

**UNIVERSITY OF PITTSBURGH MEDICAL CENTER
PRESBYTERIAN-SHADYSIDE HOSPITAL
Pittsburgh, Pennsylvania
DEPARTMENT OF PATHOLOGY
POLICIES AND PROCEDURES**

Subject: Request for Slides/Blocks for Medical Research/Clinical Trials

Effective Date: June 1, 2008

1.0 POLICY

This policy outlines the necessary steps for obtaining the release of original and duplicate diagnostic material from the UPMC Department of Pathology for Medical Research, Clinical Trial cases only.

All requests must be accommodated provided that an Informed Patient Consent Form (ICF) is received containing the subject's signature, as well as a copy of the CoPath Surgical Report. This document will be given to the Health Sciences Tissue Bank (HSTB) for processing. These documents will come from the Department of Pathology administrative staff at Presbyterian and Shadyside Hospital.

2.0 RESPONSIBILITY

All Pathology faculty and staff are required to comply with this policy.

3.0 Protocol for Obtaining Formalin Fixed Paraffin Embedded (FFPE) Unstained Slides (USS) from the Department of Pathology Clinical Paraffin Archives for patients consented as subjects into various Clinical Trials.

3.1: A request is received by the Department of Pathology administrative staff for slides/blocks for medical research/clinical trials.

3.2: To process the request, the Department of Pathology administrative staff will forward to the Health Sciences Tissue Bank (HSTB) an Informed Patient Consent Form, (ICF), containing the subject's signature as well as a copy of the CoPath Surgical Report.

3.3: HSTB will verify that the ICF contains a signature and is dated.

3.4: HSTB will order the specific paraffin blocks and corresponding H & E slides from the pathology files or Iron Mountain.

3.5: When paraffin blocks and/or H & E slides are received, HSTB will submit the blocks/slides as well as all paperwork to the pathologist responsible for originally signing out the case. This pathologist will deem sufficient if any and what material is chosen by the appropriate block(s) in supporting the efforts for the particular trial.

- If the attending pathologist (originally signed out the case) is no longer on staff, the case must be submitted to the Director of the COE for direction as to who will view the case and make appropriate choice.
- Departmental policy dictates that **NO** blocks are to be distributed to outside facilities. Most trials have alternate instructions when blocks cannot be sent. If alternate instructions are not available, HSTB will call the research project coordinator to inform of them of the policy and arrange substitution with USS, (unstained slides). Some trials do require that a block be sent. In this case, the pathologist may choose a block that is not critical to the case, (example: 3 tumor blocks exist so 1 block may be sent). If only 1 tumor block is available on a case or all blocks appear to be of value to the case, the block send out must be approved by the Director of Anatomic Pathology.

3.6: The pathologist will select a specific block(s) blocks and will forward all material (blocks, slides and paperwork) with recut instructions indicating the number of UUS (unstained slides) to HSTB. HSTB will then triage the materials and the instructions to the Research Histology Lab.

3.7: HSTB will receive from the Research Histology Lab the UUS, (unstained slides) and all original paperwork which will then be delivered to the Department of Pathology clinical support staff.

3.8: Pathology staff will arrange for pick up/delivery of materials to pertinent parties. If any original blocks are sent out, the Pathology clinical support staff is to enter the original block information in the slide send out activity in CoPath. This is for tracking purposes for the return of the materials to our department.

3.9: Copies of all paperwork is made for HSTB and filed according to the patient's name.

3.10: All Formalin Fixed Paraffin Embedded blocks/H &E slides will be returned to appropriate files by HSTB. If an original block is sent out for the study the Pathology clinical support staff must follow-up and make sure the block is returned to UPMC.