**Release of Pathologic Materials**

**Submit this form electronically to Suzanne Byan-Parker (****sbyanparker@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 applicable/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, and you will be contacted when form has been approved.**

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.

**Section A. Determine if the study needs Pathology Approval**

Is (or was) the tissue obtained solely for research purposes? [ ] Yes [ ] No (if No please go to Section B.)

If Yes, answer the questions below (If any criteria is not met, or if you are unsure if it meets criteria, answer “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
3. No pathologic evaluation of the tissue will be performed by UAB Pathology. [ ] Yes/Correct [ ] No
4. No routine (non-experimental) clinical care will be determined by evaluation of the research tissue. [ ] Yes/Correct [ ] No
5. Patients will be consented to the additional biopsy/resection including there will be no pathologic evaluation of the tissue by UAB Pathology. [ ] Yes [ ] No

If you answered YES to all questions, this study **does not** require pathology approval. Proceed with submission to obtain signature for use of non-diagnostic tissue. Otherwise, continue completing the form.

For reference purposes, include page # of protocol or lab manual that discusses type of human tissue requested: \_\_\_\_\_\_\_\_

*“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: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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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 form is not-applicable and is not required.**

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

Printed Name Signature Date

**Section B. The study is determined to require Pathology Approval**

Anatomic site: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Tissue type (e.g., Malignant, Normal, Diseased): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Please indicate the tissue preparations required (check all that apply): [ ]  Fresh [ ]  Frozen [ ]  Formalin Fixed Paraffin Embedded (FFPE) tissue block [ ]  FFPE Unstained Slides cut @ \_\_\_\_\_\_µm (NOTE: 4-5 µm are standard thickness). # Slides requested: \_\_\_\_\_\_\_

[ ]  Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

For reference purposes, include page # of protocol or lab manual that discusses requested preparation: \_\_\_\_\_\_\_\_\_\_

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.*

Principal Investigator(s) Printed Name(s): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Principal Investigator(s) Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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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.

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Head, Section of Autopsy Pathology OR Head, Section of Hematopathology

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Head, Section of Cytopathology OR Director, Division of Neuropathology

AND

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 Director, Division of Anatomic Pathology