

Guidelines for Accessing Shared Health DS Laboratory Services for Research Studies and Clinical Trials

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DS: Diagnostic Services

LIM: [Lab Information Manual](#) lists all laboratory tests available through Shared Health Diagnostic Services

SH: Shared Health

SH ACPIAR: Shared Health Approval Committee for Privacy, Impact, and Access in Research

SHRI: Shared Health Research and Innovation

1. SHARED HEALTH DS LAB SERVICES AVAILABLE FOR RESEARCH

- Studies requiring lab services may use one or any combination of these

Phlebotomy/Specimen Collection

- Collection of specimens suitable for laboratory analysis
- Performed for outpatients or inpatients
- May be used on its own or in combination with local testing and/or central laboratory services

Local (In-House) Testing

- Sample testing done at SH laboratories
- Comprehensive, turn-key solution for projects requiring lab analysis

Referral Testing

- Tests listed in the Lab Information Manual (LIM) that are not done at SH laboratories and are instead sent out to external referral laboratories
- Sample processing and shipping may be offered to studies lacking this capacity, however, arrangements with the referral laboratory must be made directly by the study

Central Laboratory Services

- Includes:
 - Sample processing
 - Storage
 - Shipping
- Intended for projects that perform their own sample analysis, ship samples to a central location for testing or bank them, but still require assistance with the intermediate steps

Pathology

- Retrieval and processing of fresh and archival pathology samples, human and non-human

Figure 1 (Types of Services)

2. STEPS LEADING UP TO ACCESS TO LAB SERVICES

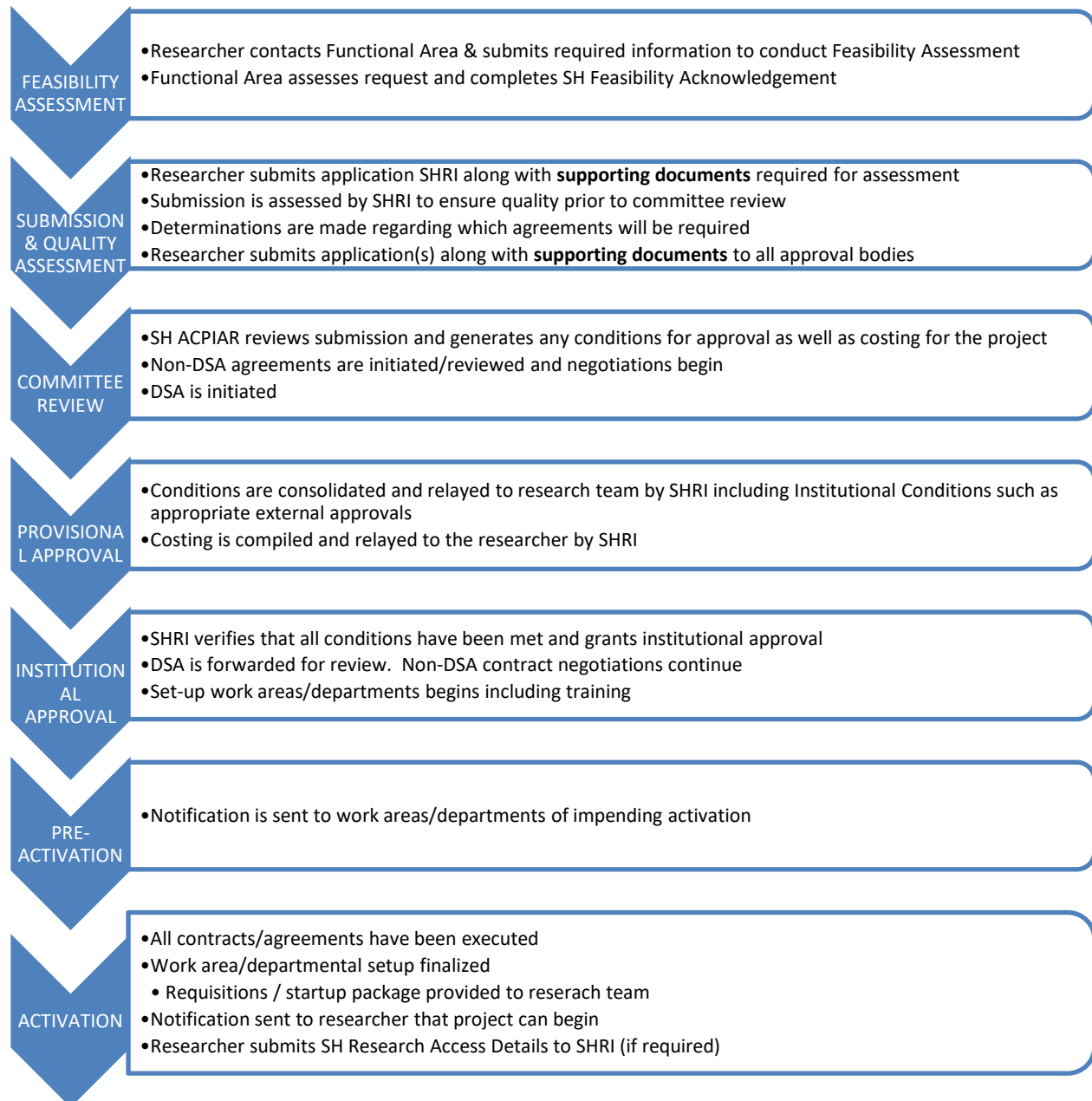


Figure 2 (Activation Process)

3. COMPLETING LAB RESEARCH REQUISITIONS

3.1 Requisition Color Coding

- Requisitions are color coded into 3 groups:
 - **In-House (Local) Services** (includes in-house testing, phlebotomy, and referral testing)
 - *Blue*
 - **Central Lab Services**
 - *Purple*: The most common central lab requisition
 - *Salmon*: Used for central lab requisitions requiring special attention by the lab or requires same-day sample shipping
 - **Pathology**
 - *Grey*

3.2 General Requisition Components

- Certain components common to all types of research requisition are covered in this section while sections specific to certain types of requisitions are discussed in the following sections

3.2.1 Top Section

Last Name		First Name		Sex	Age	Date of Birth
						DD / MM / YYYY
Doctor Last Name		Initial	Doctor Code		Location Code	
DOE		J	000000		DOE111	
Reference						
<input type="checkbox"/> SCREENING <input type="checkbox"/> WEEK 10 <input type="checkbox"/> EOT						
Study Patient ID (if required): <i>(for reference only - do not register)</i>						
Name of Study						
Training Example Study Requiring Lab Services						
Collection Date	Time	Collected By			SH DS Staff	
DD / MM / YYYY					<input type="checkbox"/> Yes	

- RESEARCHER INSTRUCTIONS:** In the top section of requisition, fill out the following:
 - Patient information: **Last Name, First Name, Sex, Age, and Date of Birth**
 - Reference:** This section lists the name(s) of visit(s) during which given testing will occur. If more than one visit is listed, check off the appropriate timepoint
 - Study Patient ID:** enter patient code/ID assigned by the study if applicable
 - Collection Date, Time, and Collected By:** Completed by staff responsible for collection. Leave blank if done by SH phlebotomy staff
- Primary Investigator is listed as the ordering physician along with their **Doctor Code** used for ordering clinical tests
 - NOTE: For PI's who are not medical doctors, doctor code will be generated prior to study activation at the discretion of SHRI*
- Location Code** refers to the project's unique identification code for lab services

3.2.2 Registration

REGISTRATION

(No sample with this requisition. Sample was picked up by coordinator, see below)

☒ REPH

☒ ADMN

- “Registration” section informs SH staff of the following during sample registration:
 - How to register sample(s)
 - Who performed phlebotomy/sample collection
 - Which administrative codes are applicable for billing purposes
- **RESEARCHER INSTRUCTIONS:**
 - No action is required in this section except on in-house requisition (see *General Requisition Components*)

3.2.3 Collection

COLLECTION

1 – 4.5 mL Light Green Top Lithium Heparin Tube (Chemistry)

1 – 4.0 mL Lavender Top EDTA Tube (CBC)

- “Collection” section lists the type(s) and quantity of required collection tubes
- Tubes are listed according to the order of draw
- *NOTE: Only tubes listed on the requisition will be collected. If additional tubes are needed, contact SHRI*
- **RESEARCHER INSTRUCTIONS:**
 - Ensure that only collection tubes required for a particular collection are listed
 - If certain tubes are not required, cross them out with a single line and initial (e.g. ~~cross out~~ JD)

3.2.4 Study Contact Information, Requisition Name, Primary SH Sites

STUDY CONTACT	Name: Anne Smith	Phone: (204) 787-000	Address: 000 – 820 Sherbrook Street
DOE111 PHLEBOTOMY ONLY 1 V1		Primary SH Sites: HSC, S8H	

- **Study Contact:** The person listed on research application next to “In case of patient visit questions, contact”. Their phone number and office address are listed as they appear on the initial application or subsequent Change of Personnel

- **Requisition Name:** Found in the left bottom corner of requisition, begins with study location code (e.g. DOE111) and specifies whether the requisition is for phlebotomy, in-house testing, central lab testing, or pathology
- **Primary SH Sites:** Lists primary and additional involved SH sites
 - **IMPORTANT:** *Local (in-house) testing requisitions can be used at any Shared Health lab within the province, while central lab requisitions can be only used at preapproved sites listed in this section since central lab sample processing requires labs to follow custom processing & storage instructions and prior project-specific training/set-up is often required*

3.3 Phlebotomy

- Only sections unique to Phlebotomy requisition are listed below. For an overview of general sections not listed here, see *General Requisition Components*

RESEARCH REQUISITION					Accessioning Number
Last Name	First Name	Sex	Age	Date of Birth	
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text" value="DD / MM / YYYY"/>	
Doctor Last Name	Initial	Doctor Code		Location Code	
<input type="text" value="DOE"/>	<input type="text" value="J"/>	<input type="text" value="000000"/>		<input type="text" value="DOE111"/>	
Reference					
<input type="text" value="PHLEBOTOMY VISIT"/>					
Study Patient ID (if required): <i>(for reference only - do not register)</i>					
<input type="text"/>					
Name of Study					
<input type="text" value="Training Example Study Requiring Lab Services"/>					
Collection Date	Time	Collected By			SH DS Staff
<input type="text" value="DD / MM / YYYY"/>	<input type="text"/>	<input type="text"/>			<input type="checkbox"/> Yes
REGISTRATION (No sample with this requisition. Sample was picked up by coordinator, see below) <input checked="" type="checkbox"/> REPH <input checked="" type="checkbox"/> ADMN					
COLLECTION 1 – 4.5 mL Light Green Top Lithium Heparin Tube (Chemistry) 1 – 4.0 mL Lavender Top EDTA Tube (CBC)					
INSTRUCTIONS <ul style="list-style-type: none"> Attach completed label to filled collection tube Retain samples until Study Coordinator (or designate) picks up samples. Have Study Coordinator (or designate) sign below to acknowledge receipt of this sample <div style="display: flex; justify-content: space-between; margin-top: 20px;"> <div style="width: 45%;"> <p>_____ Name of Receiver</p> </div> <div style="width: 45%;"> <p>_____ Signature of Receiver</p> </div> </div> <p><u>This study requisition does not go to study coordinator; please forward to laboratory for registration</u></p>					
STUDY CONTACT Name: Anne Smith Phone: (204) 787-000 Address: 000 – 820 Sherbrook Street					
DOE111 PHLEBOTOMY ONLY 1 V1 Primary SH Sites: HSC, SBH					

3.3.1 Instructions

INSTRUCTIONS

- Attach completed label to filled collection tube
- Retain samples until Study Coordinator (or designate) picks up samples.
- Have Study Coordinator (or designate) sign below to acknowledge receipt of this sample

Name of Receiver

Signature of Receiver

This study requisition does not go to study coordinator; please forward to laboratory for registration

- “Instructions” section informs SH staff what to do after phlebotomy/sample collection is complete
- **RESEARCHER INSTRUCTIONS:**
 - Once samples are collected, SH staff will collect signature from study designate as an acknowledgement that samples have been received. Leave blank until prompted by SH staff

3.4 Local (In-House) Testing

- Only sections unique to Local Testing requisition are listed below. For an overview of general sections not listed here, see *General Requisition Components*

RESEARCH REQUISITION						Accessioning Number
Last Name	First Name	Sex	Age	Date of Birth		
				DD / MM / YYYY		
Doctor Last Name	Initial	Doctor Code		Location Code		
DOE	J	000000		DOE111		
Reference						
<input type="checkbox"/> SCREENING <input type="checkbox"/> WEEK 10 <input type="checkbox"/> EOT						
Name of Study						
Training Example Study Requiring Lab Services						
Collection Date	Time	Collected By			SH DS Staff	
DD / MM / YYYY					<input type="checkbox"/> Yes	
REGISTRATION Order REQC and enter comment & RESRCH <input type="checkbox"/> REPH (register REPH if collected by SH DS Staff, see above) <input checked="" type="checkbox"/> ADMN <input checked="" type="checkbox"/> RSPR <input checked="" type="checkbox"/> NA <input checked="" type="checkbox"/> CR <input checked="" type="checkbox"/> TP <input checked="" type="checkbox"/> TB <input checked="" type="checkbox"/> DB <input type="checkbox"/> CBC						
COLLECTION 1 – 4.5 mL Light Green Top Lithium Heparin Tube (Chemistry) 1 – 4.0 mL Lavender Top EDTA Tube (CBC)						
STUDY CONTACT Name: Anne Smith Phone: (204) 787-000 Address: 000 – 820 Sherbrook Street						
DOE111 IN HOUSE TESTING 1 V1 Primary SH Sites: HSC, SBH						

3.4.1 Registration

REGISTRATION

Order REQC and enter comment & RESRCH

☐ REPH (register REPH if collected by SH DS Staff, see above)

☒ ADMN

☒ RSPR

☒ NA

☒ CR

☒ TP

☒ TB

☒ DB

☐ CBC

- “Registration” section informs SH staff of the following during sample registration:
 - How to register sample(s)
 - Who performed phlebotomy/sample collection
 - Which administrative codes are applicable for billing purposes
 - Which tests are required (listed by codes from the Lab Information Manual)
- **RESEARCHER INSTRUCTIONS:**
 - All tests are marked by ☒ or ☐
 - Empty box ☐ indicates tests that need to be manually checked off by study staff (usually tests that are not required with every collection for every participant such as pregnancy serum test). Mark optional test(s) by “x” if required for specific participant/collection
 - Box ☒ indicates pre-selected tests that will be run automatically
 - If certain pre-selected tests marked by ☒ are not required for a specific collection, cross out (1) applicable test code(s) and (2) corresponding test tubes with a single line and initial (e.g. ~~cross-out~~ JD)
 - **NOTE:**
 - Do not cross out tubes required for other tests
 - Administrative codes (e.g. REPH, ADMN, RSPR) must remain unaltered at all times

3.4.2 Collection

COLLECTION

1 – 4.5 mL Light Green Top Lithium Heparin Tube (Chemistry)

1 – 4.0 mL Lavender Top EDTA Tube (CBC)

- “Collection” section lists the type(s) and quantity of collection tubes required for tests listed in the “Registration” section
- Collection tubes are listed according to the order of draw
- **RESEARCHER INSTRUCTIONS:**
 - Ensure that only collection tubes required for a particular collection are listed
 - If certain collection tubes are not required, follow instructions in *General Requisition Components*

3.5 Local (In-House) Testing with Additional Collection

- This form is a blend of local (in-house) testing and phlebotomy requisitions; DS labs are tasked with sample analysis (local testing) and collecting samples to be picked up by study designate
- Only sections unique to Local Testing requisition are listed below. For an overview of general sections not listed here, see *General Requisition Components*



RESEARCH REQUISITION					Accessioning Number
Last Name	First Name	Sex	Age	Date of Birth	
				DD / MM / YYYY	
Doctor Last Name	Initial	Doctor Code		Location Code	
DOE	J	000000		DOE111	
Reference					
<input type="checkbox"/> SCREENING <input type="checkbox"/> WEEK 10 <input type="checkbox"/> EOT					
Name of Study					
Training Example Study Requiring Lab Services					
Collection Date	Time	Collected By			SH DS Staff
DD / MM / YYYY					<input type="checkbox"/> Yes
REGISTRATION					
Order REQC and enter comment & RESRCH					
<input type="checkbox"/> REPH (register REPH if collected by SH DS Staff, see above)					
<input checked="" type="checkbox"/> ADMN <input checked="" type="checkbox"/> RSPR					
<input checked="" type="checkbox"/> NA <input checked="" type="checkbox"/> CR <input checked="" type="checkbox"/> TP					
<input checked="" type="checkbox"/> TB <input checked="" type="checkbox"/> DB					
<input type="checkbox"/> CBC					
COLLECTION					
1 – 4.5 mL Light Green Top Lithium Heparin Tube (Chemistry)					
1 – 4.0 mL Lavender Top EDTA Tube (CBC)					
Additional tubes as follows may be provided – To be picked up by Study Coordinator, See ORDER OF DRAW and INSTRUCTIONS					
1 – 8.5 mL Red/Grey Top Serum Separator (SST) Tube					
3 – 8.5 mL Red/Green Top Cell Preparation (CPT) Tube					
1 – 2.5 mL Red Top PAXgene Blood RNA Tube					
See reverse for Order of Draw Listing and Instructions if additional tubes collected					
STUDY CONTACT Name: Anne Smith Phone: (204) 787-000 Address: 000 – 820 Sherbrook Street					
DOE111 IN HOUSE TESTING 2 V1 Primary SH Sites: HSC, SBH					

Front

COLLECTION – ORDER OF DRAW

Perform Order of Draw as follows. Note: not all tubes may be required.

- 1 – 8.5 mL Red/Grey Top Serum Separator (SST) Tube (Research)
- 1 – 4.5 mL Light Green Top Lithium Heparin Tube (Chemistry)
- 3 – 8.5 mL Red/Green Top Cell Preparation (CPT) Tube (Research)
- 1 – 4.0 mL Lavender Top EDTA Tube (CBC)
- 1 – 2.5 mL Red Top PAXgene Blood RNA Tube (Research)

INSTRUCTIONS

(If additional tubes collected)

- Attach completed label to filled collection tube
- Retain samples
- Study Coordinator (or designate) will pick-up sample
- Have Study Coordinator (or designate) sign below to acknowledge receipt of this sample

Name of Receiver

Signature of Receiver

This study requisition does not go to study coordinator; please forward to laboratory for registration

Reverse

3.5.1 Collection

COLLECTION

- 1 – 4.5 mL Light Green Top Lithium Heparin Tube (Chemistry)
- 1 – 4.0 mL Lavender Top EDTA Tube (CBC)

Additional tubes as follows may be provided – To be picked up by Study Coordinator, See ORDER OF DRAW and INSTRUCTIONS

- 1 – 8.5 mL Red/Grey Top Serum Separator (SST) Tube
- 3 – 8.5 mL Red/Green Top Cell Preparation (CPT) Tube
- 1 – 2.5 mL Red Top PAXgene Blood RNA Tube

See reverse for Order of Draw Listing and Instructions if additional tubes collected

- “Collection” section lists the type(s) and quantity of (1) collection tubes required for tests listed in the “Registration” section and (2) additional collection tubes to be picked up by study staff upon collection
- **RESEARCHER INSTRUCTIONS:**
 - Ensure that only test tubes required for a particular collection are listed
 - If certain tubes are not required for a specific collection, cross them out with a single line and initial (e.g. ~~cross-out~~ JD)

- *NOTE: Do not cross out tubes required for other tests on the requisition (not applicable for optional tubes)*

3.5.2 Collection – Order of Draw

COLLECTION – ORDER OF DRAW

Perform Order of Draw as follows. Note: not all tubes may be required.

- 1 – 8.5 mL Red/Grey Top Serum Separator (SST) Tube (Research)
- 1 – 4.5 mL Light Green Top Lithium Heparin Tube (Chemistry)
- 3 – 8.5 mL Red/Green Top Cell Preparation (CPT) Tube (Research)
- 1 – 4.0 mL Lavender Top EDTA Tube (CBC)
- 1 – 2.5 mL Red Top PAXgene Blood RNA Tube (Research)

- Collection tubes are listed according to the order of draw.

3.6 Referral Testing

- Referral testing is tests listed in the Lab Information Manual (LIM) that are not performed in house at SH laboratories and are instead sent out to contracted external laboratories (referral labs)
- For research purposes, Shared Health DS may facilitate sample processing and shipping of samples intended for referral testing when the research team lacks this capacity
- If referral testing is approved, the research team must make their own arrangements with the referral laboratory (including account set-up) and ensure everything is in place prior to samples being sent out. Shared Health DS referral lab accounts will not be used for research testing
- Referral Testing requisition closely resembles Central Lab Testing requisition since sample processing and shipping is required but not in-house testing. Refer to *Central Lab Testing* for further details

RESEARCH REQUISITION					Accessioning Number
Last Name	First Name	Sex	Age	Date of Birth	
				DD / MM / YYYY	
Doctor Last Name	Initial	Doctor Code		Location Code	
DOE	J	000000		DOE111	
Reference					
<input type="checkbox"/> Screening <input type="checkbox"/> EOT					
Name of Study					
Training Example Study Requiring Lab Services					
Collection Date	Time	Collected By			SH DS Staff
DD / MM / YYYY					<input type="checkbox"/> Yes
REGISTRATION (Do not register for In House analysis. Results will be sent directly to Investigator by In Common Labs. Samples must be accompanied by an In Common Labs requisition to be completed by study coordinator)					
<input type="checkbox"/> REPH (register REPH if collected by SH DS Staff, see above)					
<input checked="" type="checkbox"/> UNPH					
COLLECTION 1 – Red Top Serum NO GEL Tube					

Front

PROCESSING

1 – Red Top Serum NO GEL Tube – Centrifuge sample following standard process. Transfer the serum into a screw top tube. Freeze immediately at -20°C. **Batch ship FROZEN.**

PACKAGING/SHIPPING**Frozen**

- Ensure all tube(s) are correctly labeled with Subject name OR identifier, DOB and Sex.
- Place **frozen specimen(s)** into the Specimen Collection Bag with the absorbent pack. Carefully fold and seal bag. Fold and place the ICL Requisition into the pocket on the reverse side of the bag. **Note:** Do not place ICL barcode label on ICL requisition.
- Fill half the Styrofoam container with dry ice and insert the Specimen Collection Bag. Then fill the container using a total of at least 2.0 kg dry ice.
- Replace the Styrofoam lid. Seal the box.
- Ship to **In Common Laboratory.**

Reverse

3.7 Central Lab Services

- Only sections unique to Central Lab requisition are listed below. For an overview of general sections not listed here, see *General Requisition Components*

RESEARCH REQUISITION					Accessioning Number
Last Name	First Name	Sex	Age	Date of Birth	
				DD / MM / YYYY	
Doctor Last Name	Initial	Doctor Code		Location Code	
DOE	J	000000		DOE111	
Reference					
<input type="checkbox"/> SCREENING <input type="checkbox"/> WEEK 5 <input type="checkbox"/> WEEK 10 <input type="checkbox"/> EOT					
Study Patient ID (if required): <i>(for reference only - do not register)</i>					
Name of Study					
Training Example Study Requiring Lab Services					
Collection Date	Time	Collected By			SH DS Staff
DD / MM / YYYY					<input type="checkbox"/> Yes
REGISTRATION <input type="checkbox"/> REPH (register REPH if collected by SH DS Staff, see above) <input checked="" type="checkbox"/> ADMN <input checked="" type="checkbox"/> REDR					
COLLECTION <div style="display: flex; justify-content: space-between; margin-top: 10px;"> 1 – 4.0 mL Lavender Top EDTA Tube Mix gently x 10 </div>					
See reverse for Processing and Packaging/Shipping Information					
STUDY CONTACT Name: Anne Smith Phone: (204) 787-000 Address: 000 – 820 Sherbrook Street					
DOE111 CENTRAL LAB TESTING 1 V1 Primary SH Sites: WSC, SBH					

Front



PROCESSING

1 – 4.0 mL Lavender Top EDTA Tube – Immediately place the tubes upright in an ice water bath (or wrapped in an ice pack). Spin the sample in a refrigerated centrifuge at 4°C at 2000g for 10 minutes. Transfer the plasma into a labeled 5ml VWR freeze vial. Freeze and store immediately at -70°C standing upright. Record individual samples in *Research Samples Storage Log Sheet*. **Batch ship FROZEN upon notification.**

PACKAGING/SHIPPING

Frozen

- Place **frozen specimen(s)** into the Specimen Collection Bag with the absorbent pack. Carefully fold and seal bag. Fold and place a copy of the *Central Laboratory Requisition* into the pocket on the reverse side of the bag, with the barcode visible if applicable.
- Fill half the Styrofoam container with dry ice and insert the Specimen Collection Bag. Then fill the container using a total of at least 2.0 kg dry ice. Note: Ship no more than 2 Specimen Collection Bags per 2.0 kg of dry ice.
- Replace the Styrofoam lid.
- Seal the box.
- Fill in the number of packages and amount of dry ice in kg on the dry ice label.
- Complete and affix *Waybill* and completed dry ice labels.
- If applicable, complete a *Commercial Invoice*. Send the original and 2 copies with the courier for customs.
- Record the waybill/tracking number and identify shipment type on the *SH Requisition(s)* for this shipment in the space provided.
- Attach a copy of the *Waybill* to the *SH Requisition(s)* for this shipment.
 - For batch shipments, attach a copy of the completed *Batch Research Request Form*.
- Forward *SH Requisitions* for internal processing/document storage as appropriate. Note: *SH Requisition(s)* are not to be sent with shipment.
- Update the Shipping section of the *Research Samples Storage Log Sheet*.

Shipment Type: ☐ Same Day
☐ Batch

Waybill/Tracking Number:

COURIER FEDEX – Samples MUST be in the lab by 1345 to be shipped same day as collected CENTRAL LAB: Toronto Women's College Hospital

Reverse

3.7.1 Processing

PROCESSING

1 – 4.0 mL Lavender Top EDTA Tube – Immediately place the tubes upright in an ice water bath (or wrapped in an ice pack). Spin the sample in a refrigerated centrifuge at 4°C at 2000g for 10 minutes. Transfer the plasma into a labeled 5ml VWR freeze vial. Freeze and store immediately at -70°C standing upright. Record individual samples in *Research Samples Storage Log Sheet*. **Batch ship FROZEN upon notification.**

- The “Processing” section provides instructions to the DS lab staff about the following:
 - How to process and store each individual sample based on specifications provided in project’s Lab Manual
 - Whether processed samples should be recorded on Research Samples Storage Log Sheet (only applicable to samples not shipped the same day)
 - Shipping frequency (same day or batched) and shipping temperature (ambient, refrigerated, frozen)
- **RESEARCHER INSTRUCTIONS:** No action required and no alterations permitted. If processing instructions need to be adjusted, contact SHRI immediately

3.7.2 Packaging/Shipping

PACKAGING/SHIPPING

Frozen

- Place **frozen specimen(s)** into the Specimen Collection Bag with the absorbent pack. Carefully fold and seal bag. Fold and place a copy of the *Central Laboratory Requisition* into the pocket on the reverse side of the bag, with the barcode visible if applicable.
- Fill half the Styrofoam container with dry ice and insert the Specimen Collection Bag. Then fill the container using a total of at least 2.0 kg dry ice. Note: Ship no more than 2 Specimen Collection Bags per 2.0 kg of dry ice.
- Replace the Styrofoam lid.
- Seal the box.
- Fill in the number of packages and amount of dry ice in kg on the dry ice label.
- Complete and affix *Waybill* and completed dry ice labels.
- If applicable, complete a *Commercial Invoice*. Send the original and 2 copies with the courier for customs.
- Record the waybill/tracking number and identify shipment type on the *SH Requisition(s)* for this shipment in the space provided.
- Attach a copy of the *Waybill* to the *SH Requisition(s)* for this shipment.
 - For batch shipments, attach a copy of the completed *Batch Research Request Form*.
- Forward *SH Requisitions* for internal processing/document storage as appropriate. Note: *SH Requisition(s)* are not to be sent with shipment.
- Update the Shipping section of the *Research Samples Storage Log Sheet*.

- The “Packaging/Shipping” section provides DS lab staff with standardized instructions about shipment requirements for individual samples which meet TDG/IATA requirements. Instructions differ based on sample shipping temperature – ambient, refrigerated, frozen, or combination of these
- Once shipment is completed, DS lab staff records shipment type and notes waybill/tracking number on requisition
- **RESEARCHER INSTRUCTIONS:** No action required in this section and no alterations permitted

3.8 Pathology

- Only sections unique to Pathology requisition are listed below. For an overview of general sections not listed here, see *General Requisition Components*

RESEARCH REQUISITION			
<input type="checkbox"/> Request for Confirmation of Tissue Availability ONLY (request for deliverables must be submitted when required, additional charges may apply) <input type="checkbox"/> Request for Deliverables <input type="checkbox"/> Confirmation of Tissue Availability previously submitted (within 10 business days)			
Date of Request: _____		Procedure Date: _____	
Participant Name (Last, First): _____		Case Number (if known): _____	
Participant Sex: _____	Participant Age: _____	Participant Date of Birth: _____ Originating Site: _____	
Material to be returned by: _____		Reason for Request: <input type="checkbox"/> Research <input type="checkbox"/> Diagnostic <input type="checkbox"/> Both	
Requested Completion Date: _____		Is requested completion date less than standard TAT? <input type="checkbox"/> Yes <input type="checkbox"/> No	
When request is completed:		Justification for Completion: _____	
		<input type="checkbox"/> Call for Pick-Up : Name: _____ Phone: _____	
		<input type="checkbox"/> Ship to: Name: _____	
		Address: _____	
Doctor Last Name	Initial	Doctor Code	Location Code
DOE	J	000000	DOE111
Name of Study			
Training Example Study Requiring Lab Services			
<p>The following request can only be completed with J. Citizen's (or designate) signature below <u>confirming that for this patient, there is more than 1 block which contains diagnostic tissue & that there is enough tissue to proceed.</u></p> <div style="display: flex; justify-content: space-between;"> <div> <input type="checkbox"/> YES, proceed with preferred request <input type="checkbox"/> NO, proceed with alternative request </div> <div> <input type="checkbox"/> NO, decline <div style="border-bottom: 1px solid black; width: 150px; margin-top: 5px;"></div> Dr. J. Citizen (or designate) - Signature </div> </div>			
REQUEST DETAILS A signed SH Patient Information & Consent for Use of Tissues Form (or approved equivalent) must be attached. Technologist Initials _____ Study Staff: Check items required for confirmation or deliverables required below.			
Reference	Preferred Request	Alternative, if preferred request unavailable	Selected block (if applicable)
<input type="checkbox"/> Screening	1 FFPE tumor block	20 unstained, unbaked, charged slides at 4 micron thickness and 1 H&E stained slide	
<input type="checkbox"/> Recurrence	1 FFPE tumor block from	n/a	
<input type="checkbox"/> Progression	each biopsy site		
<input type="checkbox"/>	Pathology Report		
See reverse for Internal Use Only section			
STUDY CONTACT Name: Anne Smith Phone: (204) 787-0000 Address: 000 – 820 Sherbrook Street			
<small>DOE111 PATHOLOGY REQUISITION V.1 Primary SH Sites: HSC, SBH</small>			

3.8.1 Type of Request

<input type="checkbox"/> Request for Confirmation of Tissue Availability ONLY (request for deliverables must be submitted when required, additional charges may apply)	<input type="checkbox"/> Confirmation of Tissue Availability previously submitted (within 10 business days)
<input type="checkbox"/> Request for Deliverables	

- **RESEARCHER INSTRUCTIONS:** Requests for pathology deliverables can be submitted in one of two ways:
 - **Request for Confirmation of Tissue Availability ONLY:**
 - Pathology will check if there is enough tissue to proceed with the preferred or alternative study request and notify the research team. They will not proceed with preparation of deliverables
 - Useful when confirmation of tissue availability is required for enrolment but actual pathology samples are not needed until later in the research process
 - Once deliverables are required, another requisition (Request for Deliverables) must be submitted
 - **Request for Deliverables**
 - Pathology will check if there is enough tissue to proceed with the preferred or alternative request and if yes, proceed to preparing the deliverables. Upon completion, the call person will be notified for pick-up or the samples will be sent to the address specified on the requisition
- **Confirmation of Tissue Availability previously submitted (within 10 business days)**
 - Check off if applicable. If case has not been refiled, duplicate charges for sample retrieval and pathologist time may not be applied

3.8.2 Case Information

Date of Request: _____	Procedure Date: _____
Participant Name (Last, First): _____	Case Number (if known): _____
Participant Sex: _____ Participant Age: _____	Participant Date of Birth: _____ Originating Site: _____
Material to be returned by: _____	Reason for Request: <input type="checkbox"/> Research <input type="checkbox"/> Diagnostic <input type="checkbox"/> Both
Requested Completion Date: _____	Is requested completion date less than standard TAT? <input type="checkbox"/> Yes <input type="checkbox"/> No
When request is completed:	Justification for Completion: _____
	<input type="checkbox"/> Call for Pick-Up : Name: _____ Phone: _____
	<input type="checkbox"/> Ship to: Name: _____
	Address: _____

- This section provides information about the study participant, case, purpose of the request, the person to notify for pick-up once samples have been processed or shipping destination
- **RESEARCHER INSTRUCTIONS:** Fill out the following:

- **Date of Request:** date of request submission to pathology
- **Participant Name, Sex, Age**
- **Material to be returned by:** If project does not intend to keep requested deliverables after they have been analyzed and wishes to return them, specify the return date here. This will inform the lab whether returning the case file into archive should be postponed
- **Requested Completion Date:** When should the request be completed by
- **Procedure Date:** date of the procedure from which samples are being requested
- **Case Number:** Surgical number found on pathology report associated with the given procedure
- **Participant Date of Birth**
- **Originating Site:** Site at which the procedure took place
- **Reason For Request:** For all archival samples the reason for request would be for research. In case of proactive procedures where research blends with clinical care (e.g. when procedure is repeated due to disease progression), the reason may be both research and diagnostic
- **Is Requested completion date less than standard TAT:** the standard turnaround time for confirmation is 5 business days, for human sample deliverables 10 business days, and for animal sample deliverables 15 business days
- **Justification of Completion:** If an earlier completion date than the standard TAT is requested, provide an explanation of why this should be granted
- **Call for Pick-Up Name & Phone:** The person who will be contacted to pick up samples once processed (note: call person will be required to physically pick up samples from the processing location which may not be HSC)
- **Ship to Name & Address:** Destination where samples are to be shipped to once processed
- **IMPORTANT:** Choose either pick-up by indicating a call person OR shipping, not both

3.8.3 Pathologist Section

The following request can only be completed with Dr. J. Citizen's (or designate) signature below confirming that for this patient, there is more than 1 block which contains diagnostic tissue & that there is enough tissue to proceed.

- ☐ YES, proceed with preferred request
☐ NO, proceed with alternative request

☐ NO, decline

 Dr. J. Citizen (or designate) - Signature

- **To be completed by pathologist only.** Serves to record their decision as to whether there is enough tissue to proceed with study request and whether preferred or alternative request can be granted
- **RESEARCHER INSTRUCTIONS:**
 - No action required; leave blank. Once the request is received by pathology office, it will be forwarded to the appropriate pathologist

3.8.4 Request Details

REQUEST DETAILS			
A signed SH Patient Information & Consent for Use of Tissues Form (or approved equivalent) must be attached.			Technologist Initials
Study Staff: Check items required for confirmation or deliverables required below.			
Reference	Preferred Request	Alternative, if preferred request unavailable	Selected block (if applicable)
<input type="checkbox"/> Screening	1 FFPE tumor block	20 unstained, unbaked, charged slides and 1 H&E stained slide	
<input type="checkbox"/> Recurrence	1 FFPE tumor block from each biopsy site	No alternative	
<input type="checkbox"/> Progression			
<input type="checkbox"/>	Pathology Report		

- This section contains information about the study request for deliverables based on information supplied by research team in the research application
- **Reference:** Timepoint/visit at which certain deliverables are required
- **Preferred Request:** The primary request for deliverables
- **Alternative Request:** If primary request is deemed not feasible by pathologist, the alternative request which is usually less impactful will be considered
- **Selected Block:** This is section where selected FFPE block number can be listed. This would be filled out either by the pathologist affiliated with the project or the index pathologist if applicable
- **RESEARCHER INSTRUCTIONS:** Mark the appropriate box(es) to indicate which item(s) is/are required at the time of request

3.9 Pathology – Animal Studies

- *This is a simplified version of the previous pathology form. Refer to the appropriate sections under “Pathology”. See the one additional section explanation below*
- **Type of Tissue Submitted to Pathology:** Indicate what kind of tissue is being submitted to pathology for each individual request. In the example below, fresh tissue would be submitted with the request to process it into an FFPE block and/or unstained slides. However, this form could also be used to submit a previously processed FFPE block with a request to process it into unstained slides

RESEARCH REQUISITION ANIMAL STUDIES								
<p>Date of Request: _____</p> <p>Requested Completion Date: _____ Is requested completion date less than standard TAT? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Justification for Completion: _____</p> <p>When request is completed: _____</p> <p><input type="checkbox"/> Call for Pick-Up: Name: _____ Phone: _____</p> <p><input type="checkbox"/> Ship to: Name: _____</p> <p style="padding-left: 150px;">Address: _____</p>								
<p>Doctor Last Name</p> <div style="border: 1px solid black; padding: 2px;">DOE</div>	<p>Initial</p> <div style="border: 1px solid black; padding: 2px;">J</div>	<p>Location Code</p> <div style="border: 1px solid black; padding: 2px;">DOE111</div>						
<p>Name of Study</p> <div style="border: 1px solid black; padding: 2px;">Training Example Study Requiring Lab Services</div>								
<p>REQUEST DETAILS</p> <p>Study Staff: Check items required for deliverables required below. Technologist Initials _____</p> <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 40%; text-align: left; padding: 5px;">Type of Tissue Submitted to Pathology (Fresh or Archival)</th> <th style="width: 60%; text-align: left; padding: 5px;">Requested Processing</th> </tr> </thead> <tbody> <tr> <td style="padding: 5px;"><input type="checkbox"/> _____</td> <td style="padding: 5px;">1 FFPE Tumor Block</td> </tr> <tr> <td style="padding: 5px;"><input type="checkbox"/> _____</td> <td style="padding: 5px;">20 Unstained, unbaked, charged slides at 4 micron thickness</td> </tr> </tbody> </table>			Type of Tissue Submitted to Pathology (Fresh or Archival)	Requested Processing	<input type="checkbox"/> _____	1 FFPE Tumor Block	<input type="checkbox"/> _____	20 Unstained, unbaked, charged slides at 4 micron thickness
Type of Tissue Submitted to Pathology (Fresh or Archival)	Requested Processing							
<input type="checkbox"/> _____	1 FFPE Tumor Block							
<input type="checkbox"/> _____	20 Unstained, unbaked, charged slides at 4 micron thickness							

4. MODIFYING REQUISITIONS

- In general, research staff should only fill out information related to participant and visit/case.
- If tests and/or collection tubes listed on requisition are not required for a particular collection, cross out (1) the test code(s) and (2) the corresponding test tubes with a single line and initial
 - *NOTE: Only cross out collection tubes corresponding to unwanted tests IF those same tubes re not needed for any additional tests on the requisition*
 - **IMPORTANT:** No alterations are permitted on pathology requisitions
- All original content must ALWAYS remain legible
- No additional notes, comments, or alterations are permitted. If requisitions require adjustments, contact SHRI
- **Requisition Reprints:** Duplication/photocopying is not permitted. If additional copies are required, contact SHRI

<p>REGISTRATION</p> <p>Order REQC and enter comment & RESRCH</p> <p><input type="checkbox"/> REPH (register REPH if collected by SH DS Staff, see above)</p> <p><input checked="" type="checkbox"/> ADMN <input checked="" type="checkbox"/> RSPR</p> <p><input checked="" type="checkbox"/> NA <input checked="" type="checkbox"/> CR <input checked="" type="checkbox"/> TP</p> <p><input checked="" type="checkbox"/> TB <input checked="" type="checkbox"/> DB</p> <p><input checked="" type="checkbox"/> CBC JD</p>
<p>COLLECTION</p> <p>1 – 4.5 mL Light Green Top Lithium Heparin Tube (Chemistry)</p> <p>1 – 4.0 mL Lavender Top EDTA Tube (CBC) JD</p>

Example 1

- In the above example, the pre-selected CBC test is not required for a particular patient visit since it was done recently as per standard of care by family physician. The test is correctly crossed out with a single line and initialed by study coordinator. The corresponding lavender top EDTA tube has also been crossed out since none of the remaining tests require this tube

5. ACCESSING LAB SERVICES

5.1 General Principles

- **When Can Project Begin Using Lab Services:** Shared Health resources, facilities, data, and services including DS Lab services can only be accessed after project has been activated (see *Figure 1* for full overview of milestones leading up to project activation)
- **When Will Requisitions Be Issued:** Upon project activation, if applicable, a physical activation package is sent to the person indicated as contact in case of inquiries related to patient visits. This package contains all relevant study documentation including SH research lab requisitions.
- **Sending First Patient for Labs:** Once research requisitions are received, the project may begin using lab services immediately EXCEPT for projects using central lab services (purple and salmon requisitions)
 - Projects using **Central Lab Services** are required to notify SHRI via email at least 10 business days prior to first planned patient visit
- **Days & Times during which Lab Services Can Be Accessed:** Unless otherwise specified, laboratory services may only be used during business days and dayshift times (between 8:00 and 16:15)
- **Requisition Reprints:** Duplication/photocopying is not permitted. If additional copies are required, contact SHRI. The turnaround time for processing additional requisition reprints is 5 business days
- **Documentation Return:** Upon completion of a study, a member of Shared Health Research and Innovation will correlate all study related documentation.
 - Local Research Requisitions will be disposed of in a confidential manner
 - Pathology Research Requisitions will be disposed of in a confidential manner
 - Central Lab Research Requisitions will be forwarded to the research team for archiving
- **Phlebotomy:** Maximum of 6 collections per study per day is allowed without prior authorization (3 morning or fasting collections and 3 afternoon collections)

Note: Research participants are not granted priority over clinical patients

5.2 Phlebotomy - Outpatient

- Outpatient phlebotomy is performed at SH phlebotomy laboratories

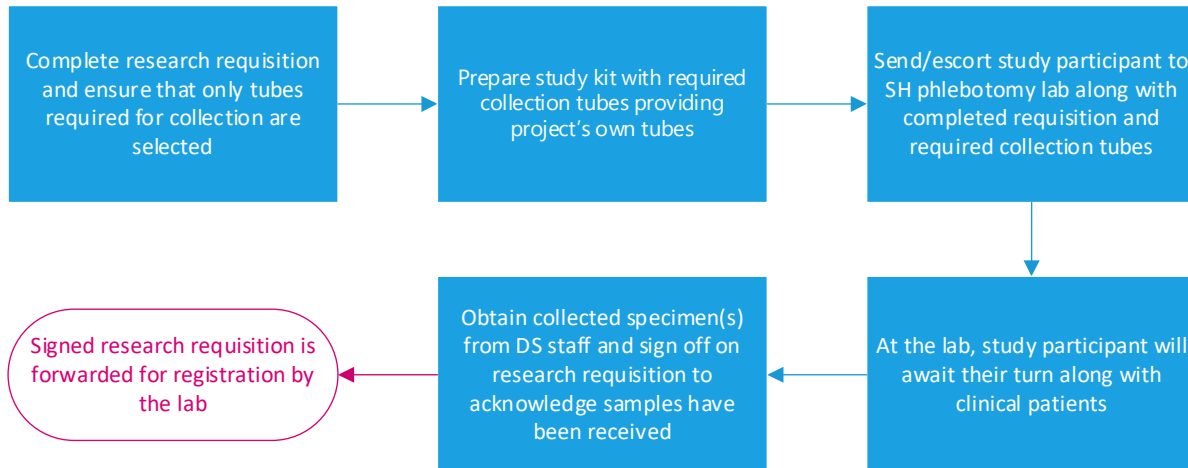


Figure 3 (Outpatient Phlebotomy)

5.3 Phlebotomy - Inpatient

- Inpatient phlebotomy is performed on hospital wards by designated staff
- Inpatient collections done by SH DS staff are to be performed along with daily clinical draws
- Research team is responsible for liaising with the nursing staff on the ward AFTER the study has been activated and PRIOR to first planned collection
- Research team must prepare **Study Kits** containing (1) all required collection tubes/containers and (2) completed research requisitions (and processing supplies in case of central lab studies) and leave them on the ward for staff to use

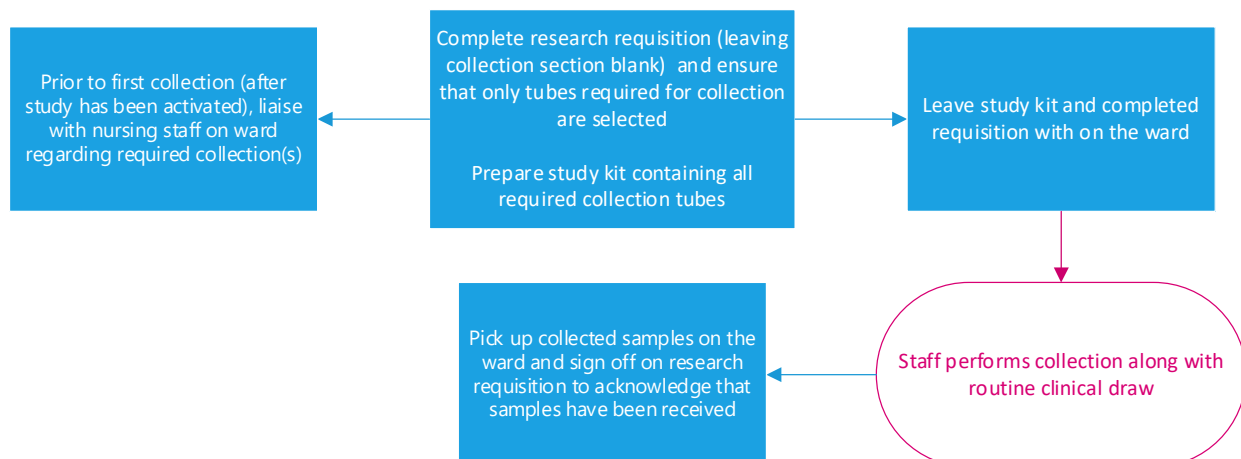


Figure 4 (Inpatient Phlebotomy)

5.4 Local (In-House) Testing

- Local (in-house) testing can take place either on the day of in-person study visit or later at any SH lab in the province. This means that study participants with a completed research requisition may get research testing done at their local lab without the need to travel to the study site

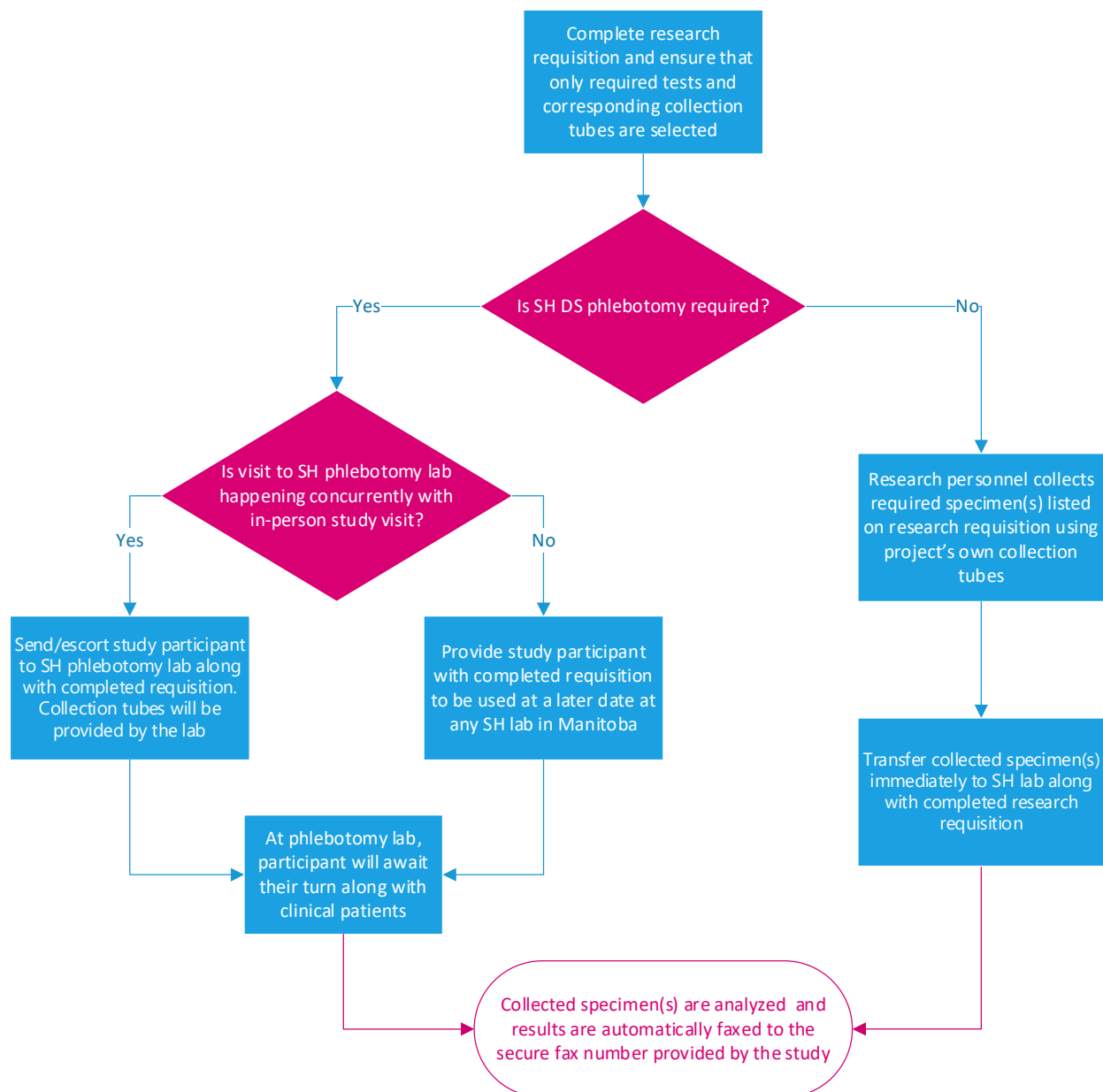


Figure 5 (Outpatient Local Testing)

5.5 Local (In-House) Testing – Inpatients

- Refer to *Phlebotomy – Inpatients* for general principles of in-patient collections.

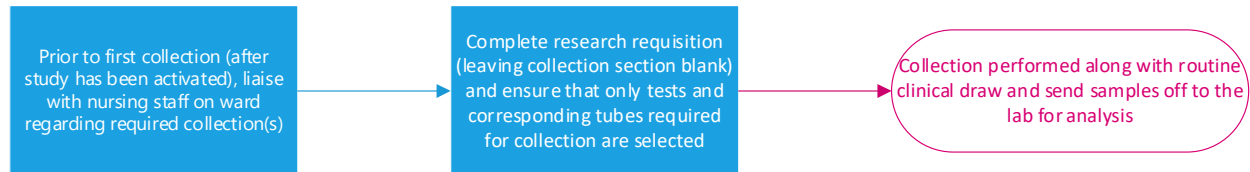


Figure 6 (Inpatient Local Testing)

5.6 Local (In-House) Testing with Additional Collection

- Local (in-house) testing with additional collection can only be done on the day of in-person study visit since the additional specimen(s) collected by the SH phlebotomy lab need to be picked-up by study designate

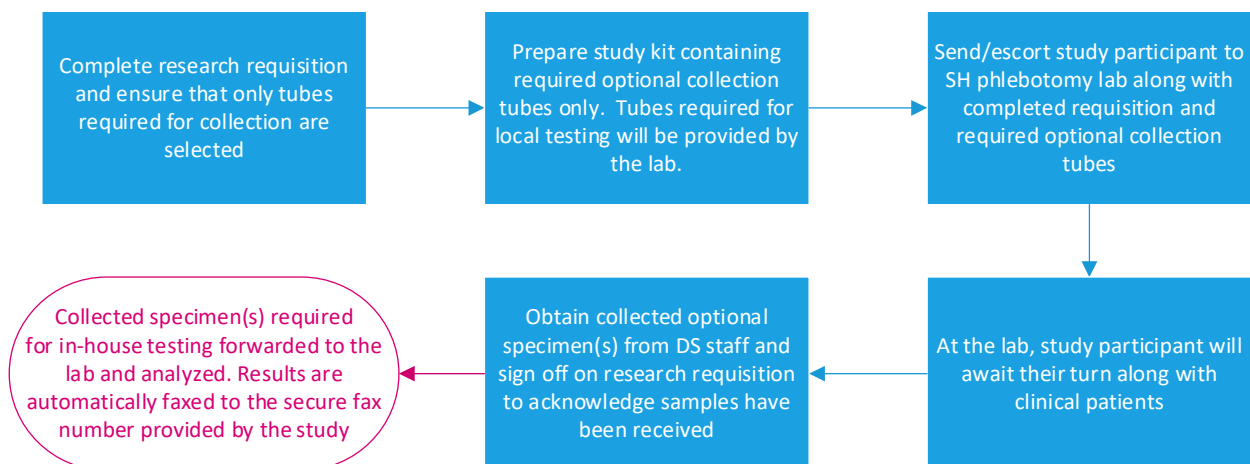


Figure 7 (Local Testing with Additional Collection)

- Inpatient Collection:** Refer to *Phlebotomy – Inpatients* and *Local (In-House) Testing - Inpatients*

5.7 Central Lab Services

- Central lab services may **ONLY** be accessed at the previously approved site(s) (listed in the lower right corner of research requisition)
- If central lab services are being used, an email notification to SHRI is required **10 business days** prior to first patient visit
- **ALL** collection, processing, and shipping supplies (e.g. collection tubes, aliquot tubes, labels, shipping boxes, etc.) are **supplied by the study**
- **Collection Supplies:** supplies necessary for collection of required specimens such as collection tubes and containers, labels
- **Processing Supplies:** supplies necessary for sample processing such as aliquot tubes and labels
- **Shipping Supplies:** supplies necessary for sample shipping such as boxes, labels, pre-filled waybill, completed study documentation (internal study-specific documents intended to accompany samples to their final location), and completed customs invoice/declaration if applicable
- **Study Specific Documentation:** DS Labs will not fill out any study specific documentation. If study documentation needs to accompany samples during shipment, this documentation is to be completed by study coordinator and submitted along with shipping supplies
- **Logging Stored Samples:** Samples requiring storage are recorded on *Research Samples Storage Log Sheet*. This is internal lab documentation and the research team is required to maintain their own sample log that could be cross-referenced in case of discrepancies

5.7.1 Sample Collection

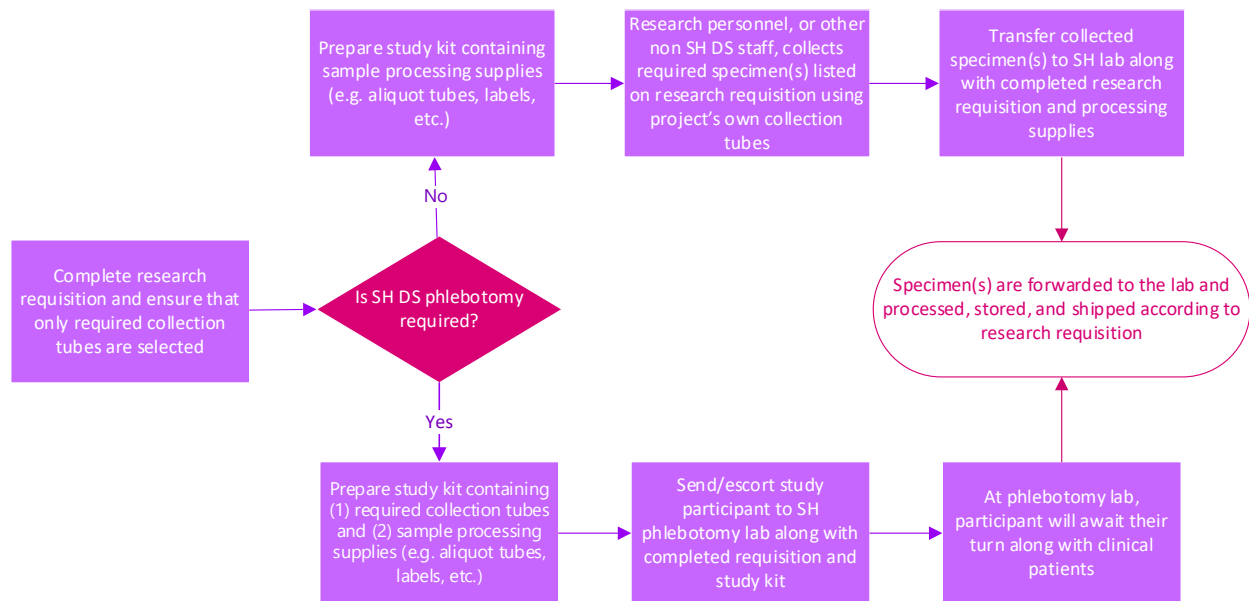


Figure 8 (Central Lab Sample Collection)

5.7.2 Sample Storage

- Samples are stored according to instructions on research requisition. If long-term sample storage is required, additional charges may apply

5.7.3 Sample Shipping

- **Same-Day Shipping:**
 - Samples are processed and shipped the same day
 - Samples must be received at the lab by the time specified on the requisition (
 - Shipping supplies must be brought to the lab drop-off area 1-3 days before the shipment or by 9:00 am on the day of shipment
 - **Frozen Samples:** Notify SHRI 10 business days prior to planned sample collection. This is to ensure that enough dry ice is available on site
- **Batch Shipping:**
 - Any time samples that are not shipped the same day will be batch-shipped upon notification **ONLY**
 - Notify SHRI 5-10 business days before requested shipment date
 - Attach a completed *Batch Research Shipment Request Form* listing all samples to be included in the shipment (available on SHRI website)

- If multiple shipments are requested, submit a completed form for each
- SHRI will inform the appropriate lab site and notify study coordinator about confirmed date
- **Shipping Supplies:** Must be brought to the lab drop-off area 1-3 days before the shipment or by 9:00 am on the day of shipment
 - **Waybill & Customs Invoice/Declaration:** Must be completed by the research team before it is dropped off with shipping supplies. Use the lab address as the sender address and use study's own FedEx account number
- *Note: A single research requisition may list samples requiring a combination of same-day and batch shipping*

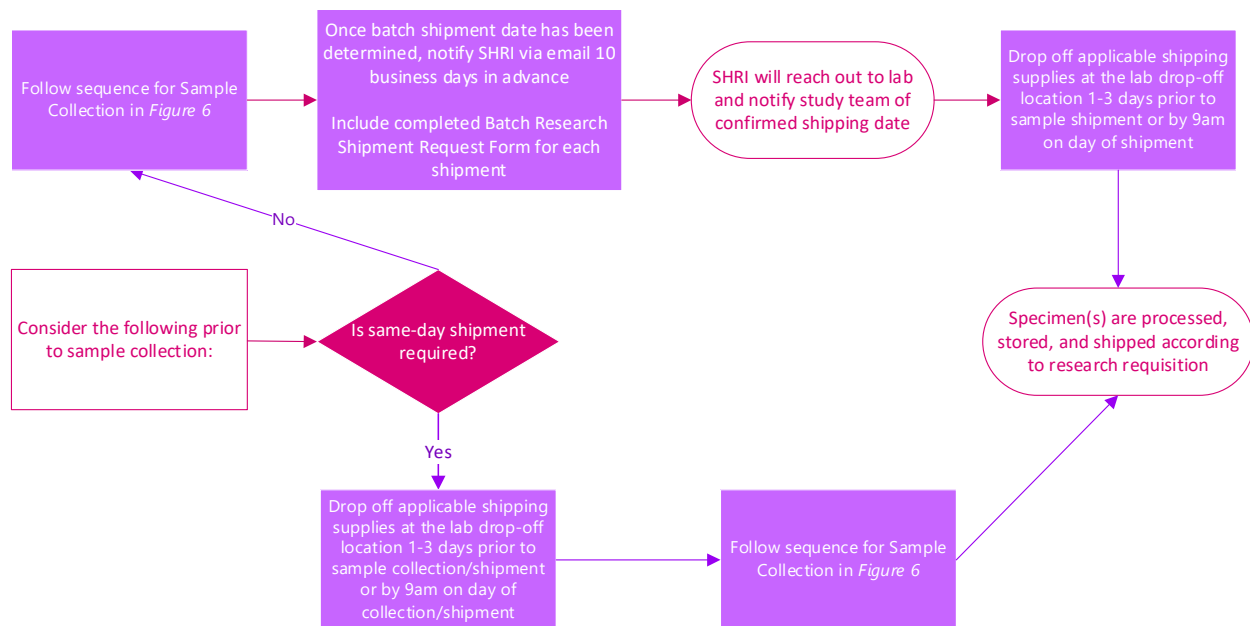


Figure 9 (Central Lab Shipping)

5.7.4 Sample Pick-Up

- If processed samples are being picked up by study designate, contact SHRI via email within 5 business days of requested pick-up date along with completed *Research Sample Pick-Up Request Form* listing all samples that are to be included with the pick-up

5.8 Pathology

- **Requisition Formats:** Pathology requisitions exist in electronic form or physical form
- **Complete Request:** Has 2 parts: (1) completed study requisition and (2) consent form signed by participant
- **Submission to Central HSC Site:** All complete requests are submitted to HSC Pathology office, either via email (electronic reqs) or interoffice/regular mail (physical reqs)
 - HSC Pathology office distributes requests to other sites if applicable and acts as a coordinating site
 - Requests can be submitted individually or in batches determined in consultation with SHRI
 - **Batched Requests:** Whenever a batch is submitted to pathology, the research team must wait until all requests have been processed and received BEFORE sending another batch
- **TAT:** The regular turnaround time for request processing is 5 business days for confirmations, 10 for human samples deliverables and 15 days for non-human samples deliverables
- **Sample Pick-Up/Shipping:** Once request has been processed, depending on what has been indicated on the requisition, the processing pathology site will EITHER contact the call person for pick-up OR ship samples to the destination specified on the requisition

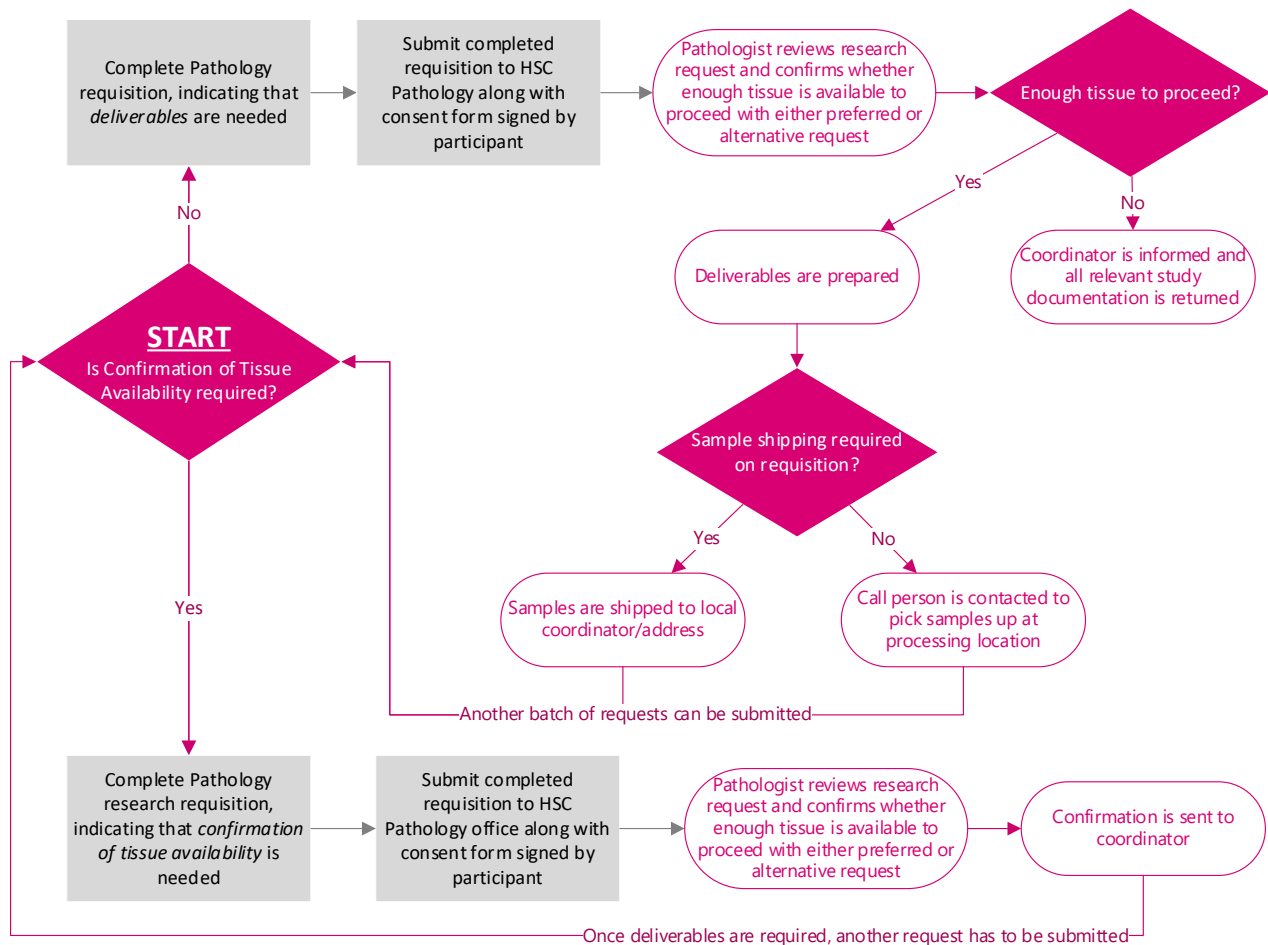


Figure 10 (Human Samples)

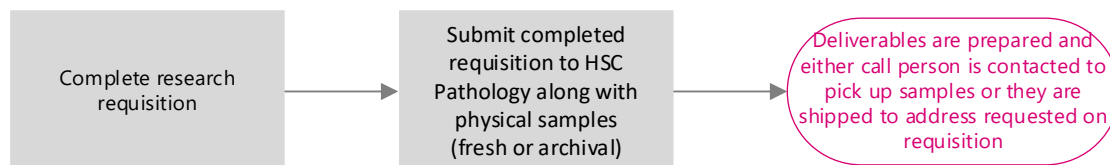


Figure 11(Animal Samples)

6. UNDERSTANDING LAB RELATED CHARGES

- **Setup Fee:** One-time fee charged for set-up of the laboratory component of the study. Includes protocol review & summary, institutional assessment, costing estimate, requisition preparation, lab system setup, billing set-up, general administration, etc.
- **Amendment Processing Fee:** Charge associated with the review of a subsequent amendment/change of personnel. Includes review of protocol and services, additional/modified requisitions, updated costing estimate, adjustments to billing, system update, general administration, etc.
- **Venipuncture / Specimen Collection:** Fee charged for each sample collection per patient / per collection
- **Specimen Accessioning:** Sample verification, labeling, and computer registry
- **In-House Processing / Instrument Load Fee:** Centrifugation and individual instrument load and analysis, completion and filing of paperwork
- **Central Laboratory Processing:** All Central Laboratory Processing is per patient / per collection and includes specimen/aliquot labeling, completion and filing of paperwork. Below are the **types of Central Laboratory Processing:**
 - **Basic Processing**
 - One centrifugation at required temperature and speed for samples
 - Up to 5 aliquots or preparation of differential slides
 - **Intermediate Processing**
 - Up to 2 different centrifugation cycles at required temperature and speed for samples
 - Up to 10 aliquots or preparation of differential slides
 - **Complex Processing**
 - More than 2 different centrifugation cycles at required temperature and speed for samples
 - Up to 20 aliquots or preparation of differential slides
 - Specialty separation
 - **Advanced Processing**
 - More than 2 different centrifugation cycles at required temperature and speed for samples
 - Greater than 20 aliquots or preparation of differential slides
 - Specialty separation
 - **Aliquot/Slide Preparation Only**
 - Up to 5 aliquots or preparation of differential slides

- **Shipping / Handling Charge:** All shipping / handling charges are per shipment and include coordination of sending out samples including retrieving packing materials/containers, completion of shipment paperwork, proper packaging of specimens, labeling containers and ensuring transport to courier pick up
 - **Ambient or Refrigerated, Same Day**
 - No additional / unique criteria
 - **Frozen, Same Day**
 - Ensuring sample(s) are frozen prior to shipping, dry ice sufficient for transportation
 - **Ambient or Refrigerated, Batch Shipment**
 - Retrieving samples, coordinating sending out multiple samples, short-term storage of samples according to specifications
 - **Frozen, Batch Shipment**
 - Retrieving samples, coordinating sending out multiple samples, short-term storage of samples according to specifications, dry ice sufficient for transportation
- **Long-Term Sample Storage:** Per patient / per visit. Storage greater than 1 year

7. LABORATORY DOCUMENTATION

- **Laboratory Accreditation:** SH laboratories are CAP and/or MANQAP accredited. For accreditation certificates, visit the [Diagnostic Services Accreditation page](#)
- **Laboratory Director's CV and Medical Licence:** Dr. Kabani's CV and medical licence are not routinely provided as these are reviewed by the accrediting body. If copies of these documents are required, contact SHRI
- **Laboratory Test Reference Ranges:** The reference ranges for Biochemistry and Hematology laboratories are updated annually and are provided by SHRI upon request. If specific tests are not listed, and for up to date information, consult the [Lab Information Manual \(LIM\)](#)
- **Lab Information Manual (LIM):** Lists all tests offered by SH laboratories. Consult [LIM](#) for test details and reference ranges
- **TDG/IATA Certification:** Laboratory staff responsible for shipments are TDG/IATA certified. Certificates are available upon request by contacting SHRI
- **Freezer Temperature Logs:** All freezer logs for freezers (-70C and -20C) used for storage of research specimens are kept rigorously by the lab. If copies of these records are required, contact SHRI with required date range(s)
- **Centrifuge Speed and Temperature Checks:** Every 6 months, all laboratory centrifuges are checked for speed accuracy and temperature if applicable. If copies of these records are required, contact SHRI with required date range(s)

8. CONTACT & INQUIRIES

- Contact SHRI directly via email at shresearch@sharedhealthmb.ca for **ALL** laboratory related inquiries such as lab services costing, requisition reprints and changes, missing test results, etc.
- **Central Laboratory Services:** Contact SHRI within 10 business days of first planned patient visit
- **Additional Copies of Requisitions:** Request should include (1) names of requisitions for which reprints are required and (2) quantity for each. SHRI will mail additional requisitions within 5 business days
- **Missing Lab Results:** Contact SHRI **immediately**. Most samples used for in-house testing are not discarded right away and testing can be repeated if missing results are reported within a couple of days
- **Requisition Discrepancies:** Before first using new and/or amended research requisitions, research coordinator needs to verify that they are free of discrepancies. Any discrepancies must be reported to SHRI immediately
- **Lab Services/Requisition Changes:** Any changes to lab services and/or changes required to research requisitions (e.g. added/removed tests, changes to processing instructions, change of coordinator, secure fax number, etc.), a completed Amendment and/or Change of Personnel (COP) form is required