Procedures for Conducting Research in VCH Anatomic Pathology Laboratories

The following is a set of procedures for researchers who wish to conduct research involving anatomic pathology ("AP") procedures at VCH AP Laboratories. Research, in this context, means using specimens for: 1) clinical trials, which entail the investigation of the effects of a drug, medical treatment or device on a group of human subjects; 2) research studies, which entail the intent of publishing the findings/results of the research, where publication, in this context, means discussing the results outside of the area in which the data were gathered; and 3) tissue banking activities, which entail the collection of tissue for future use and/or experimentation.

1. Ensure Proper Status to Perform Research

1.1. Research Request from Within VCH

All research carried out at any VCH facility or by any individual employed by or associated with VCH is deemed to be done under the auspices of Vancouver Coastal Health Research Institute (VCHRI).

1.2. Research Request from Outside VCH

Researchers from outside the VCH region who wish to conduct research as a Principal Investigator must first acquire Vancouver Coastal Health Research Institute ("VCHRI) Affiliated Investigator" status through VCHRI prior to undertaking research within VCH.

2. Apply for Ethics Approval

Unless exempted below, approval by a UBC Research Ethics Board ("REB") or equivalent* is necessary whenever a research project carried out at a VCH facility is instigated involving human subjects. Researchers are required to submit an application to the Clinical Research Ethics Board ("CREB") for research involving clinical intervention, such as testing of drugs, medical devices, and other therapeutic initiatives, obtaining any human tissues for study, as well as the analysis of clinical data obtained form medical records or studies of a clinical nature involving linkage of data from existing databases.

To obtain CREB approval, the complete ethics application, which includes the *research protocol, all attachments, consent forms, questionnaires, brochures, etc*. must be submitted to the CREB. CREB guidelines and forms are found at http://www.ors.ubc.ca/ethics/clinical/c-forms.htm. A Certificate of Approval will be issued upon approval being granted.

The CREB meets every 2 weeks; however, depending on the nature of the research, the review process could be longer or shorter than this timeframe. To learn more about the submission criteria that affect ethics approval, refer to "Guidance Notes #2" at http://www.ors.ubc.ca/ethics/forms/GNinitialapp.htm#Guide2.

Exemption
Research using human tissue for internal quality improvement‡ is exempt from this process of obtaining ethics approval; *however, the researcher is nonetheless required to adhere to the following step of applying for VCH AP Laboratory approval*.

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* REB's equivalent to UBC REB are: St Paul's Hospital REB; and British Columbia Cancer Agency REB.

‡ Internal quality improvement in this context means using specimens provided by patients who are not individually identifiable, and for the purpose of ensuring that an accurate and effective diagnostic service will continue to be provided. This includes using specimens to determine the usefulness and accuracy of new tests in the institution, and as positive control tissue. The use of human tissue for internal quality improvement should not compromise the integrity of patients' samples and prevent them from being used in further diagnostic investigations.

2.1 Requests for Specimens to be used in Research Outside VCH

Researchers requesting specimens to be used for research outside the VCH region must obtain ethics approval from their governing Research Ethics Board. That Research Ethics Board must have standards that meet the June 2003 Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans. (http://www.pre.ethics.gc.ca/english/policystatement/policystatement.cfm) A list of Canadian Research Ethics Boards may be found at http://www.ncehr-cnerh.org/english/home.php.

3. Apply for VCH AP Laboratory Approval

Researchers are required to complete a "Request for Approval to Conduct Research at VCHA" form. This form can be found under the "Vancouver Acute Submission Forms" section at http://www.vchri.ca/s/ClinicalTrials-Forms.asp. The completed form, the Checklist on the reverse of this brochure and AP Laboratory Research Survey must be submitted to the Vancouver Acute AP Laboratory Research Coordinator *along with a copy of the completed ethics application, the detailed protocol for the research and a copy of the informed consent forms to be signed by patients.*

Upon receipt of the submission, the Vancouver Acute AP Laboratory Research Coordinator will determine whether there are sufficient laboratory resources to carry out the research. If laboratory resources are adequate, the Vancouver Acute AP Laboratory will prepare a cost estimate based on the research protocol. Once approval is granted by the Site Medical Director and Operations Manager, after reviewing the research protocol and cost estimate, they will sign off on the "Request for Approval to Conduct Research at Vancouver Acute" form. A copy of this signed form, along with the cost estimate, will be returned to the researcher. No activities that compromise patients' specimen integrity will be permitted. Violations will result in the immediate cancellation of the project.

Please Note: Applications for Ethics and VCH AP Laboratory Approval may be submitted concurrently.

4. Apply for VCHRI Approval

Once the "Request for Approval to Conduct Research at Vancouver Acute" has been signed off by the Site Medical Director and Operations Manager and returned to the researcher, the researcher must submit this signed form, along with a copy of the ethics application submitted to the CREB (or for researchers outside VCH, the respective research ethics board)/Certificate of Approval and a copy of the patient consent form to the Clinical Trials Administration office. Applications will not be approved by VCHRI until the researcher receives the CREB (or for researchers outside VCH, the respective research ethics board) Certificate of Approval and forwards a copy of it to VCHRI. Once the research is approved by VCHRI, a Final Certificate of Approval letter will be sent to the researcher. The review process by VCHRI typically takes 2 to 4 weeks.

5. Submission of Final Certificate of Approval to VCH AP Laboratory

Upon receiving the Final Certificate of Approval from the VCHRI, the researcher must forward this, and the CREB (or for researchers outside VCH, the respective research ethics board) Certificate of Approval to the VCH AP Laboratory Research Coordinator to verify that he/she has approval to commence research. No work may be performed by the VCH AP Laboratory for research purposes before such time.

6. Make Payment to the VCH AP Laboratory

Upon completion of the research, (or quarterly, for studies lasting longer than 3 months) the VCH AP Laboratory will generate an invoice to bill the researcher accordingly for the AP procedures performed in the process of the research. This invoice will be issued through the VCH Finance Department. Payment should also be made to the VCH Finance Department. The VCH AP Laboratory will deny any further research applications until all outstanding bills have been fully paid.

N.B.: This document was prepared in accordance to the policies and guidelines for researchers set by the Vancouver Coastal Health Research Institute (VCHRI), and the UBC Office of Research Services – Ethical Reviews on Human Subjects. The respective websites for VCHRI and UBC Ethics are: http://www.vchri.ca/i/pdf/guidelinesApril2005.pdf and http://www.ors.ubc.ca/ethics/humansub/index.htm

Procedures for Non-VCH Staff Accessing VCH Anatomic Pathology Laboratories

The following is a set of procedures for VCH researchers who wish to recruit assistance for their research from non-VCH staff and obtain access for them to VCH AP Laboratory facilities and resources.

1. Submission of Letter of Request

The researcher must submit a letter to the Site Medical Director and Operations Manager providing details of the non-VCH staff research assistant(s) (hereinafter referred to as "Research Assistant"). This letter should include the *names of the research assistant(s) and supervising researcher, the duration of VCH AP Laboratory access required, the location and term of VCH AP Laboratory space occupancy (if applicable) and the access that they will require, specifically the equipment and supplies that will be used in the process of research, and an estimate of the amount of time and volume that the research assistant(s) will be using the equipment and supplies, respectively*. Please note: 1) the assignment of space in the VCH AP Laboratory will be subject to availability, and the VCH AP Laboratory Administration reserves the right to reallocate space as it deems necessary, as well as elect to charge rent; and 2) the research assistant(s) is unauthorized to sign out any anatomic pathology specimen.

2. Completion of Confidentiality and Waiver Forms

In addition to submitting a letter of request, the research assistant(s) is required to complete Confidentiality and Waiver forms. These forms are obtained from the VCH AP Laboratory Administration. It is the responsibility of the researcher to ensure that these forms are completed and sent back to the VCH AP Laboratory. Upon granting approval for non-VCH staff AP Laboratory access by the Site Medical Director and Operations Manager, a copy of this letter, with the Site Medical Director's approval, and the completed Confidentiality and Waiver forms will be forwarded to the Medical Affairs department for review. Approval will not be granted by Medical Affairs until these forms are signed. Once AP Laboratory access is granted to non-VCH staff by Medical Affairs, an approval letter will be issued to the VCH AP Laboratory, and a copy is forwarded to the researcher.

3. Obtaining Identification for VCH AP Laboratory Access

The copy of the approval letter must be taken by the research assistant(s) to *Heather Pavilion, B Floor, Room 110* to obtain photo identification. The research assistant(s) must wear this photo identification in a visible manner at all times to verify their authorized VCH AP Laboratory access. It is the responsibility of the researcher to ensure that his/her research assistant(s) adheres to this requirement. Failure to display the photo identification may result in the denial of access to the VCH AP Laboratory.

4. Documentation of Usage of Resources

Research assistant(s) must document the amount of time spent using the equipment for billing reference purposes. In addition, research assistant(s) will be provided with a checklist to keep track of supplies used. Research assistant(s) must maintain this list as it is validated against the research protocol upon completion of the research to determine the total amount of supplies billed.

5. Make Payment for VCH AP Laboratory Resources Used

Upon completion of the research, VCH AP Laboratory will update the invoice (for AP procedures performed) in accordance with equipment and supplies used. If VCH AP Laboratory space was occupied by the research assistant(s), rent may also be billed on the invoice.

Before requesting laboratory procedures, please complete the following checklist:

Checklist	Yes	No
1. Is the procedure or test performed in the laboratory part of the routine diagnostic workup of the patient and to be documented in the patient's final report? If you checked "yes", please skip the following checklist items and proceed with your request through CoPath. If you checked "no", please proceed with the following checklist items.	☐	☐
2. Is your request for additional laboratory procedures for quality improvement/assurance* or teaching† purposes? If you checked "yes", please skip the following checklist items and proceed with your request on the rear of this form. If you checked "no", please proceed with the following checklist items.	☐	☐
3. Does your study require approval from the UBC REB or equivalent and the VCHRI? Please refer to the Vancouver Coastal Health Research Institute website www.vchri.ca for more information. If you checked "no", please skip the following checklist items and submit a document detailing your request indicating *inter alia* the estimated duration of your study. If you checked "yes", please proceed with the following checklist items.	☐	☐
4. Do you have approval from a UBC REB or equivalent? If you checked "yes", please write your Submission Number: _____ If you checked "no", please proceed with applying for UBC REB approval.	☐	☐
5. Do you have approval from the VCHRI? If you checked "yes", please write your V Number: _____ If you checked "no", please proceed with applying for VCHRI approval.	☐	☐
6. Please complete the Anatomic Pathology Laboratory Research Survey clearly indicating the details of your request on the rear of the survey.	☐	☐
7. Name: _____	☐	☐

*Quality Assurance activities that do not require VCHRI or CREB approval include, for example; 1) ordering immunostains or special stains on individual cases or small case series to confirm reported utility of an immunomarker; 2) and comparing different prosection strategies when the information will be used to define prosection protocol.

† Teaching and other academic activities that do not require VCHRI or CREB approval include, for example; 1) ordering re-cuts for teaching sets; 2) reviewing interesting cases from the archives; and 3) resident or small pilot research projects not intended for publication.

Price List

FOR OFFICE USE ONLY

Anatomic Pathology Procedures	Price $	Qtty	Anatomic Pathology Supplies	Price $	Qtty
Histology			Formalin		
Parafin Process			• 1 Litre	4.40	
• Embed Only	20.00		• 90 ml Prefilled Container	0.94	
• Decal & Embed	28.00		• 60 ml Prefilled Container	0.86	
• Re-Embed	6.40		Gloves		
Sectioning from block (per slide)			• Sterile Surgical (per pair)	4.40	
• Parafin or Frozen Section	7.20		• Examinable (per pair)	0.24	
Staining (per slide)			Microtome Blades (per blade)	5.20	
• H&E	9.00		Tissue Cassettes (per cassette)	0.22	
• Special Stain- Simple	17.40		Microscope Slides		
• Special Stain- Complex	27.40		• Regular (per slide)	0.14	
• Immunofluorescence	42.80		• Charged (per slide)	0.20	
• Immunohistochemistry	67.00		Alcohol (per litre)	8.34	
• Enzyme	27.40		Scalpel Blades (per blade)	0.60	
			Sterile Container- 90ml (per unit)	0.24	
Electron Microscopy			Saline (per litre)	2.70	
TEM Specimen Preparation*	528.00				
• Standard Fixation, Dehydration & Embed					
• Toluidine Blue Section			**Anatomic Pathology Equipment**		
• 2 Standard Double Stained Grids			Cryostat (per hour)	46.00	
TEM Scope Time (per hour)	144.00		Microtome (per hour)	36.00	
*Additional Samples $176.00 ea.			Light Microscope (per hour)	18.00	
			Gross Dissection Bench (per hour)	18.00	
Gross Histology					
Tissue Freezing –90° (per tissue)	32.00				
Digital Photography (per exposure)	20.00				
Block/Slide Retrieval			**Handling Fees**		
From Off-Site Storage (per case)	28.40		Packaging and Shipping	75.00	
From On-Site Storage (per case)	20.00		Block Review/Verification	25.00	
Re-printing report (per case)	10.00				

Requested by: _____ Invoice #: _____

Send invoice to: _____ Date: _____

Laboratory Research Coordinator's Authorization: _____

Laboratory Medical Director's Authorization: _____

Operation Manager's Billing Confirmation: _____

Vancouver Coastal Health

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Anatomic Pathology Laboratory

Research Checklist Procedures & Price Lists

Any processes/procedures not required for specimen diagnosis and/or patient management must be documented. This includes all research, teaching projects and quality assurance activities not mandated by laboratory accreditation.

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