

Use of Prospective Pathology Samples

PRINCIPLE

Surgical Pathology operates on the principle that all tissue removed from a patient, unless designated on the Specimen Exemption List (Policy Lab 3 Appendix 1), must be submitted intact to the pathology laboratory for examination by pathology staff. Exceptions are samples of tissue for diagnosis and patient care which must be removed sterilely, eg. for culture. Material is not considered excess until pathological examination and diagnosis are completed and appropriate samples are saved and stored as per standard pathology laboratory protocols.

Clinical Pathology operates on the principle that ordered tests are run promptly and that leftover sample is saved to allow for repeat or additional testing. The length of retention of remaining sample is dependent on the stability of the sample and therefore differs with specimen type. The criteria are specified in each clinical pathology laboratory area and for each specimen type.

It is recognized that some research projects will require access to patient material sooner than is our standard practice. Also, some research projects will need the sample to be processed differently than standard practice. The following requirements are to be followed to facilitate these project needs while not interfering with patient care or violating the principles of human subjects research, specifically respect for persons (autonomy) or beneficence (minimizing risks in the setting of no benefit to the patient).

The following requirements apply to studies that are not sponsored clinical trials. For sponsored clinical trials the patients are consented and separate handling of their specimens is part of their clinical care for the trial.

For any protocol for which the patient sample will be handled differently than our SOP, patients must be specifically consented to allow this. This requirement will apply even for studies for which the samples will be de-identified or anonymized.

SURGICAL PATHOLOGY

NO tissue specimen is classified as LEFTOVER/REMNANT/DISCARDED/EXCESS until the specimen diagnosis is signed out by the attending pathologist.

The sign out process may take a few days to a week or more. The unprocessed portion of the specimen is retained in formalin in the event that additional material needs to be submitted for microscopic examination. Therefore, to obtain fresh or frozen tissue, several requirements must be fulfilled as outlined below.

General

- All procedures must follow the IRB-approved protocol. All personnel handling the specimen for the research protocol must be part of the IRB application.
- **CONSENT:**
Patient consent must reflect the difference in tissue handling and refer to the fresh tissue as a sample or piece of tissue rather than leftover/ remnant / discarded/ excess tissue.
- **PROTOCOL & PATHOLOGY APPROVAL:**
Sampling will be conducted under the guidance of the pathology personnel unless special permission has been granted by the research representative of the pathology department.
- The procedure for opening and sampling the specimen will be reviewed and agreed upon by pathology at the time the research protocol and pathology approval Step I are written and will be part of both documents. This will apply whether pathology, surgery, or research personnel are taking the sample.

TUMOR SPECIMENS coming to Surgical Pathology:

1. A study **pathologist** must be included on the project and must assume responsibility for taking the sample.
2. **Minimum Size of Tumor** must be specified in protocol and pathology forms. Samples may not be taken from tumors below this pre-determined minimum size. The minimum size requirement will depend on the type of specimen. Where available, the size of lesional tissue should be judged on radiographic studies prior to surgery and discussed with the pathologist and then verified by the pathologist on gross examination of tissue.
3. **Size of sample** to be taken must be specified in protocol and pathology forms.
4. **Tumor type.** If a report is available, the study pathologist must preview any biopsy or biopsy report to see if any unusual circumstances of the case preclude taking sample (ie. combination tumors).

5. Statements regarding avoidance of **margins, interface with key structures, and depth of invasion** when taking the sample must be included in both the protocol and pathology documents.

Study pathologist must dissect the tumor for the research tissue sample. Any margin which will be disrupted should be inked prior to dissection.

6. Photographs of gross specimen may be required, based on specimen type, and must be taken by the pathologist before and after sampling.
7. The study pathologist must consult with the grossing resident and sign-out pathologist and communicate the details of the gross description of the tumor and the sample taken. This may be accomplished via providing a descriptive sheet with the appropriate details or by entering the gross description directly into CoPath. The choice of approach will be stated in the pathology approval and protocol and agreed upon for each study.

TUMOR SAMPLES removed in OR

PRINCIPLE: For surgeries of definitive removal of tumor, grading and staging of cancer cannot be compromised. These proposals will need to be carefully reviewed by pathology for feasibility. Please see Instruction sheet.

1. Pathology will need to be notified in advance of surgery if a tumor specimen is to be sampled in the OR. The specifics of the case (radiographic evidence of tumor size, issues of tumor histology, etc) will be reviewed so that any needed modification of the specific approach can be agreed upon.
2. No tumor <1 cm in size may be sampled for research in the OR. No sampling may involve a margin of resection.
3. If tissue is removed in the OR, the surgeon will note this in the operative report and on the pathology request sheet. The size of the tissue removed will be noted and the area from which it was removed will be indicated.
4. Size of sample to be taken must be specified in protocol and pathology forms.
5. The pathology attending responsible for the case will indicate in his/her sign-out that a sample was removed in the OR.

NON-TUMOR SAMPLES coming to Surgical Pathology or taken in the OR

- Many of the same considerations apply, the details depending on the lesion (or normal) tissue being sampled. These need to be provided in the protocol and pathology feasibility review (Step 1) and will require meeting with a designated pathology representative depending on the type of cases.

CLINICAL PATHOLOGY

- No left-over specimen may be taken prior to running and verifying the requested tests.
- Any specimens removed from the laboratories will be noted in a log book kept for the individual project.
- The conditions of specimen retrieval and research personnel involved will follow the IRB-approved protocol. Laboratory supervisors will be notified as to the names of the approved personnel.