

## **POLICY: Review of Research Protocols Involving Use of Human Tissues by Anatomic Pathology Laboratories**

**Introduction:** Research protocols using human tissues removed at the time of diagnostic or therapeutic procedures must be reviewed and approved by the Clinical Laboratories responsible for the clinical examination and diagnosis of these tissues. This review is needed to avoid any compromise of the standards of practice of clinical pathology and, thus, compromised patient care. Laboratory review is also needed to insure that specialized tissue procurement/handling requirements stipulated in research protocols are not beyond the available resources or expertise of the clinical laboratory. Consultation between researchers and clinical laboratory staff at the time of protocol development is advisable to avoid these resource and standard of care problems. Review of research protocols using human tissues removed at the time of diagnostic or therapeutic procedures by the responsible Clinical Laboratory is required as a condition of IRB approval of the protocol.

**Procedure:** Research protocols involving use of human tissue obtained during diagnostic or therapeutic procedures should document that clinical practice standards are maintained during procurement of tissue. If a portion of a specimen removed for diagnostic or therapeutic purposes is also used for research, the research protocol should describe methods and procedures to coordinate tissue procurement with examination of the specimen(s) by the Pathology Laboratories.

Investigators must submit a completed Pathology Laboratory Tissue Procurement Review Form and a copy of the research protocol and relevant draft consent forms to the OHSU Anatomic Pathology Division, L471 (503-494-9496). The Anatomic Pathology Division will forward the documents to the relevant OHSU laboratory for review and comment. The Pathology Laboratory will document its review and recommendations on the same form (the Pathology Laboratory Tissue Procurement Review Form) and transmit it to the IRB and investigator.

**Scope of Laboratory Review:** Protocols will be reviewed by members of the involved Anatomic Pathology Laboratory Section (Surgical Pathology, Cytopathology, Hematopathology, or Neuropathology) or of other OHSU Pathology Laboratories (Casey Eye Institute or Dermatopathology Laboratory, and Dental School laboratories) and approved by the laboratory director. The review will document concerns and recommend either: approval, disapproval, or approval contingent on modification of the protocol. If protocols are disapproved or approved contingent on modification, the reviewers will make comments and recommendations for modification of the protocol. The review and recommendations will be based on conformance with standards of clinical practice, and the feasibility of obtaining the amount and type of tissue from the specimen for the proposed research, consistent with the requirements for clinical diagnosis.

**Tissue Use Review Form** [PDF](#) | [Word](#)