**Department of Pathology and Laboratory Medicine**

**UTHealth Medical School**

Procedures and Forms for Human Tissues for Research.

**NEED FOR DEPARTMENT OF PATHOLOGY APPROVAL:** Scientific advances have greatly expanded the studies that can be done on human tissues. At the same time, biopsies are becoming smaller so there is less tissue available. We are required to document that a proposed study will not compromise pathologic evaluation of tissues required for current or future clinical care. Tissue research must comply with multiple authorities including:

1. CLIA (Clinical Laboratory Improvement Amendments) for accreditation of diagnostic laboratories) See appendix A. Tissues sufficient for future diagnostic studies must be retained for 10 years and can not be used for research.
2. IRB (Institutional Review Board) for human subjects research. A human subject is defined as a live person. The purpose of the IRB is to ensure that all human subject research be conducted in accordance with all federal, institutional, and ethical guidelines.
3. IAORC (Institutional Anatomical Oversight Review Committee) for anatomical gifts. “Anatomical specimens are human body parts, including bones and viscera, whether obtained from deceased human bodies or surgical specimens; small quantities of tissue or sections of bone or viscera are not considered to be anatomical specimens” ([HOOP policy 97](https://www.uthouston.edu/hoop/policy.htm?id=1448042)).
4. HIPAA (Health Insurance Portability and Accountability Act), the federal law that protects personal medical information.

This document addresses policies related to CLIA that are the joint responsibility of the hospital who operates the histology laboratory and the pathologists. Our goal is make tissues available for research to the greatest extent possible consistent the regulations of CLIA.

Investigators are advised to discuss potential projects with a pathologist during the planning phase in parallel with the IRB application process to insure that tissue requests are consistent with applicable regulations.

For more information please contact:

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**UT Department of Pathology Form to Request Tissue Use for Research Purposes**

Pathology Tissue # \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ - to be assigned by pathology

Study Title:

IRB#:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Approval date\_\_\_\_\_\_\_\_\_, pending or not applicable

IAORC# \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Approval date\_\_\_\_\_\_\_\_\_, pending or not applicable

Principal Investigator (PI): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Tel #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Person completing this form, if not PI, and contact information:

Please describe briefly what tissues will be needed for this study:

**SECTION A: Determine if the study needs Pathology Approval in addition to IRB approval.**

1. Is (or was) the tissue obtained solely for research purposes?

(All criteria a-e must be true to answer “yes”. If any criteria is not met, or if you are unsure if it meets criteria, answer “no”). Choose YES or NO.

1. The biopsy or surgery is an additional procedure performed for the sole purpose of collecting tissue for the study. \_\_\_\_\_YES \_\_\_\_\_NO
2. The patient will have an established diagnosis at the time of the additional biopsy.

\_\_\_\_\_YES \_\_\_\_\_NO

1. No pathologic evaluation of the tissue from the biopsy will be performed.

\_\_\_\_\_YES \_\_\_\_\_NO

1. No routine (non-experimental) clinical care will be determined by evaluation of the research tissue. \_\_\_\_\_YES \_\_\_\_\_NO
2. Patients will be consented to the additional biopsy including the lack of any pathologic evaluation of the tissue \_\_\_\_\_YES \_\_\_\_\_NO

If you answered YES: This study has automatic pathology approval. Otherwise proceed below. Please note that the PI will be solely responsible for collecting, processing, storing, shipping, and disposing of any tissues obtained for research.

**SECTION B: Information needed for full Pathology Review**

1) Please provide a copy of the research summary.

2) Will the study use archival paraffin embedded tissues, smears, or cytologic specimens?

**Choose YES or NO.** \_\_\_\_\_YES \_\_\_\_\_NO

 3) Where are the desired tissues stored?

If NO, skip to question #3) below.

If YES, please complete the questions below.

1. Describe the plan to identify the desired archival cases to be used for the study, or specify that the investigator will be responsible for identifying the desired archival cases. *Please note that pathology assistance to identify desired cases requires prior arrangement. The hospital charges a fee for retrieving blocks and cutting slides.*
2. Describe the plan to choose the desired blocks to be cut from archival cases identified above. *Pathologist assistance is available if needed to identify appropriate blocks to recut on a fee for service basis.*
3. Describe in detail the type and quantity of material to be prepared from the archival paraffin blocks (i.e. unstained slides, stained slides, section thickness, type of glass slide, special handling of sections, etc).
4. For blocks only, name of CLIA certified histology laboratory to which the blocks will be going? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
5. How soon will the blocks be returned? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
6. Please provide the name of the UTHealth staff pathologist who has agreed to review the slides and blocks to verify compliance with the regulations on use of clinical archival paraffin tissue (see Appendix A below), or state that you will be asking for a pathologist to perform this review on a fee for service basis:
7. Will clinical care be based on an outside pathology review or special studies?

**Choose YES or NO.** \_\_\_\_\_YES \_\_\_\_\_NO

If YES, then describe the plan for notifying the UTHealth Pathology department of the external pathology review results or special studies, including the time anticipated to receive a written copy of the report and/or slides for Pathology files.

Include the name and contact information for the outside laboratory and indicate whether the laboratory is CLIA-certified.

3) Will the study use non-archival tissues (for example, fresh or flash frozen tissue or body fluids other than blood normally submitted for cytologic evaluation)?

**Choose YES or NO.** \_\_\_\_\_YES \_\_\_\_\_NO

If YES, please complete the questions below. *Please note that there is a fee for pathology assessment and handling for any fresh tissue donated through surgical pathology for research.* Tissue samples from autopsies require prior review and approval by the director of the autopsy service. Use of diagnostic cytopathology specimens for research requires documentation of prior approval from the director of cytopathology.

a) Describe the tissue type and quantity (size or weight) needed for the study:

b) Describe the plan for identifying when and where the desired tissue will be available (Pathology assistance to identify desired cases is not generally provided without prior arrangement), or specify that the investigator will be responsible for identifying when and where the tissue will be available:

c) Describe the plan for pathology assessment of the specimen/tissue prior to its use.

d) Describe how the specimen/tissue should be processed/stored in the Pathology department prior to receipt by the PI. If Pathology will not collect, process, store, or ship tissue, enter “Not Applicable”

e) Will clinical care be based on outside pathology review or special studies?

**Choose YES or NO.** \_\_\_\_\_YES \_\_\_\_\_NO

If YES, then describe the plan for notifying the Pathology department of the outside pathology review results or special studies, including the time anticipated to receive a written copy of the report and/or slides for Pathology files. Include the name and contact information for the outside laboratory and indicate whether the laboratory is CLIA-certified.

4) Is a UTHealth Pathologist a listed investigator in this project? (This is advised where pathology tissue procurement/activities will require substantial efforts and/or exercise of professional judgment)

**Choose YES or NO.** \_\_\_\_\_YES \_\_\_\_\_NO

If YES, then please identify the pathologist: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Section C. Autopsy specimens:**

Research using autopsy tissues must comply with the Autopsy Consent form, HIPAA and the IAORC (Institutional Anatomical Oversight Review Committee). The IRB does not review research on deceased persons.

1. Must have a State of Texas Postmortem Examination or Autopsy Consent Form and abide by any restrictions stated on the form.
2. Decedent must be a MH-TMC patient. Other decedents would require special arrangements with the MH-TMC hospital .
3. Recognizable body parts must have IAROC approval.
4. Small pieces of tissue require neither IRB nor IAROC approval.
5. Procedure:
	1. Prepare a description of the research, tissues needed including how they should be processed, and how the patient confidentiality will be handled.
	2. Obtain IAORC approval as needed.
	3. The documents will be reviewed by the director of the autopsy service and hospital for compliance with applicable regulations.
	4. If approved, the prosectors will be tasked with collecting tissues.

TO BE COMPLETED BY REVIEWING PATHOLOGIST:

Approval means only that requested tissues are likely to be available for research.

It does not replace IRB approval that is also necessary.

Approved:

Deferred with rationale:

Disapproved with rationale:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature Reviewing Pathologist. Date

**APPENDIX A:**

**Request for Pathology Approval for Research involving Human Tissues**

**Policy:** Use of Clinical Archival Paraffin Tissue for Research, Teaching, Clinical Assay Validation and the Preparation of Control Material within the Clinical laboratories. Our goal is to make tissues available for research in the least cumbersome manner possible consistent with compliance with regulatory requirements for retention of diagnostic specimens.

**Part 1:** For uses other than for the clinical care of patients, release of FFPE block recuts (unstained slides or ‘paraffin curls’) is permitted as follows:

1. Recuts of clinical archival FFPE blocks can only be performed if:
	1. The case associated with the block is not a small biopsy case (eg. FNAs, cell blocks from fine needle aspirate collections, needle core biopsies, skin punch biopsies, endoscopic biopsies, etc.). Preparing recuts of these specimens poses too high a risk of sample depletions which would be in violation of block retention regulations.
	2. For the case associated with the block, the diagnostic findings are not limited to a single block.
	3. The block does NOT contain a unique medically significant finding, even if this finding is not the primary diagnostic finding (eg. the only block with lymph node metastasis for a cancer case, a block with positive margins, blocks that document tumor stage, frozen section remnants)
	4. The block is NOT being held for legal review.
	5. The recuts are performed in a CAP-accredited Laboratory of UTHealth, or MHHS.
2. All of the slides and paraffin blocks from the associated case must be reviewed by a UTHealth pathologist with clinical privileges in anatomic pathology to verify that recuts will not deplete the paraffin block and that sufficient material remains for further diagnostic work if it should become required.
	1. The review must be documented and documentation should be retained by the pathologist of record and sent to the Anatomic Pathology Laboratory for archiving.
3. The release of archival FFPE recuts for research is permitted only in the context of IRB approved protocols with appropriate patient consent.

**Part 2:** For research use, removal of a core of tissue (2-5mm) from a clinical archival FFPE block using a punch biopsy device is permitted as follows;

1. A core of tissue can be removed from a clinical archival FFPE block if:
	1. The case associated with the block is not a small biopsy case (eg. FNAs, cell blocks from fine needle aspirate collections, needle core biopsies, skin punch biopsies, endoscopic biopsies, etc.). Preparing cores of these specimens poses too high a risk of sample depletions which would be in violation of block retention policies.
	2. For the case associated with the block, the diagnostic findings are not limited to two or fewer blocks.
	3. The block does NOT contain a unique medically significant finding, even if this finding is not the primary diagnostic finding (eg. the only block with lymph node metastasis for a cancer case, a block with positive margins, blocks that document tumor stage, frozen section remnants)
	4. The block is NOT being held for legal review
	5. The cores of tissue is removed from the block by a CAP-accredited laboratory
	6. >50% of the tissue which contains the diagnostic finding remains in the block after removal of the core
2. All of the slides and paraffin blocks from the case must be reviewed by a UTHealth pathologist with clinical privileges in anatomic pathology to verify that a core biopsy will not deplete the paraffin block and that sufficient material remains in the blocks for further diagnostic work if it should become required.
	1. The review must be documented and documentation should be retained by the pathologist of record and sent to the Anatomic Pathology Laboratory for archiving.
3. Every effort should be made to use blocks that are greater than 2 years old.

**CAP –CLIA Regulatory Requirements**

CAP Anatomic Pathology Checklist 7/29/2013 Pages 29-30

ANP. 12500 RECORD RETENTION Phase II Surgical pathology records are retained for an appropriate period.

NOTE 2: Regarding extra-institutional release of blocks for research purposes: Federal regulations require that a laboratory retain paraffin blocks for two years unless the tissue is blocked specifically for research and not used for patient diagnostic purposes.\* The CLIA requires, however, that paraffin blocks used for patient diagnostic purposes must be kept for at least 10 years. Nevertheless, such blocks may be released for research purposes after the two-year regulatory requirement if all of the following criteria are met:

1. For laboratories subject to US regulations, formal written authorization is obtained in accordance with the requirements of HIPAA if identifiable patient information is released.
2. The laboratory retains sufficient blocks to support the diagnosis for the full10- year period.
3. Provision is made for retrieval by the laboratory of any blocks or material that remain after use in research, if the blocks or material are needed for diagnostic, legal, or other legitimate purposes
4. The laboratory meets other relevant requirements including but not limited to the requirements of the institution, the directives of any applicable institutional review board (lRB) or similar entity; and state and local laws and regulations.

\*The restriction on release of blocks does not prohibit release of blocks for purposes of treatment, diagnosis, prognosis, etc., for patients on research protocols as long as release is consistent with patient privacy regulations (e.g. HIPAA) and applicable state and local regulations; and there is IRB approval, as applicable.