

GUIDELINE FOR OBTAINING OPERATIONAL APPROVAL OF RESEARCH AT VANCOUVER COASTAL HEALTH

These notes are offered as guidances 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

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://vchri.ca/forms>

DEFINITIONS

LGH – Lions Gate Hospital
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://vchri.ca/forms>. 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.

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://vchri.ca/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 2.1** below for additional information on this appointment).

2.1 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.

To obtain a VCHRI Affiliated Investigator appointment, the following documentation should be submitted to Dr. W. Robert McMaster, Executive Director, VCHRI, for review:

- (a) A letter describing the Investigator’s research program and requesting this appointment;
- (b) A letter of support from the Investigator’s Head of School;
- (c) The “Application for an Affiliated Investigator Appointment at Vancouver Coastal Health Authority”; and
- (d) A copy of the Investigator’s academic CV.

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 Wylo Kayle at wylo.kayle@vch.ca or (604) 875-5125 for further information.

GUIDANCE NOTE #3: INVESTIGATOR’S DEPARTMENT AND DIVISION

Include the Investigator’s department.

Include the Investigator’s division (as applicable).

GUIDANCE NOTE #4: VCH COLLABORATOR

If the Investigator is a VCHRI Affiliated Investigator, the name of the VCH Collaborator must be included in this section (See Section 2.1 above for additional information on VCH Collaborators).

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.

GUIDANCE NOTE #8: NAME OF FUNDING SOURCE

Include the name of the funding source(s).

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.

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 of the *“VCH Application for Operational Approval to Conduct a Research Study”* 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. For questions related to operational signature requirements, please contact the appropriate VCHRI HSDA contact (refer to Appendix A for VCHRI HSDA contact information).

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 where the research study will be conducted (all VCH sites), 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, 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.

RADIOLOGY

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.

VGH: The above documentation should be sent to the attention of the Radiology Department Research Coordinator at G940 Ground Floor, 899 West 12th Avenue. Please note that the Radiology Department at VGH charges a \$100 fee 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. John Mayo) must sign the “***VCH Application for Operational Approval to Conduct a Research Study***” If the Investigator already has access to PACS for clinical purposes, a signature of approval from the Radiology Department must still be obtained.

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 the attention of Romy Chan, Technical Support Coordinator, Laboratory Administration, Room 1354, 910 West 10th Ave, Vancouver BC V5Z 4E3

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 submitted to the Manager, Equipment and Supplies, OR, at the Operating Room Administration Office, JPP North, Room 2304–2, Vancouver, BC V5Z 1M9.

UBCH: The above documentation should be submitted to the Patient Service Manager Surgical Suites & Surgical Clinic, 2211 Wesbrook Mall, Vancouver BC V6T 2B5.

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 to Conduct a Research Study***” 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 to Conduct a Research Study*” along with a cover sheet outlining the requirements of the Anesthesiologist and submit this documentation to 2449 JPP2N, 910 West 10th Ave Vancouver, BC V5Z 1M9, 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;
- 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 to Anatomical Pathology, 855 West 12th Ave, JPP, Vancouver, BC V5Z 1M9, c/o Research Coordinator, 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

- a) Indicate the Investigator’s affiliation with VCH.
- b) If the Investigator is a VCH employee, indicate which professional discipline the Investigator is a member.
- c) 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 Approval to Conduct a Research Study*”, 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 – DECISION SUPPORT AND HEALTH RECORDS

DECISION SUPPORT:

Decision Support 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 Decision Support for the Research Study, Decision Support must sign the “*VCH Application for Operational Approval to Conduct a Research Study*”.

Please send all Decision Support requests c/o Susan Sirett, Technical Coordinator, Decision Support at 116 HP B2 855 W. 12th Ave, Vancouver BC.

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 to Conduct a Research Study*”. The Investigator must submit the complete “*VCH Application for Operational Approval to Conduct a Research Study*” to the department for review. Please note that VGH, UBCH, GF Strong, Mary Pack Arthritis Centre, LGH and Richmond Hospital each have their own Health Records Departments and signatories.

*Effective September 1, 2005, for all industry sponsored studies, Health Records charges a \$5 per patient chart retrieval fee.

Approval is for access to the patient chart. Photocopying is not permitted.

In order 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. John Mayo
- **For access to PCIS (new research team members),** please complete the *PCIS Training Registration Form for Research Personnel* and fax it to 604-875-4064. 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*.

If a researcher requires access to/data from a VCH Clinical System, a *VCH Data Application* must be completed and submitted together with the “*VCH Application for Operational Approval to Conduct a Research Study*” to VCHRI.

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/ASSESSMENTS

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 – MEDICAL DEVICE REPROCESSING

This section is only applicable if the research study involves a medical device

GUIDANCE NOTE #20: EXTERNAL RESOURCES

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

GUIDANCE NOTE #21: ADVERTISEMENTS

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

- a) Posting a notice in a hospital ward/clinic/department/community site;
- b) Posting a notice in any public/common areas of VCH (e.g. elevators, cafeteria, doors, bulletin boards);
- c) VCH E-Broadcasts (information sent via email); or
- d) Posting on the VCHRI website under the “Active Research Studies” section.

VCH E-Broadcasts: If you are planning to use the VCH E-Broadcast method for recruitment, please complete the *Recruitment Support Form/VCHRI Website / VCH Email Distribution form(attachment a)of the “VCH Application for Operational Approval to Conduct a Research Study”* and submit it to Wylo Kayle at wylo.kayle@vch.ca

VCHRI Website: If you are planning to use the VCHRI Website as a method for recruitment, please complete the *Recruitment Support Form/VCHRI Website / VCH Email Distribution form(attachment a)of the “VCH Application for Operational Approval to Conduct a Research Study”* and email it to: Wylo Kayle at wylo.kayle@vch.ca If the research study is industry initiated, the *Recruitment Support Form/VCHRI Website / VCH Email Distribution form(attachment a)of the “VCH Application for Operational Approval to Conduct a Research Study”* 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 circulated by VCHRI via e-broadcast or posted on the VCHRI website.

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 for **one year, or the expiry date of the UBC ethics application (whichever date is sooner)**. If the research study remains active after one year, 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 to Conduct a Research Study”*. The new department/clinic/ward or community site being impacted may sign the original *“VCH Application for Operational Approval to Conduct a Research Study”*– 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:

- One copy of the informed consent form(s)/letter of initial contact
- One copy of the “*Confidentiality Undertaking for Research Projects*” for all research team members if one hasn’t been submitted since March 2016
- One copy of the “*VCH DataApplication*”
- One copy of the “*OR Research Form*”
- One copy of the “*Anatomical Pathology Laboratory Utilization Form*”
- One copy of the “*Specimen Collection for Research – Special Handling Instructions Form*”
- One copy of the “*Certificate of Ethical Approval*”. *If at the time the VCHRI application is submitted, 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.*

Appendix 1

HSDA and	Address:	For Information or Assistance:	Contact Information:
<p>Vancouver Acute, Multi-Site (HSDA) and Corporate Research Projects</p> <p>(Vancouver Acute encompasses the following sites: Vancouver General Hospital, Mary Pack Arthritis Centre, G.F. Strong Rehabilitation Centre, UBC Hospital, Diamond Health Care Centre, VGH Research Pavilion, Blusson Spinal Cord Centre (ICORD), and the Burnaby Centre for Mental Health and Addiction)</p>	<p>Vancouver Coastal Health Research Institute Room 3665 – 910 West 10th Avenue Vancouver, BC V5Z 1M9</p>	<p>Ms. Wylo Kayle Coordinator, Research Approvals, Clinical Trials Administration</p>	<p>Tel: (604) 675-2565 Email: wylo.kayle@vch.ca</p>
		<p>Ms. Stephania Manusha Director, Clinical Trials Administration</p>	<p>Tel: (604) 675-2567 Email: stephania.manusha@vch.ca</p>
<p>Coastal (Coastal encompasses hospitals, community health centres and residential care facilities in the following sites: North Vancouver, West Vancouver, Garibaldi, Sunshine Coast, Bella Bella, and Bella Coola)</p>	<p>Lions Gate Hospital c/o Medical Administration 231 East 15th Street North Vancouver, BC V7L 2L7</p>	<p>Ms. Wylo Kayle Coordinator, Research Approvals, Clinical Trials Administration</p>	<p>Tel: (604) 675-2565 Email: wylo.kayle@vch.ca</p>
<p>Richmond Health Services (Richmond Health Services encompasses the following networks: Richmond acute care, community care, primary health care, mental health and addiction sites)</p>	<p>Quality Initiatives Room 3004 7000 Westminster Highway Richmond, BC V6X 1A2</p>	<p>Ms. Marion Wardley Administrative Assistant Quality Initiatives</p>	<p>Tel: (604) 244-5209 Email: marion.wardley@vch.ca</p>
		<p>Ms. Wylo Kayle Coordinator, Research Approvals, Clinical Trials Administration</p>	<p>Tel: (604) 675-2565 Email: wylo.kayle@vch.ca</p>
<p>Vancouver Community (Vancouver Community encompasses community health centres, mental health centres, additional sites and residential care facilities in Vancouver)</p>	<p>#200-520 West 6th Avenue Vancouver, BC V5Z 4H5</p>	<p>Assistant, Medical Affairs Vancouver Community</p>	<p>Tel: (604) 708-5253 Email:</p>
		<p>Ms. Wylo Kayle Coordinator, Research Approvals, Clinical Trials Administration</p>	<p>Tel: (604) 675-2565 Email: wylo.kayle@vch.ca</p>

Appendix 2

GUIDELINE FOR THE REVIEW AND APPROVAL OF A RESEARCH STUDY IMPACTING VCH OPERATING ROOMS

1. INTRODUCTION

The purpose of this guideline is to describe the process for review and approval of a research study (including tissue banking) that impacts the VCH Operating Room (OR) and that may involve the collection of tissue specimens for research purposes from the OR.

2. REQUIRED DOCUMENTS

- Request for Approval to Conduct Research Form
- Study protocol
- OR Research Form
- Specimen Collection for Research – Special Handling Instructions Form
- Anatomic Pathology Laboratory Resource Utilization Form

All research forms are located on the VCHRI website:

<http://www.vchri.ca/forms>

3. TERMS

OCTA -- Office of Clinical Trials Administration

OR PSM -- Operating Room Patient Service Manager or Manager, Equipment and Supplies

PI-- Principal Investigator

PSM -- Patient Service Manager

VCH -- Vancouver Coastal Health Authority

VCHRI -- Vancouver Coastal Health Research Institute

4. PROCEDURES

Research Studies Impacting the OR

- 4.1. All research studies that impact the OR must be reviewed and approved by the OR prior to the start of the research study.
- 4.2. The PI must submit a copy of the following documents to the OR PSM for review:
 - 4.2.1. Study protocol;
 - 4.2.2. “VCH Application for Operational Approval to Conduct a Research Study”, and
 - 4.2.3. “OR Research Form”.
- 4.3. The OR PSM will review the documentation listed in Section 4.2 for all research studies, regardless if the procedure is considered standard of care or research.
 - 4.3.1. If the OR will be impacted by the research study, the OR PSM will sign the VCH Operational Research Review Application once all OR requirements have been met. The OR PSM signature confirms that the OR has been made aware of the research study and that the OR will provide the necessary resources for the research study.
 - 4.3.2. If the OR will not be impacted by the research study, the OR PSM will state on the form that there is “no involvement of the OR”.

- 4.3.3. A copy of the signed “VCH Application for Operational Approval to Conduct a Research Study” and the “OR Research Form”, together with all other applicable VCHRI documents must then be submitted to VCHRI for final review.

ALL TISSUE SPECIMENS COLLECTED IN THE OR FOR RESEARCH PURPOSES MUST BE SENT TO VCH PATHOLOGY. RESEARCH ASSISTANTS AND SURGEONS MAY NOT RETRIEVE TISSUE SPECIMENS FROM THE OPERATING ROOM

If tissue specimens are collected in the OR for research purposes, the following must occur:

- 4.4. VCH Pathology must review and approve the research study PRIOR to the OR.
- 4.5. VCH Pathology must receive the following documentation for review:
 - 4.5.1. The “VCH Application for Operational Approval to Conduct a Research Study”;
 - 4.5.2. A copy of the study protocol;
 - 4.5.3. A copy of the “Anatomic Pathology Laboratory Resource Utilization form”;
 - 4.5.4. If tissue specimens collected in the OR for research purposes require special handling, the PI will also be required to submit the “Specimen Collection for Research – Special Handling Instructions Form” to VCH Pathology for review and approval.
 - 4.5.4.1. If VCH Pathology agrees that the standard route for sending tissue specimens to VCH Pathology is not appropriate, VCH Pathology will sign the “Specimen Collection for Research – Special Handling Instructions Form”.
 - 4.5.4.2. By signing the “Specimen Collection for Research – Special Handling Instructions Form”, VCH Pathology agrees that special handling or a “RUSH” procedure is necessary, VCH Pathology is aware of the urgent need to process the sample and/or VCH Pathology is aware of the special handling instructions.
- 4.6. Once the “VCH Operational Research Review Application”, the “Anatomic Pathology Laboratory Resource Utilization Form”, and the “Specimen Collection for Research – Special Handling Instructions Form” (if applicable), have been completed and signed by VCH Pathology, then the OR must receive the appropriate documentation for review (refer to Sections 4.2).
- 4.7. In addition to the documentation listed above in 4.2, if VCH Pathology has signed a “Specimen Collection for Research – Special Handling Instructions Form”, this form must also be provided to the OR for signature.

VCHRI Approval

- 4.8. Once all required documentation for the research study has been received and reviewed by VCHRI, final approval to conduct the research study at VCH will be granted.
 - 4.8.1. If a “Specimen Collection for Research – Special Handling Instructions” Form has been signed by VCH Pathology and the OR, this form must also be submitted to VCHRI with the other applicable paperwork. VCHRI must sign and date the “Specimen Collection for Research – Special Handling Instructions Form”. VCHRI will photocopy the signed “Specimen Collection for Research – Special Handling Instructions” Form onto brilliant **Green** paper for the PI.
- 4.9. Upon approval of the research project by VCHRI, VCHRI will provide the PI with:
 - 4.9.1. the letter of final approval to conduct the research study at VCH;
 - 4.9.2. a sheet of **Fluorescent Pink** labels. The fluorescent pink labels will include the study specific VCHRI number (e.g. V06-0000), the name of the service (e.g. ENT)

- and a short name for the research study. These labels must be attached to the research informed consent form. See section 4.10 for further details; and
- 4.9.3. as many **Green** “Specimen Collection for Research – Special Handling Instructions Forms”, as requested by the PI or the PI’s designate (if applicable). This form must be attached to the patient chart. See Sections 4.10 to 4.12 for further details.

Collecting Tissue Specimens

Prior to surgery:

- 4.10. Requirement of Informed Consent:
- 4.10.1. If a patient is undergoing surgery in a VCH operating room, and tissue will be collected during surgery for research purposes, research consent must be obtained from the patient prior to his/her surgery.
- 4.10.2. Research subjects must have adequate time between initial contact to the actual consent phase, to consider whether or not they wish to participate.
- 4.11. The PI or his/her designate is responsible for placing two copies of the signed research informed consent form on the patient chart; one copy is to be kept with the patient chart, the other copy will be sent with the tissue specimen to VCH Pathology. A white VCH patient label must be attached to each copy of the signed research informed consent form (on the first page, top right hand corner) and the **Green** “Specimen Collection for Research – Special Handling Instructions Form” (if applicable) by a VCH health care professional only. In addition, the PI or his/her designate must place a **Fluorescent Pink** VCHRI label on each copy of the research informed consent form (bottom, right hand corner of the first page). The label must be visible to the surgeon and the surgeon’s designate (OR nurse), as the surgeon or the surgeon’s designate will be required to write the VCHRI # on the standard pathology requisition titled “M140 Surgical Pathology Consultation Requisition”.
- 4.12. If applicable, the **Green** “Specimen Collection for Research – Special Handling Instructions Form” must be attached to the front of each patient’s chart. The PI or PI designate must remember to complete the question relating to informed consent on the **Green** “Specimen Collection for Research – Special Handling Instructions Form” (question in the shaded box) before the **Green** “Specimen Collection for Research – Special Handling Instructions Form” is placed on the chart.
- 4.13. If the patient is seen in the preadmission clinic – the forms are placed on the patient chart in the pre-admission clinic. If the patient is not seen in the preadmission clinic, then the forms are placed on the chart in the appropriate area: (1) Pre-op at UBC Hospital; or (2) Peri-op in JPOR.

IF TWO COPIES OF THE SIGNED RESEARCH CONSENT ARE NOT PLACED ON THE PATIENT’S CHART PRIOR TO SURGERY, THE TISSUE WILL BE SENT TO PATHOLOGY ACCORDING TO STANDARD PROTOCOL. IT BECOMES THE RESPONSIBILITY OF THE RESEARCHER TO FOLLOW UP WITH VCH PATHOLOGY REGARDING CORRECT HANDLING OF THE TISSUE SPECIMEN.

In the OR:

- 4.14. Once the tissue sample is collected, the OR nurse will complete the “M140 Surgical Pathology Consultation Requisition”. The OR nurse will confirm with the surgeon that the tissue specimen is required for research purposes. If additional tissue has been collected for research purposes, the surgeon will advise which tissue specimen is for

research purposes, and which specimen is for clinical purposes. If there is any uncertainty about which specimen has been collected for research purposes, VCH Pathology will contact the surgeon directly to clarify.

- 4.14.1. If the surgeon confirms that the tissue specimen is for research purposes, the OR nurse will tick the “Research/Tissue Harvesting” box and will write the VCHRI# on the “M140 Surgical Pathology Consultation Requisition.” OR staff **DO NOT** need to indicate on the “M140 Surgical Pathology Consultation Requisition” or on the label, which specimen is for research. The tissue specimen will be sent to VCH Pathology, along with a copy of the informed consent form. The tissue specimen will be sent according to routine protocol (distribution or tube) or as indicated on the **Green** “Specimen Collection for Research – Special Handling Instructions Form”. The **Green** “Specimen Collection for Research – Special Handling Instructions Form” is sent to VCH Pathology together with the tissue specimen.
- 4.14.2. If the surgeon advises that the tissue specimen is not related to research, the “Research/Tissue Harvesting” box will NOT be selected on the “M140 Surgical Pathology Consultation Requisition.” The tissue specimen will be sent to VCH Pathology according to routine protocol (distribution or tube) with the “M140 Surgical Pathology Consultation Requisition” and will be processed for diagnostic purposes only.
- 4.14.3. If there is more than one research specimen collected in a case (i.e. during one surgical episode), it will not be necessary to attach a copy of the research informed consent form to each “M140 Surgical Pathology Consultation Requisition”. A copy of the informed consent form will only be required for the first tissue specimen collected during the surgical episode.

In VCH Pathology:

- 4.15. When the tissue specimen is received by accessioning staff, the “M140 Surgical Pathology Consultation Requisition” will be reviewed to confirm that the tissue specimen was collected for research purposes.
- 4.16. The tissue specimen will then be directed to the VCH Pathologist for processing. (The VCH Pathologist is listed as a co-investigator on the UBC Ethics Certificate of Approval.)
- 4.17. If the PI has indicated on the “Anatomic Pathology Laboratory Resource Utilization Form” that the tissue specimen will be picked up from VCH Pathology by a research assistant/study coordinator, upon receipt of the tissue specimen by VCH Pathology, the contact person listed on the “Anatomic Pathology Laboratory Resource Utilization Form” will be contacted and notified that the tissue specimen is ready for pick-up.
- 4.18. If it is necessary for non-VCH research personnel to have access to VCH Anatomic Pathology facilities and resources for a specific research project, VCH researchers must follow the procedures outlined in the VCH Anatomic Pathology Research Brochure for obtaining such access.