

## **PATHOLOGY REVIEW - GENERAL INFORMATION**

### **I. Purpose**

Research using human tissue from patients at NYPH-WMC must have Pathology review and approval. This is necessary --

- to ensure procurement does not adversely impact patient care,
- to ensure sufficient tissue is available for diagnostic, prognostic, staging and therapeutic monitoring purposes,
- to ensure compliance with federal, state, local and hospital regulations and
- to facilitate procurement of tissue by investigators that have approved protocols.

### **II. Tissue Submission Policy**

As per JCHO, all human tissue removed during a diagnostic or therapeutic procedure must be submitted intact to Surgical Pathology, with the exception of tissues designated as surgical waste by NYPH-WMC's Medical Board (see below).

### **III. Definition of Human Tissue - for purposes of Pathology and IRB Review**

Human tissue **includes**:

- placentas,
- umbilical cords,
- umbilical cord blood,
- bone marrow aspirates,
- fine needle aspirates, and
- cytologic specimens.

Human tissue **excludes**:

- Fluids such as blood, urine, CSF, and amniotic fluid at the time of rupture of membranes prior to or during labor
- "Surgical waste" as **specifically** defined below (#3).

### **IV. Definition of Surgical Waste**

"Surgical waste," as per the Medical Board, is specifically defined as:

- Subcutaneous tissue removed to facilitate wound closure
- Tissues significantly altered or diluted by the procedure such as
  - lens phakoemulsifications,
  - vitrectomy specimens,
  - liposuction specimens.

Any research study requesting tissue that does not fit within these narrow definitions of "surgical waste" must be submitted for Pathology review.

### **V. Release of Tissue**

Tissue may be released by Pathology for research purposes **only** after sufficient tissue has been reserved for any and all clinical diagnostic, prognostic, staging and therapeutic monitoring procedures. **Pathology may not be able to release tissue for every patient/case requested and the amount of tissue requested may not always be available for research studies. In addition, the Department of Pathology and Laboratory Medicine must retain a certain amount of archival tissue for future clinical diagnostic, therapeutic and/or prognostic**

**studies and disease monitoring (as per NYCRR 58-1.13, tissue blocks and slides must be retained for a minimum period of 20 years).**

**Tissue Blocks:** As per policy, diagnostic tissue blocks **cannot and will not** be released from the Department of Pathology and Laboratory Medicine. There are several possible solutions:

- Blank slides and tissue sections for molecular genetics and other studies may be obtained so long as sufficient tissue is present in the tissue block. The outside laboratory or agency usually will accept unstained slides from blocks in lieu of the tissue blocks. Please ask your outside collaborator if this is possible.
- In some cases, fresh tissue which is not necessary for clinical diagnostic, therapeutic or prognostic purposes may be obtained at the time of surgery. This tissue may then be sent to the outside lab which may then create a tissue block.
- If the patient can be identified before surgery, an additional prospective tissue block may be prepared (in collaboration with the Pathology Department and in coordination with a specific Pathologist) which will be separate from the blocks submitted for clinical purposes.

## INSTRUCTIONS FOR PATHOLOGY REVIEW

I. Pathology review is required on all research projects which involve human tissue. Please submit prior to submission to the IRB.

### II. Submission instructions

- A. Submit individual pdf files electronically to [submit2pathology@med.cornell.edu](mailto:submit2pathology@med.cornell.edu).
- B. Provide Principle Investigator's (PI) name and contact information in email
- C. Please name individual pdf files as indicated
- D. For new studies
  - 1. Human Tissue Request Form (PI Name A.pdf).
  - 2. Protocol Form (PI Name B.pdf)
  - 3. Study-specific informed consent, if applicable (PI Name D.pdf)
- E. For continuing reviews
  - 1. Human Tissue Request Form (PI Name A.pdf)
  - 2. Original protocol form or most recent revision (PI Name B.pdf)
  - 3. Continuing review form with PI signature (PI Name C.pdf)
  - 4. Study-specific informed consent, if applicable. (PI Name D.pdf)
- F. Supplemental information e.g. sponsor information, adverse event forms, financial disclosures etc do not need to be submitted and should not be included in the above documents.
- G. Forms may be downloaded from the IRB website at:  
[http://www.med.cornell.edu/research/for\\_pol/ins\\_rev\\_boa.html](http://www.med.cornell.edu/research/for_pol/ins_rev_boa.html)
- H. Revisions may be requested
- I. When approved, electronically signed documents will be emailed to contact person
- J. When IRB approval obtained, investigator must send IRB approval letter and signed tissue form to Pathology at [submit2pathology@med.cornell.edu](mailto:submit2pathology@med.cornell.edu)

### III. Specific information needed in Human Tissue Request Form

- A. Section C1, #3 – Brief summary.- include the following information
  - 1. What tissue is requested, e.g. gastric mucosa, lymph node, etc.
  - 2. From what anatomic site tissue is requested, e.g. stomach, lung, etc.
  - 3. From what procedures tissue will be obtained e.g. resection, needle biopsy, etc.
  - 4. Amount of tissue requested,
    - a. mm x mm x mm for fresh tissue
    - b. Number of slides for archival tissue in paraffin blocks
  - 5. What specific testing will be done with the tissue, i.e. specific antibodies etc
  - 6. Who will do technical work, i.e. WCMC Pathology or other
  - 7. Do not include instructions for cutting sections, mailing, sending etc
- B. Section C2 – Exception to tissue submission policy
  - 1. Include type of tissue
  - 2. Include reason for exception
  - 3. Examples of justification for exception
    - a. Bone marrow aspirates – tissue does not normally go initially to Pathology
    - b. Tissue is being taken for research only and consent is being obtained
    - c. Additional tissue is being taken for research and consent is being obtained

d. Tissue is not defined as surgical waste but likely will not show pathology (evaluated on a case by case basis)

C. Section C3

1. Some information is repeated from Section C1 but this form is designed for quick evaluation when tissue is requested
2. Include type of tissue as in C1
3. Check appropriate type and indicate number of patients/subjects
  - a. Fresh for fresh
  - b. Formalin-fixed paraffin embedded if requesting slides
  - c. Fresh frozen tissue procurement and/or storage if asking Pathology to store or freeze tissue or obtained tissue from tissue bank or frozen archival tissue
  - d. Paraffin block processing if requesting prospective blocks to be processed by Pathology
4. If requesting slides, indicate in #7, number of blocks per case and number of slides per block
  - a. Stained if asking Pathology perform standard H&E stain
  - b. Unstained if requesting only cutting and no staining
  - c. Unstained for immunohistochemistry if requesting cutting slides to be later stained for immunohistochemistry
  - d. Special stains if requesting that Pathology perform other than H&E stains (must be specified in Section C1)
  - e. Paraffin sections for DNA – if appropriate for study

D. Please keep a copy of the electronically signed Human Tissue Form

After IRB approval, the investigator must submit a copy of the approved Human Tissue Section and a copy of the IRB approval letter (pdf files) to Pathology (as [submit2pathology@med.cornell.edu](mailto:submit2pathology@med.cornell.edu)). No tissue will be released until these documents are on file in the Department of Pathology and Laboratory Medicine.

Any questions should be directed to the Dr. Rebecca Baergen at [rbaergen@med.cornell.edu](mailto:rbaergen@med.cornell.edu), or x62768.