

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/services/operational-approval>.

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.