# I. Specimen Procural Procedures

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| **Picking up Specimens from OR** | Circulating nurses must receive the **written request for notification** and details of what is needed per each protocol and the **patient’s signed BioNet or research consent** prior to case start. Cases must be closely monitored throughout the day for any schedule changes.**Specimens must be picked up immediately after notification of excision**.When picking up a specimen in the operating room, ensure that the specimen is labeled with patient label and a written description of the specimen source and alphabetical designation e.g. “A. Uterus, tubes and ovaries”, “B. Omentum” and verbally confirm with the circulating nurse that it is the correct specimen. The circulating nurse will enter that you picked up the specimen in the electronic record. Take specimen to gross room. If a PA is there, let him/her know that a case from which we would like tissue is out. If a PA is not available, ask a senior resident or staff to give us tissue, outlining what we would like from the case. A PA or a senior resident (the one who is currently covering frozens) should be paged if there is no one in the gross room. Tissue can be given to TPF by PAs, Surgical Pathology staff, or residents in training with prior staff approval (i.e. moonlighting residents for collection after standard business hours).  |
| **Procurement of Tissues**Responsible Parties: All Technicians, Lab Coordinator | **When collecting tissues you MUST wear eye protection and other PPE (gloves, jacket or lab coat) and use universal precautions***. (http://www.dehs.umn.edu/PDFs/exposecontrol-plan.pdf* Log the time that the tissue was excised on the demographic sheet and which specimen was obtained (A, B, etc.). The PA, resident or staff will examine the specimen (e.g. weigh, measure, ink for margins, etc. as needed) and may gross the case in at this time. If grossed in, an accession number will be generated by the gross room staff prior to the examination and labeled cassettes will be generated for that case. If the pathologist determines that there is waste tissue that will not be needed for diagnosis, s/he will give a portion to the TPF for research purposes. Tissue samples should then be moved to the Biological Safety hood for processing.**Tissue samples should be collected per researcher/study protocols**. Copies of study protocols are kept in the lab procedure book as well as next to the Biological Safety hood where tissues are processed. Any tissue available after procural for prospective studies should be collected and banked for future potential studies.For General Biobanking:* Ensure that clean instruments and blades are used for each case. If collecting multiple disease states or tissue types (i.e. tumor and normal) a clean set of instruments/blades must be used to prevent contamination.
* Snap freezing samples:
	+ Samples should be divided so that they fit loosely in 1.8 ml cryovials. Samples should be weighed either by using a weighing boat/weighing paper (must be changed per tissue type and ensure that the scale is zeroed each time a sample is weighed) or may be weighed in the storage container after zeroing out the scale using the container to be used. If orientation may be an issue, such as full thickness colon, samples should be frozen flat in double thickness foil packets instead of cryovials.

Specimen aliquots are then frozen by immersing them in a thermos of liquid nitrogen for at least two minutes.* Fixing Samples to be Embedded:
	+ All specimens with sufficient tissue must have a mirrored sample fixed in formalin and paraffin embedded so that a scout slide can be created and read for quality control. If the tumor has grossly different areas, a separate mirrored sample should be put processed for paraffin embedding to ensure that the scout slide accurately reflects the frozen sample. If the sample is not of sufficient quantity, the adjacent area embedded for the clinical case should be noted for review. The sample to be embedded should be put in a labeled cassette and placed in the formalin container. Sufficient formalin must be in the container to ensure proper fixation! The fixed samples and associated log sheets must be taken to the BioNet histology lab nightly.
* If at all possible, samples should be processed within 30 minutes of excision.

Barcoded labels will be created in caTissue once the case is entered. To ensure accuracy, the following hand labeling system will be used for unplanned collections.Label appropriate storage container in the following manner:Foils/cryovials/OCTs/researcher provided media Use a black permanent marker. first line: TYYXXXX – X (T, two-digit year, sequential TPF #, sub-id to designate piece of same tissue type), second line: tissue source (if there is any question about malignancy, label “mass” instead of “tumor”) and third line, date of tissue procural. If an error is made, the storage container must be discarded and a new one labeled. The error must not be simply crossed out or altered.Example: A piece of the left ovary tumor mass was procured on April 2, 2010 at 10:45 AM. The next sequential tissue number is “789”. The second sample of this ovary would be designated:1rst line: T100789-22nd line: left ovary mass 3rd line: 4/2/10Paraffins: holding the blue cassette with thumb inside the concave area and slanted edge on top, and using a #2 pencil, start on left side and write the T# and sub-id (ie. T100789-4). Rotating counter-clockwise, label the side of cassette with the specimen source (e.g. Left ovary mass). On the opposite flat edge, write the T# again on the side.  |
|  | Log all T-numbers on the QC sheet (see example attached). If there is a cassette for that T #, include the sub-id of the paraffin specimen and put “1” for number of cassettes, “1” for the number of slides to be made and then check that there is a QC. Add the pathology number (if accessioned immediately) and the type of tissue and the time and date that a specimen was placed into formalin. After procural, double check with whomever gave you tissue that specimen can be placed in formalin. If s/he confirms that the specimen can be fixed, place specimen in the pathology container and place in formalin. Place a label that says **“PLEASE DICTATE: Representative tissue was procured for potential future studies from specimen \_\_\_\_\_\_”** on the container as well as on the paperwork for the case. Place pathology container with specimen inside on the right side of the computer where specimens are accessioned. Clean area where tissue was procured using bleach (bleach is available underneath the hood as well as on the shelves of the grossing stations), and place instruments used in a soaking bath (on Surgical Pathology specimen cart). All disposable items such as weighing boats should be discarded in the biological hazard waste. Remove all blades from handles and dispose of them in a sharps container.* Have whoever gave the tissue sign the bottom of the clinical data and specimen collection sheet to indicate that s/he has given you tissue after tissue samples have been processed. **NOTE: Any samples given out fresh prior to sign out of the clinical case must have an additional signed permission from Pathology staff or designee (PA) that s/he is aware that the specimen is going to be given out fresh and cannot be retrieved for the clinical case.**
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| **Storage of Specimens** | * Transfer of specimens should minimize the amount of time frozen samples might be exposed to warmer temperatures. Once frozen, samples should be placed in a dry ice cooler to be transferred to the freezer room. Using plenty of dry ice, samples should be sorted in numerical order and placed in the appropriate temporary boxes by process type (cryovials, foils or embedded in OCT blocks)
* The temporary boxes are stored in the -80 mechanical freezer (1) until cases are logged into caTissue and storage locations are assigned. (See caTissue protocols for space assignation guidelines.)
* Samples for prospective procurement that are sent out monthly, OCT blocks, urine samples and DNA samples are kept at -80 C. Solid tissue to be banked is kept in vapour phase liquid nitrogen.
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| **Quality Control** | * As soon as the Pathology Case on which tissue samples have been procured for potential research is final, review the case to ensure that a) documentation of procurement is written into the pathology report and b) that the pathology report matches the patient and the patient’s presumed clinical history. If there are any concerns, for example, if there was presumed tumor and no tumor was found, the pathologist who signed out the case must review and, if applicable, give approval for the research samples to be utilized rather than be put through as part of the case.
* If the dictation “Representative tissue was procured for potential future studies from specimen \_\_\_\_\_\_” is missing or with the incorrect specimen, a form notifying the pathologist who signed out the case must be filled out and given the the pathologist.
* As soon as the scout slides and FFPE specimens are processed in BioNet histology, slides and embedded samples are confirmed received on the log and the slides are sent to the Surgical Pathology fellow assigned to review the slides. The Surgical Pathology fellow will review the case for histologic quality and confirm the diagnosis as well as note the percentage of tumor making up the sample as well as the percentage of necrosis within the tumor on the scout slide log sheet. The fellow may review these slides with the staff pathologist signing out the clinical case.
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**Informed Consent and Institutional Review Board (IRB) Status and Protection of Human Subjects Assurance Declaration**

The UMN IRB mandates that we submit an annual progress report (continuing review) for the activities of the Tissue Procurement Facility. This has been approved each year since 1996.

Researchers internal to the UMN must either have a UMN IRB approval or documentation from the UMN IRB that the project for which they are utilizing biospecimens or data is exempt. External entities must have independent IRB approvals for the project, or if de-identified as part of an agreement (i.e. on the UMN BTDSA, the BAA section is checked as “Not Applicable”), will have distribution documented with the IRB at the time of continuing review. Information given to the UMN IRB includes the entity to whom distribution of either data or specimens was completed and a list of relevant documents (maintained in BioNet) that regulate that distribution.

**Material Transfer Agreement (MTA)**

**Material Transfer (MTA) and Data Use Agreements (DUA) are routinely used at the University of Minnesota. A standard DUA template from the UMN IRB is listed at the following website: (**www.irb.umn.edu/download/DATA%20USE%20AGREEMENT.rtf - 2010-05-18)**. BioNet, in conjunction with the Office of General Counsel, the Institutional Review Board and the Office of Privacy and Security developed a template for a standard BioNet Tissue and Data Services Agreement (UMN BTDSA,** [www.ogc1.umn.edu/stellent/groups/ogc/documents/contract/OGC-SC129.doc - 2011-09-01](http://www.ogc1.umn.edu/stellent/groups/ogc/documents/contract/OGC-SC129.doc%20-%202011-09-01)) **for the procurement and distribution of Biospecimens and data to entities external to the UMN.**