

1. Research Study Title (and Protocol Number, if applicable):		
2. PI (VCH or VCHRI affiliated): Name: Tel: Fax: Email:	3. Department: Division:	4. Coastal Site Sponsor/Supervisor:
5. Contact Person: Name: Tel: Fax: E-mail:	6. Internal Mailing Instructions / Address:	
7. Type of Funding Source: <input type="checkbox"/> Industry <input type="checkbox"/> Grant <input type="checkbox"/> Grant-in-Aid <input type="checkbox"/> Unfunded <input type="checkbox"/> Other		
8. Name of Funding Source(s):		
9. Type of Study: <input type="checkbox"/> Drug/Natural Health Product Study <input type="checkbox"/> Medical Device Study <input type="checkbox"/> Chart Review <input type="checkbox"/> Other: <i>If a drug/natural health product will be administered to human subjects, obtain a signature of approval on this form from the Pharmacy Department.</i>		
10. P.I.'s Department Head if different from Department Head who approved the UBC ethics application: _____ (print name) (signature) (date)	NOTES:	
11. P.I.'s Division Head: _____ (print name) (signature) (date)		
12. P.I.'s Supervisor/Manager: (See Guidance Notes – Applicable to VCH employees only.) _____ (print name) (signature) (date)		
13. Principal Investigator: _____ (print name) (signature) (date)		

14. Coastal HSDA department approvals.			B. Approval signatures required.		C. Department cost analysis. (please attach)	
Hospital: <input type="checkbox"/> N/A	Yes	No	Hospital Site Manager Name of Signatory	Signature	Yes	No
Pharmacy	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Radiology (MRI, CT, x-ray, ultrasound, etc.)	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Clinical Chemistry	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Microbiology	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Operating Rooms	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Anatomical Pathology	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Hematopathology	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Clinical Unit/Site/Program Area (1):	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Clinical Unit/Site/Program Area (2):	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Clinical Unit/Site/Program Area (3):	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
QUIST	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Health Records (hard copy) / PCIS	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
VCH database: (e.g. PACS, ORMIS)	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Other database:	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Other Resources: (Specify)	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>

15. Name of Coastal Community Site or Program Area <input type="checkbox"/> N/A	Name and Signature of Coastal Site/Program Manager.		C. Impact analysis.	
	Name of Signatory	Signature	Yes	No
			<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>

16. STUDY PERSONNEL:

a) The Principal Investigator on this research study (one of the following must apply - select one only):

- Has a medical appointment at VCH
- Is an employee of VCH (e.g., nurse, respiratory therapist, manager)
- Has a VCHRI Affiliated Investigator Appointment
- Is in the process of applying for a VCH Affiliated Investigator Appointment

***If the Principal Investigator has a VCHRI Affiliated Investigator Appointment, he/she must have a VCH co-investigator named on the research study (on this form and the UBC REB ethics certificate).

***If the Principal Investigator does not fall under one of the above categories, please contact Stephania Manusha at (604) 875-5649 or stephania.manusha@vch.ca

<input type="checkbox"/> Audiology	<input type="checkbox"/> Occupational Therapy	<input type="checkbox"/> Speech Language Pathology	<input type="checkbox"/> N/A
<input type="checkbox"/> Clinical Nutrition	<input type="checkbox"/> Pharmacy	<input type="checkbox"/> Spiritual Care	
<input type="checkbox"/> Dentistry	<input type="checkbox"/> Physiotherapy	<input type="checkbox"/> Other:	
<input type="checkbox"/> Diagnostic Imaging	<input type="checkbox"/> Psychology		
<input type="checkbox"/> Laboratory	<input type="checkbox"/> Recreation Therapy		
<input type="checkbox"/> Music Therapy	<input type="checkbox"/> Respiratory Therapy		
<input type="checkbox"/> Nursing	<input type="checkbox"/> Social Work		<input type="checkbox"/> Yes <input type="checkbox"/> No

(ii) Is their position at VCH at a Manager/Director level? Yes No

b) Will research personnel **not employed by /affiliated with** VCH (e.g. volunteer research assistants, research personnel affiliated with external institutions) participate in the conduct of this study? If YES, please describe Yes No

17. PERSONAL HEALTH INFORMATION:

a) Will you access identifiable personal information of VCH patients/clients/residents/staff in this research study (e.g., medical records are reviewed and the patient's name is known)? Yes No

If YES, complete the Confidentiality Undertaking for Research Projects form (this form may be downloaded from the VCHRI website).

18. DECISION SUPPORT, HEALTH RECORDS AND VCH DATABASES:

a) Will this research study involve the services of DECISION SUPPORT? (If YES, please complete and attach a **Data Access for Research Project Application Form** and obtain a signature of approval from DECISION REPORT on this form.) Yes No

b) Will you require access to patient medical records located in a Coastal HSDA Hospital Health Records Department? (If YES, obtain a signature of approval from the appropriate Health Records Department on this form.) Yes No

c) Will you review patient medical records located in a clinician's office, hospital clinic/ward or hospital department located in a Coastal HSDA Site? If YES, advise where the patient records are located: Yes No

<p>d) Will you require access to a <u>VCH database</u> (e.g. PACS, ORMIS etc.)?</p> <p>If YES, list the database(s) you will require access to: If YES, obtain a signature of approval to use the database for research purposes from the appropriate VCH department.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>e) Will you require access to any <u>internal department/program databases</u> (e.g. orthopedic-trauma database)?</p> <p>If YES, which internal database(s)? If YES, do you have approval to retrieve data from the database(s)? (If NOT, obtain a signature of approval from the department/person in charge of the database on this form.)</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No

<p>19. STUDY PROCEDURES/ASSESSMENTS: For research studies that do not involve the participation of human research subjects, this section is not applicable.</p>	<input type="checkbox"/> SECTION 20 Not Applicable
<p>a) Will research subject recruitment occur on a hospital ward/clinic? (If YES, a signature of approval from the patient service manager of <u>each</u> hospital ward/clinic must be obtained.)</p> <p>If YES, list the hospital ward(s)/clinics where research subjects will be recruited from:</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>b) <u>Where</u> will patient informed consent be obtained? (NOTE: If informed consent will be obtained on a hospital ward or clinic, a signature of approval from the applicable patient service manager/clinic manager must be obtained.)</p>	
<p>c) Will any research study visits/assessments/ take place on a hospital ward or in a clinic? (If YES, A signature of approval from the patient service manager/clinic manager of <u>each</u> hospital ward or clinic impacted must be obtained.)</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>d) If a questionnaire will be administered, where will this occur?</p>	<input type="checkbox"/> N/A
<p>e) If a focus group will be held or interview conducted, where will this occur?</p>	<input type="checkbox"/> N/A
<p>f) Will research subjects undergo any surgical procedures in the <u>OPERATING ROOM</u>?</p> <p>If YES, a signature of approval from the manager of the Operating Room must be obtained on this form.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>g) Will tissue specimens be collected from subjects in the <u>OPERATING ROOM</u>?</p> <p>If YES, both the Operating Room and Anatomical Pathology must review the study. STEP 1: Anatomical Pathology must review the research study protocol, the “Anatomical Pathology Laboratory Utilization Form”, The “Specimen for Research Collection – Special Handling Instructions” form and sign the “Request for Approval to Conduct Research at Coastal HSDA” form. STEP 2: Once Anatomical Pathology has signed off, the OR must receive and review all documentation outlined above in 20f as well as the “Specimen for Research Collection – Special Handling Instructions” form with Anatomical Pathology’s signature of approval.</p> <p><i>REMINDER: Tissue specimens collected in the Operating Room may <u>NOT</u> be picked up from the Operating Room – all tissue specimens must be sent to VCH Pathology. For further information, please see the guidelines posted on the VCHRI website titled “The Review and Approval of a Research Study Impacting VCH Operating Rooms”.</i></p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>h) Will <u>VCH ANATOMICAL PATHOLOGY</u> process tissue specimens collected in the Operating Room or tissue specimens collected in a VCH ward or clinic?</p> <p>If YES, the procedures in 20g (STEP 1 and STEP 2) above must be followed. In addition, the VCH Pathologist involved must be listed as a co-investigator on the research study (on this form and on the UBC ethics certificate).</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

<p>i) Does this study involve the utilization of VCH ANATOMICAL PATHOLOGY diagnostic material (e.g. microscopic slides, tissue blocks or tissue specimens?)</p> <p>If YES, Anatomical Pathology must review the research study protocol, the “Anatomical Pathology Laboratory Utilization Form”, and sign the “Request for Approval to Conduct Research at Coastal HSDA” form.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
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<p>20. EXTERNAL RESOURCES:</p> <p>a) If VCH will not be performing part of the study (i.e. lab-work, x-rays, CT scans), please advise which procedures will be performed externally and advise who will be performing the procedure and/or analysis:</p>	<input type="checkbox"/> N/A
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<p>21. ADVERTISEMENTS:</p> <p>a) Will any advertisements for recruitment be posted in a Coastal HSDA hospital ward or clinic? (If YES, a signature of approval from the applicable patient service manager/clinic manager of the hospital ward/clinic must be obtained.)</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>b) Will any advertisements for recruitment be posted in any general areas of a Coastal HSDA hospital (e.g. elevators)?</p> <p>If YES, once the recruitment advertisement has been approved by the REB, please forward an electronic copy of the recruitment advertisement to Lisa Carver (lisa.carver@vch.ca).</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No

Please submit the following documentation to VCHRI for review:

- “Request for Approval to Conduct Research at Coastal HSDA” form with signatures of approval
- One copy of the ethics board application (if other than UBC)**

If applicable, please also submit the following documentation:

- One copy of the informed consent form(s)/letter of initial contact (if other than UBC)**
- One copy of the Health Canada Notice of Compliance or Medical Device License
- One copy for each study team member who will have access to personal data of the “Confidentiality Undertaking for Research Projects form”
- One copy of the “VCHRI Medical Device Form” (required for studies involving an experimental medical device)
- One copy of the “OR Research Form” (required for all studies involving surgical procedures)
- One copy of the “Anatomical Pathology Laboratory Utilization Form” (required for studies involving the services of Anatomical Pathology)
- One copy of the “Specimen Collection for Research – Special Handling Instructions” form (required for studies involving the collection of tissue in the operating room)
- One copy of the “Radiology Department Resource Utilization Form” (with cost analysis attached).
- One copy of the Study Protocol - Flowchart of Activities (for industry/grant funded studies, where such a flow chart exists).

The VCHRI research submission should be sent to the following address:

Attention: Dr. Cynthia Hamilton
 Lions Gate Hospital
 c/o Medical Administration
 231 East 15th Street
 North Vancouver, BC
V7L 2L7

If you have any questions, please contact Dr. Cynthia Hamilton at 604-988-3131 local 4374 or cynthia.hamilton@vch.ca