room, will advise the Investigator if any additional documentation/information is required. The Operating Room will sign the **VCH Application for Operational Approval** 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 Manager, Equipment and Supplies, Operating Room, will sign the form and will indicate that there is “no involvement” of the Operating Room in the Research Study.

If **tissue specimens** will be collected for research purposes during a surgical procedure in the Operating Room, Anatomical Pathology AND the Operating Room must review and approve the study.

Please see the *Appendix 2: “Guideline for the Review and Approval of a Research Study Impacting VCH Operating Rooms”* for further details.

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.

VGH: Please submit the **VCH Application for Operational Approval**along with a cover sheet outlining the requirements of the Anesthesiologist and submit this documentation via email, c/o Dr. Raymer Grant for review and approval.

### ANATOMICAL PATHOLOGY

If a research study involves the services or resources of Anatomical Pathology, the following documentation must be submitted to the Anatomical Pathology Department for review:

* VCH Application for Operational Approval to Conduct a Research Study;
* A copy of the ethics application (pending or approved)
* Anatomic Pathology Laboratory Resource Utilization Form;
* Research Study protocol; and
* 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, c/o Research Coordinator, Simon Cheung, simon.cheung2@vch.ca, Anatomical Pathology.

Please 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).

**B. APPROVAL SIGNATURES REQUIRED**

If the research study involves the resources or services of a VCH hospital ward/clinic/department or community site, print the name of the individual signing on behalf of the hospital ward/clinic/department or community site, and obtain his or her signature.

**C. DEPARTMENT COST ANALYSIS**

Indicate if a VCH hospital ward/clinic/department or community site cost analysis is required. If a cost analysis is required, please provide a final copy to VCHRI together with the VCH Operational Research Review Application.

## GUIDANCE NOTE #15: STUDY PERSONNEL

1. Indicate the Investigator’s affiliation with VCH.
2. If the Investigator is a VCH employee, indicate which professional discipline the Investigator is a member.
3. Indicate if there are research personnel involved with the conduct of the Research Study that are not affiliated with VCH. Name these individuals and briefly describe their roles.

A ***Confidentiality Undertaking for Research Projects Form*** should be signed by all external Research Study personnel.

**As of March 22, 2016, these forms will be valid for 2 years and it is the researcher’s responsibility to submit a new form every two years. The forms are no longer linked to a research project.**

## GUIDANCE NOTE #16: PERSONAL HEALTH INFORMATION

“Personal information” is defined in The Freedom of Information and Protection of Privacy Act (British Columbia) as any recorded information about an identifiable individual (excluding business contact information). Personal information can be recorded in any format including books, documents, maps, drawings, photographs, letters, vouchers, papers, and any other thing on which information is recorded or stored by graphic, electronic, mechanical or other means. Personal information includes information that can be linked back to or can identify a specific individual through association or inference. For example, generic information about an individual (e.g., ethnic origin) could be linked to one or more individuals if they lived in a small town with a limited number of people with that ethnic background. Examples of personal information include but are not limited to:

* The individual’s name, address or telephone number;
* The individual’s race, national or ethnic origin, colour, or religious beliefs or associations;
* The individual’s age, sex, sexual orientation, marital status or family status;
* An identifying number, symbol or other particular assigned to the individual;
* The individual’s fingerprints, blood type or inheritable characteristics;
* Information about the individual’s health care history, including a physical or mental disability;
* Information about the individual’s educational, financial, criminal or employment history;
* Anyone else’s opinions about the individual; and,
* The individual’s personal views or opinions, except if they are about someone else.

On the ***VCH Application for Operational***, indicate whether Investigator and/or his/her research study personnel will access ‘personal information’ of VCH patients/clients/residents/staff in this research study.

If the Investigator and his/her research study staff will access ‘personal information’ of VCH patients/clients/residents/staff in this research study, an online ***Confidentiality Undertaking for Research Projects*** module must be completed by the Investigator and his/her research study personnel. The Confidentiality Undertaking will be valid for 2 years and they will not be linked to a research project. The Confidentiality Undertaking for Researchers is available online through the PHSA Learning Hub<https://learninghub.phsa.ca>.

NOTE: If a new research team member is added after receiving VCHRI approval for the research study, and if they haven’t completed the ***Confidentiality Undertaking for Research Projects***, he/she must complete the ***Confidentiality Undertaking for Research Projects*** module before they access any identifying data.

## GUIDANCE NOTE #17: DATA AND ANALYTICS, AND HEALTH RECORDS

### DATA AND ANALYTICS:

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 and Analytics must sign the “***VCH Application for Operational Approval to Conduct a Research Study”***.

Please send all Data and Analytics requests c/o Sasha Pavlovich, Director, Data Access & Governance – sasha.pavlovich@vch.ca

### 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 ***VCH Application for Operational Approval.***  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: 604-875-4066

UBC and GFS: 604-822-7745

Richmond: 604-244-5573

LGH: 604-984-5910

## GUIDANCE NOTE #17 cont’d – VCH CLINICAL SYSTEMS/DATABASES:

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 sign a ***Confidentiality Undertaking for Research Projects Form***.

If the Investigator already has access to the system/database for clinical purposes, separate approval to access the system/obtain data for research purposes may be required.

* **ORMIS (Operating Room Management Information System)**: If a researcher requires access to this system/data from this system, please obtain a signature of approval from Leanne Appleton, Operations Director Perioperative Services.
* **PACS (Picture Archive Communication System)**: If a researcher requires access to/data from PACS for research purposes, for Radiology Department records, please obtain a signature of approval from Dr. Savvas Nicolaou
* **PCIS**: Access to PCIS will be provided once all of the following requirements have been met:
	+ The new research team member has completed PCIS training;
	+ PCIS has received a copy of the Certificate of Ethical Approval;
	+ PCIS has received a copy of the VCHRI Certificate of Approval; and
	+ PCIS has received confirmation that the research team member is listed on the ethics application, and has signed a ***Confidentiality Undertaking for Research Projects Form.***
* **CERNER**: If a researcher requires access to this system/data from this system, a signature is NO LONGER required. Access to the database must be mentioned in the ethics application and operational approval.

If the Investigator requires access to an internal department database, a signature of approval must be obtained from the appropriate department allowing access to the database for research purposes.

## GUIDANCE NOTE #18: STUDY PROCEDURES/ASSESMENTS

This section is only applicable if the research study involves the participation of human research subjects or the utilization of VCH diagnostic material.

## GUIDANCE NOTE #19: REUSBLE MEDICAL DEVICES

This section is only applicable if the research study involves a device that contacts the patient directly or is used within the sterile field.

## GUIDANCE NOTE #20: BIOMEDICAL ENGINEERING

Biomedical Engineering determines if a review is required of **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 to the biomedical engineering department.

The scope of the biomedical engineering review differs depending on whether the electrically powered device will be used in a clinical environment versus a non-clinical environment (refer to Table [1]).

For planning purpose, researchers can use the following as a general guide for biomedical reviews:

* Paper-based review: One Week
* Complex / Novel research devices: One – Three Weeks
* Manual Inspection: Typically scheduled within a week after the paper-based review is completed.

Important notes of clarification:

1. *If a medical device is electrically powered, but falls under the exclusion list (refer to Table [2]), 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***.**

**Table [1]** Expectations for Electrical Powered Devices Used in Research Studies Occurring in a Clinical Environment v Non-Clinical Environment

|  |  |
| --- | --- |
| **A. Clinical Environment** | **B. Non-Clinical Environment** |
| 1) The **clinical environment** is defined as areas where care (diagnosis, treatment) is provided to VCH patients, such as in a hospital. | 1) The **non-clinical environment** is defined as areas intended for research purposes where VCH patients do not receive care (e.g. diagnosis, treatment). Some examples include research labs at ICORD and non-clinical research rooms at GF Strong. |
| **2) All medical devices used in research studies must have:*** A Health Canada license
* An investigational testing authorization (ITA) from Health Canada if unlicensed

For more information on the ITA, visit [Health Canada](https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/guidance-documents/investigational-testing-authorizations-guidance/guidance-document.html) | **2) Medical devices used in research studies will not be assessed:** * For Health Canada license and Investigational testing authorization (ITA) by Biomedical Engineering.

Health Canada licenses and Investigational testing authorization (ITA) might still be required. Contact VCHRI’s Research Quality Assurance Specialist if there are any questions. |
| **3) All electrical-powered devices must have:*** Technical Safety BC approved certification labels on all electrical components (e.g. AC to DC power supply)
* For a list of current Technical Safety BC approved certification labels, visit [technicalsafetybc.ca](https://www.technicalsafetybc.ca/alerts/approved-certification-marks-electrical-products). Any label on the list is satisfactory.
* Enclosed wires with intact insulation
* A hospital-grade power cord, which is indicated by a green dot on the terminus of the plug
* Leakage currents (current escaping its intended path – occurs in all electrical devices to varying degree – important consideration for medical devices) below CSA defined thresholds
* Devices that draw high currents tend to have higher leakage currents (e.g. motors, amplifiers).
* To minimize leakage currents, consider using a Technical Safety BC approved isolation transformer or double-insulated device.

All **wireless-capable devices** must have broadcast powers lower than 100 mW. Powers greater than 100 mW will be assessed on an individual basis and may be denied.  | **3) Requirements for electrical-powered devices used in a non-clinical environment:*** The equipment should be in generally good physical condition:
* Clean
* Undamaged (e.g. case intact without unguarded openings, no missing parts)
* Readable labels
* Intact controls
* The equipment should not have apparent hazards:
* No obvious physical hazards (e.g. sharp edges, unguarded moving parts, instability)
* No obvious energy hazards (e.g. noise, heat, bright light, radiation)
* Cables should be intact:
* Communication cables should be undamaged, with no exposed conductors
* Power cables and power strip should be undamaged, with intact plugs (no adapters), intact receptacles, undamaged strain
 |
| **4) To expedite the approval process:*** Always try to have CSA approved components
* Provide any and all device specifications
* Label components of device indicating their function (e.g. switches, circuit boards)
 |  |
| **5) Questions you will be asked:*** Please provide:
* Study protocol
* Research ethics board application
* Documentation available for device:
	+ Manufacturer, model and serial number of device
	+ Device labelling and Instructions for Use
	+ Operators manual
	+ Service manual
* Photos of any labelling/markings on device and power supply
* Is the device in question considered a medical device (does the device provide therapy, diagnosis or monitoring)? (Y/N)
* If this is a medical device, please identify whether it is:
* Licensed by Health Canada
* Unlicensed and has a Health Canada Investigational Testing Authorization (ITA)
* Unlicensed and does not have a Health Canada Investigational Testing Authorization (ITA)
* How many devices will be used in the study?
* Where will the device be used? Are you aware of any other medical equipment operating within the vicinity of the device?
* Hospital (describe where within hospital)
* Research pavilion
* Private clinic
* Participant home (circle highlight all that apply)
* Other (please describe)
* Will the device connect to the Health Authority network? (Y/N)
* Will the device store patient information? (Y/N)
* If yes, please provide information on what patient information will be stored on the device.
* Is there any real-time wireless transmission during the research activity? (Y/N)
* What frequency (range) is used to transmit data?
* What is the output power for wireless transmission?
* Will there be any modifications made to the device during the course of the study? (Y/N)
* If yes, please provide more details
* Any other important device information
 | **5) Questions you will be asked:*** Please provide:
* Study protocol
* Research ethics board application
* Device type (e.g. vital signs monitor)
* Manufacturer, model and serial number of device
* Where will the device be used?
* Hospital (describe where within hospital)
* Research pavilion
* Private clinic
* Participant home (circle highlight all that apply)
* Other (please describe)
* Will the device connect to the Health Authority network? (Y/N)
* Will the device store patient information? (Y/N)
	+ If yes, please provide information on what patient information will be stored on the device.
* Any other important device information
 |
| **6) Researcher responsibilities:*** Assess the risks associated with the use of the device(s)
* Obtain informed consent from study participants
* Ensure that the device(s) used in the study are maintained appropriately
 | **6) Researcher responsibilities:*** Assess the risks associated with the use of the device(s)
* Obtain informed consent from study participants
* Ensure that the device(s) used in the study are maintained appropriately
 |
| **7) Important notes:*** A hands-on inspection will likely be required for device approval.
* International certifications are not recognized in Canada (European certification (CE), FDA certification, etc).
* Investigational devices used in clinical trials whose results are intended to be submitted to Health Canada require Health Canada authorization for use in the Health Authority.
 | **7) Important notes:*** A visual inspection will likely be required for device approval.
* Researchers do not need to seek biomedical engineering approval for devices inspected within the previous year. If the device has been inspected within the previous year, the date on the biomedical engineering inspection label will reflect this.
 |

**Table [2]** Device Exclusions List
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.

|  |  |  |
| --- | --- | --- |
| **Device** | **Conditions** | **Example** |
| Previously inspected devices used in non-clinical areas | Researchers do not need to seek Biomedical Engineering approval for devices used in non-clinical areas that have a LMBME research device inspection label with an inspection date within the last year. | ECG machine with a LMBME research device label used in non-clinical area in ICORD that has an inspection date within the last year. |
| Devices used in private clinic | Researchers do not need to seek Biomedical Engineering approval for devices used in private clinics on VCH property | Vital signs monitor used in physician’s private clinic in Diamond Healthcare Centre. |
| Devices used in homecare environment | Researchers do not need to seek Biomedical Engineering approval for devices used in homecare environment | Holter monitor used in homecare environment |
| VCH Owned Assets | Exempt if the intended use of the device in the study matches the intended use the device was designed for | Health authority owned vital signs monitor |
| Consumer Tablet/Smartphone | Exempt if the device is unmodified and has no patient applied parts | iPad |
| Activity monitors | Exempt unless used in a critical care or operating room environment | Fitbit |

## GUIDANCE NOTE #21: EXTERNAL RESOURCES

Include information about external resources utilized in the research study (i.e. x-rays, CT scans).

## GUIDANCE NOTE #22: ADVERTISEMENTS

Information about research studies may be communicated via the following methods:

1. Posting a notice in a hospital ward/clinic/department/community site;
2. Posting a notice in any public/common areas of VCH (e.g. elevators, cafeteria, doors, bulletin boards);
3. Promoting the study in the Research Insider newsletter; or
4. Posting on the VCHRI website under the “Active Research Studies” section.

VCHRI Website: If you are planning to use the VCHRI Website as a method for recruitment, please complete the **Attachment A *Recruitment Support Form,*** and email it to: Phoebe Luyun at phoebe.luyun@vch.ca.

If the research study is industry sponsored, the **Attachment A *Recruitment Support Form*** must also be completed.

**NOTE:** Details of all methods of recruitment must be included in your ethics application. If you will be recruiting subjects via the methods listed above in (c) or (d), the completed VCHRI forms must be submitted to the UBC REB for review and approval together with your ethics application before the information is posted by VCHRI.

### 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 send the form with a copy of the current UBC ethics certificate of renewal to VCHRI. Once VCHRI receives this information, VCHRI will prepare a VCH Certificate of Renewal.

### 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 **VCH Application for Operational Approval*.***

The new department/clinic/ward or community site being impacted may sign the original **VCH Application for Operational Approval**– 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 or a Letter of Acknowledgement.

### SUBMISSION TO VCHRI FOR REVIEW

Once the Investigator has completed the “***VCH Application for Operational Approval to Conduct a Research Study”***, please submit this form along with the following documentation to VCHRI for review:

* One copy of the ethics board application if the board of review is **not** UBC

**If applicable, please also submit the following documentation:**

* Informed consent form(s)/letter of initial contact
* Completed ***“OR Research Form”***
* Signed ***“Anatomical Pathology Laboratory Utilization Form”***
* Signed ***“Specimen Collection for Research – Special Handling Instructions Form”***
* “***Certificate of Ethical Approval***”.

If ethical approval has not been granted, please submit a copy of the Certificate of Ethical Approval once it is issued by the research ethics board. Ethical approval is required prior to release of the VCHRI Research Study approval.