Introduction

The Pathology Core Facility (PCF) Clinical Trials Unit specializes in the procurement, processing, and shipping of clinical trial related biological specimens. PCF-CTU is led by a Clinical Operations Manager and is comprised of 2 Senior Research Study Coordinators, 4 Research Study Coordinators and 2 Program Assistants.

Scope

The PCF-CTU is involved in every step of the clinical trials process at RHLCCC from study start-up to study close-out. We are involved in the following processes:

- Scientific review of each new protocol prior to IRB submission
- Clinical Specimen Release Committee application submission
- Budget development
- Feasibility assessments
- Sample procurement, processing and storage
- Sample shipment per IATA standards
- Inventory maintenance of study kits
- Protocol amendment review

Daily Work Flow of CTU

- **Patient consents to participate in a clinical trial**
  - **Study Coordinator sends Fluid Requisition to CTU**
  - **Study Coordinator sends Fresh Tissue Requisition and ICF to CTU**
  - **Study Coordinator sends Archival Tissue Requisition, ICF and Path Report to CTU**

- **CTU prepares study kit and delivers it to clinic/floor the night before the patient’s visit**
  - **Fluid is drawn and CTU is paged for pick up**
  - **CTU processes fluids according to the Protocol and Study Lab Manual**
  - **CTU ships fluid samples as per IATA standards to Sponsor selected Central Lab for Review**

- **CTU either retrieves pathology materials from NM or requests pathology materials from OSH**
  - **CTU verifies with Pathologist that there is sufficient tissue to fulfill study requirements**
  - **CTU requests slides/cores from PCF Histology Lab**

- **CTU prepares flash frozen tissue for shipment to Sponsor selected Central Lab for review**
  - **CTU verifies shipping information and submits tissue to Sponsor selected Central Lab for review**

- **CTU receives lab reports/confirmation of patient eligibility and sends to Study Coordinator**
  - **Study Coordinator sends Fresh Tissue Requisition and ICF to CTU**
  - **CTU prepares fresh tissue collection kit and coordinates pick up with clinical staff**
  - **CTU prepares fresh tissue collection kit and coordinates pick up with clinical staff**

- **CTU flash freezes tissue or places tissue in formalin**
  - **CTU prepares formalin fixed tissue for shipment or delivers formalin fixed tissue to PCF Histology Lab for further processing before shipment**

- **CTU receives lab reports/confirmation of patient eligibility and sends to Study Coordinator**

Study Disease Sites

- Breast
- Lung
- Neuro Oncology
- Melanoma/Sarcoma
- Genitourinary Oncology
- Gastrointestinal Oncology
- Hematologic Malignancies
- Ophthalmology
- Internal Medicine
- Rheumatology
- Infectious Disease
- Physical Medicine