SH Guidelines for Clinical Trials and Research Studies

SH reserves the right to adjust charges at its discretion without notice. A copy of the current Guidelines will be available online for reference.

If any tests or services required are not listed in the following document, please contact the SH Research Support Office (RSO)

Version Date: January 2020
Initial Documentation
In order to open a study for the laboratory component, the laboratory impact must first be assessed. The following documents are required in order to do so:

- Copy of current study protocol and any future amendments or amended copies for review and subsequent operational laboratory impact approval
- Completed SH Laboratory Research Impact Application
- If applicable, a copy of the Central Laboratory Manual
  - If laboratory manual is not available, complete the Central Lab Testing section of the SH Laboratory Research Impact Application

Study Submissions will be reviewed and assessed for laboratory impact within 10 business days of receipt of above documentation and once any questions regarding laboratory involvement have been addressed satisfactorily. At this time management sign off will be obtained and a cost estimate for laboratory services will be provided.

When completing a submission, please ensure that only testing that is above standard of care is being requested for research purposes. Standard of Care tests would be ordered on the patient even if the patient was not in the study & ordered on clinical requisitions. The results would be in the participant’s chart for access through Health Records. Above Standard of Care and Central Lab tests will require a Research Requisition custom-made for the study. Remember, frequency of testing is also a consideration when determining if a test is standard of care (eg. A battery of tests may be standard care every 4 weeks, but the study may require these same tests weekly).

Activating Laboratory Component
The following items are required following laboratory impact assessment in order to open a study for a laboratory component

- Central Laboratory Manual, if applicable
- Initial Central Laboratory Supplies, where required
- Research Ethics Board (REB) Approval

Study specific requisitions (local, central and/or pathology) will be created and forwarded within 2 weeks of receipt of all applicable requirements. If laboratory services are required sooner, notify the RSO as soon as possible to discuss.

Note: Pathology Study Requisitions requesting tissue must have a signed SH Patient Information and Consent for Release of Tissue or equivalent attached.

Ongoing Requirements
The following items are required as the study continues:

- Protocol amendments
- Copy of REB Annual Study Status form
- Subsequent Central Laboratory Supplies
- Notification of study closure for the laboratory component. The study requisitions and other study materials will be returned to you for archiving upon closure.
General Information

**Laboratory Notification**
When the 1st patient visit of a study is scheduled or expected, email the RSO.

If shipping of frozen samples is required on the day of collection, send a Study Visit Notification Form of scheduled visits 1 week prior to the patient visit. These forms may be implemented for all visits for certain projects.

**Laboratory Hours of Operation**
Laboratory dayshift is 0800h – 1615h

Any samples that are require shipping on day of collection, must be received in the laboratory by 1345h for processing, packaging and shipping, unless otherwise arranged during laboratory impact assessment.

Samples not requiring same day shipping must be received in the laboratory by 1500h to be processed on dayshift.

**Specimen Collection / Phlebotomy**
A maximum of 6 collections per study is allowed without prior authorization (3 morning or fasting collections and 3 afternoon collections)

For further information of specimen collection hours of availability, please contact the RSO. Only samples listed on the SH study requisition will be drawn for research purposes.

**Monitor, Site Selection or Site Initiation Visits**
To schedule an appointment or tour of the laboratory, contact the RSO at least 1 week prior to the intended visit.

**Accessing Study Documentation**
To arrange access or to request copies of any study documentation within the laboratory, contact the RSO.

**Central Laboratory Supplies**
Once a study has opened, all central laboratory supplies are to be forwarded directly to the laboratory, attention “Study Bench” with the Laboratory Study Code clearly marked on all supplies sent to the laboratory.

Due to space restrictions, at times a maximum number of shipping containers per study may be imposed.
Laboratory Documentation
Copies of the following documentation will be forwarded to the appropriate site Clinical Research Offices and all current study coordinators yearly. If you require copies the documents at any other point in the year, please contact the RSO.

LABORATORY ACCREDITATION
SH laboratories at St. Boniface General Hospital and Health Sciences Centre are CAP accredited along with the Pathology Laboratories at other SH sites.
All other SH laboratories are MANQAP accredited.
Copies of the current accreditation certificates can be found at http://SHanitoba.ca/about-SH/quality-management/accreditation/ or by contacting the RSO.

LABORATORY DIRECTOR’S CV & MEDICAL LICENCE
The Chief Medical Officer for Shared Health Diagnostic Services is Dr. Amin Kabani and he is responsible for all Manitoba’s public laboratory services. A copy of Dr. Kabani’s CV and Medical License are available upon request by contacting the RSO.

LABORATORY TEST REFERENCE RANGES
The Reference Ranges for Biochemistry and Hematology are updated yearly. If you require the reference values for a test that is not listed, you can access our Lab Information Manual online at http://apps.sbgh.mb.ca/labmanualviewer/index.do or contact the RSO.

TDG/IATA CERTIFICATIONS
Copies of Staff’s TDG & IATA Certifications for any staff involved with the shipping / handling of specimens.

FREEZERS & FREEZER TEMPERATURE LOGS
Copies of all freezer logs (-70°C and -20°C) used for storage of research specimens are kept on file. In the event that a monitor requires either the logs and/or freezer discs, please notify the RSO.

CENTRIFUGE SPEED AND TEMPERATURE CHECKS
Every 6 months, all Laboratory centrifuges are checked for speed accuracy and for temperature, if applicable. Clinical Engineering handles equipment repairs as required.
Definitions

**Participant**
Subject who is enrolled in a research study or clinical trial run in a SH facility

**Local Testing**
Any testing which is done within a SH facility, regardless of the need to refer testing to a referral laboratory within SH

**Local Testing Requisition**
A study specific requisitions which is created by the RSO. This requisition lists the testing required for a particular visit.

**Central Laboratory**
A laboratory which will be completing testing for a particular project and is contracted by the study sponsor. Samples going to this facility must be processed and sent out according to specifications set out by the Central Laboratory. These requirements will be listed on the SH Central Laboratory Requisition.

**SH Central Laboratory Requisition**
A study specific SH requisitions which is created by the RSO and outlines the requirements for collection, processing and shipping for a particular visit.

**Properly Completed Requisition**
A study test requisition which has been filled out completely so as to indicate that an appropriate specimen has been collected to correspond to the orders on the requisition

**Internal Referral Laboratory**
SH reference laboratories: Westman Laboratory, Health Sciences Centre and St Boniface General Hospital

**External Referral Laboratory**
Non-SH laboratories to which diagnostic testing is referred (i.e. Mayo Clinic, Hospitals-in-Common, etc).

**Biological Materials**
Human tissue (including normal and abnormal organ materials), hair, blood serum or plasma, body fluids, DNA, etc.

**Designated Pathologist**
The pathologist who has been contacted by the principal investigator, has agreed to be the main pathology contact person in partnership with the Principal Investigator, and will be responsible for the selection of tissue (blocks/slides) to be released.

**Essential Tissue Blocks**
Any paraffin blocks containing patient tissue deemed to be of diagnostic importance for the staging of disease.

**Non-Essential Tissue Blocks**
Paraffin blocks containing patient tissue deemed not to be of diagnostic importance for the staging of disease.

**SH Research Advisory Committee (RAC)**
The committee established by SH to oversee use of tissue and/or pathology data for health research requested from SH Sites (formerly PACT). The role of the RAC is to review the efficacy and scientific and ethical value of a research proposal.
involving human subjects and biological materials and ensure that the Principal Investigator proposing the research has adequate safeguards in place to protect the confidentiality of personal health information.

**Principal Investigator**

The person who is designated as being responsible for the intellectual direction of a particular clinical trial or other research project.

A clinician or basic scientist with proven qualifications.

**Reporting Pathologist**

The pathologist that is responsible only for the diagnosis of the biological material and is the reporting pathologist for legal purposes. A reporting pathologist may also serve as a Designated Pathologist through a consensual agreement between the Reporting Pathologist and the Principal Investigator.

**U of M Research Ethics Board**

The University of Manitoba Biomedical Research Ethics Board (BREB) and the Health Research Ethics Board (HREB)
Pricing Information

**Clinical trial/research study setup/admin fees**
Protocol review & summary, laboratory impact assessment, management review & sign off, communications, estimate/quote preparation, requisition preparation, computer system setup (delphic), laboratory setup, staff in-services, document management and billing

- Local Testing Only
- Central Laboratory Study
- Pathology Only
- Complex Study

**Alternate/additional site setup/admin fee**
Cost of admin/set up to provide service at alternate/additional site(s) – per site Example: additional hospital or laboratory site

**Protocol change fee**
Subsequent protocol review due to change and/or amendment that requires additional/modified requisitions, updated cost estimate, etc.

**Miscellaneous admin work / meetings**
Attending study meetings, attending courses, pulling reports, compiling results, etc.

**Venipuncture / Specimen Collection**
Per patient / per collection
Identification, laboratory or unit collection, labeling and transportation of specimens

**Specimen Accessioning**
Verification, computer registry and sample labeling

**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 as well as one of the criteria below

**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 6 months

Notes:

- Batch shipment charges are applied after shipment has been sent. Information will be recorded at time of shipment including # of samples / aliquots sent, quantity of dry ice, etc.
- Shipping supplies are to be supplied by the clinical trial or research study.
- Clinical trial or research study must supply preprinted waybills and are responsible for all charges
- Cancelled clinical trials/research studies will be charged setup/admin fee as appropriate
- Shipping cost of tests being conducted at MAYO / HICL not included