



Title: Human Biological Material
Policy

Site(s): DSM

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Written By: Research Support Office

Signature:

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1.0 **PURPOSE:**

- 1.1 To ensure that human biological materials are provided to researchers in accordance with the University of Manitoba's Guidelines for Research Involving Stored Biological Materials and the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans August 1998.
- 1.2 To ensure that biological materials are released for clinical trials and research studies only in a manner that will not compromise clinical care to the patient or medical legal obligations of the reporting pathologist, Diagnostic Services Manitoba (DSM), and the attending physician.
- 1.3 To detail the conditions and restrictions on DSM's ability to provide human biological material to researchers.

2.0 **DEFINITIONS:**

- 2.1 Biological Materials: Human tissue (including normal and abnormal organ materials), hair, blood serum or plasma, body fluids, DNA, etc.
- 2.2 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.
- 2.3 Essential Tissue Blocks: Any paraffin blocks containing patient tissue deemed to be of diagnostic importance for the staging of disease.
- 2.4 Non-Essential Tissue Blocks: Paraffin blocks containing patient tissue deemed not to be of diagnostic importance for the staging of disease.
- 2.5 DSM Research Advisory Committee (RAC): The committee established by DSM to oversee use of biological material and/or data for health research requested from DSM Sites (formerly PACT). The role of the RAC is as follows:
 - To review the efficacy and scientific and ethical value of a research proposal involving human subjects and biological materials.
 - To ensure that the Principal Investigator proposing the research has adequate safeguards in place to protect the confidentiality of personal health information.
- 2.6 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 and is responsible for the conduct of a study.
- 2.7 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.
- 2.8 Research Ethics Board: The Biomedical Research Ethics Board (BREB) and the Health Research Ethics Board (HREB) at the U of M, Bannatyne Campus.

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- The BREB reviews all research ethics protocols involving clinical trials and other biomedical research interventions.
- The HREB reviews research from the Bannatyne Campus involving the behavioral sciences, surveys, examinations, of medical records and protocols of generally lesser risk.

2.9 Stored Biological Materials: Biological materials stored for future reference.

2.10 Subject: The donor of the biological sample to be consistent with the Tri-Council Policy Statement. Also referred to as the 'participant'.

2.11 Tissue: Fresh tissue and frozen samples of fresh tissue, tissue slides, paraffin embedded blocks, and tissue cores from paraffin embedded blocks.

3.0 **POLICY**:

3.1 Requests to access human biological materials from all DSM Sites in Manitoba shall be submitted to and approved by the U of M REB (or equivalent).

3.2 The Principal Investigator is responsible for ensuring that all applicable approvals are in place prior to initiation.

3.3 The Principle Investigator shall submit the following documents to the DSM Research Support Office for all research requests:

- Completed DSM Laboratory Research Impact Application
- The study protocol and all subsequent amendments.

3.4 The Laboratory Site Director must approve the utilization of any DSM resources for all research projects.

3.5 For all requests involving access to biological materials and/or data:

3.5.1 The DSM Research Support Office shall advise the Principal Investigator, whether the research project is approved or refused, including the laboratory fees that apply to the approved projects.

3.5.2 The DSM Research Support Office shall advise the applicable departments/staff of all approved research projects.

3.5.3 When a request for biological material is submitted, a DSM Study Requisition must be submitted.

3.5.4 When a request for biological material is submitted, a signed copy of an approved DSM Patient Information and Consent form, or equivalent must be submitted.

3.6 For all requests involving access to pathology materials and/or data:

3.6.1 The Principle Investigator shall identify and recruit a Designated Pathologist. Designated Pathologists will familiarize themselves with the details of the study, including tissue release and will sign off on the Pathology Study Requisition.

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- 3.6.2 The Principal Investigator shall forward requests to access tissue and/or pathology data from DSM Sites to the RAC for approval.
- 3.6.3 RAC shall advise the Principal Investigator whether access to the tissue and/or pathology data is granted or refused.
- 3.6.4 The processing technologist/technician shall consult with the Designated Pathologist when slides are requested in accordance with the terms as set out in the Pathology Study Requisition.
- 3.6.5 When tissue blocks are requested and the Designated Pathologist determines that more than one block is available, any block deemed non-essential to diagnosis that contains representative diagnostic tissue may be selected (by the Designated Pathologist) and released.
- 3.6.6 When the Designated Pathologist has determined that there is only one remaining block that contains diagnostic tissue, that block will not be released.
- 3.6.7 When the Designated Pathologist determines that tissue blocks in the file contain evidence of diagnostic importance to stage of disease (surgical margins, lymphovascular invasion, etc) they will not be released.
- 3.6.8 The Pathology Study Requisition will be signed off by the Designated Pathologist specifying the tissue which may be released.
- 3.6.9 Fees shall be charged for the pathologist to assess the tissue and any work incurred for the request.

4.0 **PROCEDURE:**

- 4.1 The Principal Investigator is responsible for submitting the approval of the U of M Research Ethics Board (or equivalent) to the DSM Research Support Office prior to the project initiation. Once received a DSM Study Requisition will be created by the Research Support Office to facilitate collection and billing information. The DSM Study Requisition(s) will be provided to the PI or Study Coordinator
- 4.2 For all requests involving access to tissue and/or pathology data:
 - 4.2.1 Tissues or slides that are removed from the files are documented as an event in the Anatomical Pathology System.
 - 4.2.2 The DSM Research Support Office will obtain the approval/signature of the DSM Pathology Medical Director in the event that the Research work is being done in lieu of clinical workload, as approved by DSM Pathology Medical Director as stated on the DSM Laboratory Research Impact Application.
 - 4.2.3 When a pathology request must be amended or declined, the processing technologist/technician will return the Pathology Study Requisition, the signed Patient Consent and other pertinent request documents to the PI or Study Coordinator to inform them of this decision.

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5.0 **REFERENCES:**

Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans August 1998.
U of M Research Ethics Guidelines for Research Involving Stored Biological Materials.
DSM Research Advisory Committee
Records & Materials Retention Policy

6.1 **APPENDIX:**

- (A) Patient Information and Consent for Use of Tissues (Form F220-10-02A)
- (B) DSM Laboratory Research Impact Application
- (C) Sample DSM Study Requisitions