DIAGNOSTIC SERVICES
MANITOBA

Research Support Office

Suite 1502 – 155 Carlton Street Winnipeg, Manitoba R3C 3H8 Telephone 204-926-7020 Pager 204-931-2011 Email RSO@dsmanitoba.ca

DSM Guidelines for Clinical Trials and Research Studies

DSM 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 DSM Research Support Office (RSO)

Version Date: January 2018

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 DSM 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 DSM 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.

Please ensure that only testing that are above standard of care are 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.

Please note that site approval is required prior to the commencement of study related activities. Laboratory approval does not constitute site approval and it is the responsibility of the principal investigator to ensure that all adequate approvals have been received prior to initiation.

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.

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 DSM 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

DSM laboratories at St. Boniface General Hospital and Health Sciences Centre are CAP accredited along with the Pathology Laboratories at other DSM sites.

All other DSM laboratories are MANQAP accredited.

Copies of the current accreditation certificates can be could at http://dsmanitoba.ca/about-dsm/quality-management/accreditation/ or by contacting the RSO.

LABORATORY DIRECTOR'S CV & MEDICAL LICENCE

The Chief Medical Officer for Diagnostic Services of Manitoba (DSM) 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 are available upon request by contacting the RSO.

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 DSM facility

Local Testing

Any testing which is done within a DSM facility, regardless of the need to refer testing to a referral laboratory within DSM

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 DSM Central Laboratory Requisition.

DSM Central Laboratory Requisition

A study specific DSM 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

DSM reference laboratories: Westman Laboratory, Health Sciences Centre and St Boniface General Hospital

External Referral Laboratory

Non-DSM 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.

DSM Research Advisory Committee (RAC)

The committee established by DSM to oversee use of tissue and/or pathology data for health research requested from DSM 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