Interim Pathology Study Process

1. The Principal Investigator (PI) is responsible for identifying and recruiting a Collaborating Pathologist. A signed Pathology Collaboration Agreement (Form # F170-120-01C, available on DSM Website) between the PI and the Collaborating Pathologist must be submitted by the PI to the Research Technician or laboratory contact person.

2. The Principal Investigator is also responsible for submitting the following documents to the Research Technician or laboratory contact person:

    - The study protocol and all subsequent amendments.
    - A University of Manitoba Research Ethics Board (REB) approval. (An up-to-date REB approval is required if any amendments have been made to the original study protocol).
    - Pathology Access Committee for Tissue (PACT) approval.
    - Operational impact approval with Signature of Laboratory Supervisor and Site Manager**. (**Without operational impact approval, the clinical trial or research project will not be allowed to proceed even if all other approvals have been granted).
    - St. Boniface Research Review Committee Approvals (where applicable).

Once all approvals as stated above have been received, a DSM Pathology Study Requisition will be created by the Research Technician (or laboratory contact person) to facilitate collection and billing information. The DSM Pathology Study Requisition(s) will be provided to the PI.

3. When the PI submits a request for tissue to pathology, the DSM Pathology Study Requisition and a copy of a signed DSM Patient Information and Consent for Use of Tissue form (Form # F170-120-01B, available on DSM Website) must be included with the request.

4. The Collaborating Pathologist will be consulted when slides are requested in accordance with terms as set out in the Pathology Study Requisition.

5. When tissue blocks are requested and the Collaborating 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 Collaborating Pathologist) and released.

6. When the Collaborating Pathologist has determined that there is only one remaining block that contains diagnostic tissue, that block will not be released.

7. When the Collaborating 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.

8. The Pathology Study Requisition will be signed off by the Collaborating Pathologist specifying the tissue which may be released. When a request must be amended or declined, the pertinent documents will be returned by the processing technologist/technician to the Study Coordinators / Principal Investigators to inform them of these changes.

9. Pathology must document what has been given to the research study from the clinical specimen.
    a. Tissues or slides that are removed from the files are documented as an "**EVENT**" in the AP system.