

Release of Pathologic Materials

Submit this form electronically to ROPrequest@uabmc.edu along with a copy of the associated IRB Human Subject Protocol. In the case of clinical trials, please provide a copy of the clinical protocol, informed consent (if applicable) and if available, a copy of the Laboratory Manual or document describing specimen collection and preparation. All forms will be logged in and routed for appropriate signatures. You will be contacted when form is approved.

The purpose of this form is to communicate to Pathology as to what types of tissue specimens will be needed for this study; specifically, whether RESEARCH only material (obtained with patient permission) will be required (Option A), whether diagnostic archival material will be required (Option B) and/or whether the study may utilize both (Option C).

Principal Investigator: _____ Date Submitted for Review: _____

UAB Protocol #: UAB _____

Project Title: _____

Is this a Clinical Trial? Yes No If YES, name of Sponsor: _____

Does the project involve the provision of human tissue specimens: Yes NO

If NO, this form is not required to be completed.

Option A. RESEARCH (Non-Diagnostic)

Will some or all of the tissue be obtained **solely** for research purposes? Yes No (if No please go to Option B.)

If Yes, answer the questions below (If any criteria is not met, or if you are unsure if it meets criteria, answer "no").

- The research only biopsy or surgery is an additional procedure that will be performed for the sole purpose of collecting tissue for the study. Yes No
- The patient will have an established diagnosis at the time of the additional biopsy. Yes No
- No pathologic evaluation of the research only tissue will be performed by UAB Pathology. Yes/Correct No
- No routine (non-experimental) clinical care will be determined by evaluation of the research tissue. Yes/Correct No
- Patients will be consented to the additional biopsy/resection including there will be no pathologic evaluation of the tissue by UAB Pathology. Yes No

Please indicate the tissue preparations required for the RESEARCH only tissue (check all that apply): Fresh; Frozen; Wet Fixed; Formalin Fixed Paraffin Embedded (FFPE) tissue block; Other: _____

Option B. ARCHIVAL – Complete if archival/diagnostic material may be needed.

Anatomic site: _____

Tissue type (e.g., Malignant, Normal, Diseased) and Site or Tumor Type: _____

Please indicate the tissue preparations required (check all that apply): Formalin Fixed Paraffin Embedded (FFPE) tissue block; FFPE Unstained Slides cut @ _____ μm (NOTE: 4-5 μm are standard thickness). # Slides requested: _____

Other: _____

Option C. BOTH Research Only and Archival/diagnostic tissue may be needed. Many studies may prefer archival material but request fresh tissue if archival is not available. For studies that may require BOTH research only and archival material, **please complete information requested for both Option A and Option B above.**

FOR ALL REQUESTS:

For reference purposes, include page #(s) of protocol and/or lab manual that discusses type of human tissue requested and preparation(s) requested of tissue:

Please include details about the specific type of tissue/material being requested (use additional space if needed):

Briefly describe the research purposes of the above-mentioned material:

Will tissue be collected through the UAB Tissue Biorepository (UAB-TBR)? Yes No

If YES, after IRB approval is obtained, please submit request form/s found on UAB-TBR website:

<https://sites.uab.edu/tissuebank/clinicalprotocol/>

If NO:

- Who will be collecting the tissue for this project? _____
- Where will the tissue be collected? _____
- Who will be responsible for consenting patients for this project? _____
- Will specimens be required to be de-identified? Yes No
- If yes, who will be responsible for de-identifying the specimens? _____

I (we) certify that all publications, including poster or platform presentations, verbal or abstract presentation, will contain no identifiers which could allow the identification of person or persons from whom pathologic material was obtained to become public.

I (we) also certify that pathologic material will be received only after appropriate informed consent has been obtained or after the responsible pathologist certifies that the pathologic material needed for these studies is excess material not needed for further diagnostic evaluation and participant care.

I (we) further certify that pathologic materials obtained by us in the course of these investigations will not be removed from the UAB campus for any purpose without written prior permission from the Institutional Review Board for Human Use at UAB

Principal Investigator(s) Printed Name(s): _____

Principal Investigator(s) Signature: _____ Date: _____

IF STUDY REQUIRES RESEARCH ONLY TISSUE (no archival/diagnostic)

To be filled out by Pathology Personnel making this determination:

Because this request utilizes only non-diagnostic, non-therapeutic tissue that would not otherwise be submitted to Pathology for assessment, **this request does not require review or approval by Pathology Faculty.**

Printed Name	Signature	Date
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IF STUDY REQUIRED ARCHIVAL/DIAGNOSTIC MATERIAL

I (we) have reviewed the above request for possible risks to the rights and welfare of the participant(s) or next-of-kin. Signatures below certify that the responsible principal investigator has made available to me (us):

- (1) A description of the project AND
- (2) A properly executed copy of the informed consent document for removal of pathologic materials for research

I (we) further certify that in the latter case we have designated these pathologic materials as excess and that, therefore, no risk to a living participant or invasion of privacy appears possible. For research projects in which pathologic evaluation is crucial for proper interpretation of results, we acknowledge that the Principal Investigator has been informed of the desirability of including a knowledgeable pathologist as part of the research team.

Head, Section of Autopsy Pathology	OR	Head, Section of Hematopathology
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Head, Section of Cytopathology	OR	Director, Division of Neuropathology
	AND	

Director, Division of Anatomic Pathology