



## CHILDREN'S & WOMEN'S HEALTH CENTRE OF BRITISH COLUMBIA

AN AGENCY OF THE PROVINCIAL HEALTH SERVICES AUTHORITY

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PATHOLOGY ADMINISTRATION - DEPARTMENT OF PATHOLOGY AND LABORATORY MEDICINE

4480 Oak Street, Vancouver, BC, Canada V6H 3V4

PHONE: 604 875 2305 FAX: 604 875 3479

# Laboratory Research Guidelines

The C&WHC Laboratory is committed to supporting clinical trials and other research projects approved by the Child and Family Research Institute (CFRI) that could improve patient care. The guidelines have been developed to outline the laboratory fee structure and procedures for research.

## Fees

As per the current versions of the C&WHC Research Fees – Appendix I and MSP Fee guidelines.

### Non-refundable Protocol Review Fee

This is a fee for the initial review of the study proposal to determine the extent of laboratory involvement, the feasibility of the laboratory to participate and the contract preparation prior to receiving the CFRI's final certificate of approval. This fee is charged once per study whether the study is approved or rejected by the CFRI. See C&WHC Research Fees – Appendix I.

Level 1 – Minimal lab review with simple study procedures and little or no consultation with directors and managers required.

Level 2 – Moderately complex study, fairly detailed lab review and some consultation with directors and managers required. Most studies that involve sponsor companies will fall into this category.

Level 3 – Very complex study with detailed lab review and extensive consultation with directors and managers required.

### Laboratory Set-up Fee

This is a fee applied according to the complexity of the lab requirements to cover the cost of the set up, ongoing monitoring and invoicing of the study. This fee is applicable only after the study receives approval and subsequent to the actual laboratory set-up and is charged once per study. However, as the fee is quoted on the costing letter which may be prepared many months, it may not include any extra set up work that may be necessary. In these cases, revision fees will be billed to the study account at the current rate as per the C&WHC Research Fees – Appendix I.

C&W CONSISTS OF BC CHILDREN'S HOSPITAL & SUNNY HILL HEALTH CENTRE FOR CHILDREN  
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Level 1 – Minimal lab set-up and maintenance required with no detailed protocols to write. Small number of requisitions and collections and no frozen shipment required. There is minimal or no lab storage of samples. Minimal staff training required.

Level 2 – Moderate lab set-up and maintenance required with fairly detailed laboratory protocols and requisitions to prepare. There are a large number of kits and visits to coordinate with the corresponding collections. May or may not require frozen and/or ambient shipments. There is some lab storage of samples. Moderate staff training required. Most industry sponsored studies involving central albs with collection kits will fall into this category.

Level 3 – Extensive lab set-up and maintenance required. Detailed lab protocols and requisitions to prepare. Moderate to extensive staff training required.

### **APPLICATION AND CONTRACT FOR LAB SERVICES**

The researcher must submit a completed "Pathology and Laboratory Medicine Resource Utilization" form along with a copy of the protocol to the Laboratory Research Coordinator.

The form is available on Child and Family Research Institute intranet site – Clinical Research Support – Laboratory Services.

Laboratory approval will be acknowledged with the form signed by appropriate department leaders and Lab Director within one - three weeks of receiving all documents. A signed copy of the document will be made available to the Principal Investigator.

### **INITIATION OF CLINICAL TRIALS**

The Principal Investigator must give notification to the Lab Research Coordinator and also send a copy of the "Certificate of Final Approval" four – six weeks prior to commencing the study.

### **Responsibilities**

The Laboratory:

- Prepare requisitions and lab logistics as required.
- Accession and stores specimens according to the study requirements.
- Analyze blood tests and distribute reports as requested.

Principal Investigator and Clinical Trial Coordinator:

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- Complete requisitions and prepares collection kits if required; ensures the patient's code and/or full name, birth date and unit number appear on the requisition with the exception being blinded studies.
- Ensure that non-laboratory staff that collect and centrifuge blood specimens meet Laboratory Standard Operating Procedures for the blood collection and sample preparation.
- Ensure that specimens are transported through the hospital in a safe manner following WHMIS regulations. *Patient must not transport their blood specimens.*
- Supply TDG certified shipping containers for shipments outside of C&WHC.

### INVOICING

The Laboratory Research Coordinator will keep records for billing. Invoices will be sent to the C&WHC, Finance Department as per a set up internal billing cycle or by fiscal period end taking into consideration the activity of the study.

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