

**OBTAINING FRESH HUMAN TISSUES FOR RESEARCH****PREAMBLE**

The need for fresh human tissue for research projects is a recognized need in any academic medical center. The Medical College of Ohio is committed to providing this resource in support of its research mission, but because of the nature of this material certain controls are required. The Department of Pathology has been designated as the "Gatekeeper" for investigator access to fresh human tissues. All tissues taken from patients **MUST** be examined by Pathology before release. It is essential that Pathology assure that the harvesting of tissues does not supercede the necessary evaluation of the pathologic specimen for diagnosis or extent of disease, needed for the proper treatment of the patient.

The Department of Pathology has formulated a policy on the use of surgical tissues for research and a copy of that policy appears below. To assure proper application of this policy, Pathology should have on file a list of the tissues which you wish to obtain, and a copy of your IRB approval memorandum for the protocol authorizing the research use of the tissues you require. In addition, individual patient consent for the research use of their tissues removed during surgery should be available before the tissue is released. Generally, patient consent for this purpose is contained in the MCO procedure consent form which is a part of the medical record. In short, any tissue transfer should be documented clearly for authorization and that documentation should be retained by the Department of Pathology.

Policy No. A-02-004

Effective Date: 6/30/95**SURGICAL PATHOLOGY POLICY ON USE OF SURGICAL SPECIMEN MATERIALS  
FOR RESEARCH**

**INTRODUCTION:** In an academic institution, the use of human anatomic materials, especially those obtained at surgery will naturally quite frequently be sought. It is important that such activities be supported if possible but that all actions are carefully and closely monitored and regulated, such that regard for the patient's welfare is always the prime consideration. Any use of such materials must strictly observe the guidelines set down by the Institutional Review Board, and be exercised with unimpeachable ethical conduct.

**PURPOSE:** To provide guidelines for workers in Surgical Pathology to assist in the appropriate use of surgical materials for legitimate, approved research studies.

**PROCEDURES AND REQUIREMENTS:**

The following text is reproduced from a memorandum from the office of the Chairman of the Department of Pathology, setting policy on this matter on 1 November 1994.

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The procedures outlined below will be followed:

1. The Department of Pathology will have the responsibility of monitoring all human tissues, which are removed surgically, or at autopsy and made available for research purposes.

2. Each investigator must obtain approval by the IRB, and provide proof that the project has been approved or exempted to the office of the Chairman of Pathology (Suite 140, Health Science Bldg., ext. 3469).
  - A copy of the complete IRB approval should also be filed with the Histology service in the hospital Division of Anatomic Pathology.
  - In cases where fresh or fresh frozen tissues are required (or any immediate retrieval), a copy of the signed patient surgical consent with especial attention to the checking of the appropriate stipulation that tissues may be used in research should also be filed, for each patient, with the Histology service before or at the time tissues are claimed.
3. All approved investigators will be responsible for providing the Department of Pathology with a list of the tissues they wish to obtain and a protocol for the proper collection of the desired samples. This will include whether the tissue can be fixed, needs to be frozen, or must be obtained in a special medium.
4. It will be the responsibility of the investigator:
  - To indicate the time limits, which are acceptable for harvest after the tissue, has been removed surgically or after the death of the patient.
  - To provide any transport fluid and containers required for tissue collection, other than buffered formalin.
  - To contact the department to ascertain if any autopsy will be performed or to review the operative schedule to ascertain whether appropriate tissue will be removed (ext. 3485: surgical pathology, ext. 5349: Jim Leonard/Autopsy Service).
  - It is the investigator's responsibility to coordinate tissue collection with the pathology resident or attending responsible for the case. In no instance should tissue be obtained from surgery without documentation by the Department of Pathology.
5. If the tissue requires diagnosis by a pathologist or the ongoing research requires the direct participation of the Department of Pathology, proper acknowledgment of this participation should be made in any publications.
  - It may be helpful for each investigator to identify an attending Pathologist, who is willing and able to become acquainted with the research and can serve as a pivot in the Department of Pathology to assist in, and assure, the proper handling of tissues.
6. Problems of any sort, which arise during the progress of the research, should be referred to the Chairman's office for resolution (ext.3469).
7. No use of the data for such things as patents, etc. should be made without prior approval of the Office of Research and Grants Administration (ext. 4251).

Revised March 1997 \_\_\_\_\_