Application Rec'd _____Supporting Docs Rec'd _____SOW completed & shared _____ Amendment/Update Rec'd_____

CLINICAL TRIAL SERVICE REQUEST

UAB TISSUE BIOREPOSITORY (UAB-TBR)

I. PURPOSE

The purpose of this request form is to provide the UAB Tissue Biorepository (TBR) with information needed to request TBR services to assist with specimen collection and preparation for a UAB Clinical Trial.

II. DIRECTIONS

The information requested in these forms is necessary to ensure that your request for tissue and other services for a clinical trial is correctly documented.

A. To obtain an estimate for UAB TBR participation, all information must be entered as specific as possible on this form. Forward complete service request application to TBR Protocol staff at (TPprotocol@uabmc.edu). A Statement of Work (SOW) will be prepared with an estimate of cost based on the information provided. **Please notify TBR at least four weeks prior to first patient enrollment and after the clinical trial being approved by the PRC (Protocol Review Committee).**

B. Neatly print or type.

C. All samples will be coded (de-identified with TPN#) and prepared as specimens with requested method at an appropriate processing fee.

D. Please fill out the application form with thorough and detailed answers. If there are any amendments or addendums with information changes or updates, kindly notify the service team at TPprotocol@uabmc.edu.

III. REQUIRED DOCUMENTS:

The following documents should be provided to TBR with this completed application:

- A copy of the **Study Protocol**
- A copy of the **Laboratory Manual**, or any other documentation that provides details regarding specimen collection, processing, and/or shipping. *(NOTE: important information may be included in an Appendix).*
- Copies of any **forms/requisitions** that TBR will need to complete.
- A copy of the **informed consent document** (*the signed consent is not required; TBR may need to review the language included in the consent document to help in drafting the SOW*).

IV. GENERAL CLINICAL TRIAL INFORMATION

A. Study Protocol Name: _____

UAB Protocol ID # or acronym that will be used to ID protocol (*e.g., UAB 1234*): _____
(NOTE: When emailing about protocol, please list this protocol ID first in subject line.)

Protocol version#/date _____ Lab Manual version#/date_____

Principal Investigator: _____ O'Neal Cancer Center Member? ☐ Yes ☐ No

Sponsor: _____☐Industry ☐Non-Industry

Study Coordinator: _____ Phone: _____ Email: _____

Return Estimate to: _____ Acct # for billing: _____

B. Anticipated protocol duration _____

Study Objective *(Note: **simplify primary objective/study goal in 2-3 sentences**, usually mentioned in the STUDY SYNOPSIS):*

Study Population Target enrollment_____ (number of participants at UAB)

Key Patient Criteria/Diagnosis for Study (*we do not need the trial criteria, we are just looking for a simple description, such as pts with a diagnosis of epithelial ovarian cancer*):

V. SUMMARIZATION OF SERVICES REQUESTED

A. Please check the boxes of the services you are requesting from UAB TBR:

Specimen Pick Up

☐ Study Personnel to deliver specimen to TBR

OR

☐ TBR Personnel to pick up specimen (in OR, at patient's bedside, or in procedure room)

Shipping of Specimens

☐ Study Personnel to ship specimens

OR

☐ TBR Personnel to ship specimens

De-Identification/Media Transfer ONLY

☐ Study personnel will deliver specimen(s) to TBR for de-identification and/or other non-histology lab work, i.e. tissue media change (formalin to ethanol); study personnel will ship specimen(s)

B. Requisition Details

Note: Provide the page number(s) of the protocol/lab manual (refer to the previously filled version#/date of both documents) that may be pertinent to tissue collection/processing/labeling/storage/shipment in which TBR will be involved. This will help should us to refer to the protocol for specific requirements.

*Please refer to the Instruction on page 5-6 for definitions and explanations of the terms.

1. **The samples requested will be** *Protocol pg#_____ Lab Manual pg#_____*

- ☐ *Archival (Diagnostic or SOC)
- ☐ *Protocol (research) only
- ☐ Combination of both

2. **Please indicate the timepoints per patient for which it is anticipated that tissue will need to be collected and processed by TBR:** *Protocol pg#_____ Lab Manual pg#_____*

Timepoint (*e.g., Baseline, C1D1*)	**Type of Specimen** (*e.g., Biopsy, Core needle bx, Sx resection)*	**# of Specimens Anticipated from timepoint**	**Tissue Preparation*** (*e.g., OCT frozen, snap frozen, formalin fixed, fresh in media, fixed processed to FFPE block*) *If multiple preps are needed from same timepoint, describe separately. **To be completed by TBR staff**.

3. **Collection supplies** *Protocol pg#_____ Manual pg#_____*

The following supplies will be provided by the Clinical Trial Coordinator to TBR:

_____

_____

Note: please make sure all labels and the supplies are provided to TBR within 24hours before the collection

4**. Completion of Requisition Form(s) for each participant** *Protocol pg#_____ Manual pg#_____*

- TBR personnel will need to view a copy of the requisition form before completion of the SOW, so they will know what information they are to document.
- Typically, requisition forms are partially completed by study staff then transferred to TBR staff to complete after specimens are collected.
- The clinical trial coordinator should review the instructions for completing the requisition form with TBR personnel prior to the first tissue collection.
- Online forms should be completed by study staff, NOT TBR. However, TBR can provide data for the online forms, as needed.
- If a specific study ID is required on the requisition, this should be communicated to TBR BEFORE specimens are shipped.

☐ TBR personnel will NOT be required to complete or provide data for a requisition form for this study.

5. **Shipping** *Protocol pg#_____ Manual pg#_____*

If TBR is requested to package and ship specimens, please indicate above the pages in the protocol and/or Lab Manual where shipping instructions are provided.

Will specimens be shipped outside the US? ☐ Yes ☐ No

If YES, will a commercial airbill (*this refers to a specialized airbill required for international shipping*) be provided to TBR? ☐Yes ☐No ☐Unsure

Shipping vendor: (e.g., Fed Ex, UPS) _____

Shipping dates: (e.g., Monday and Tuesday) _____

Provide Shipping Account # to be used or provide details of how shipping costs will be covered:

_____

_____

(*NOTE: TBR will NOT be responsible to pay for shipping)*

6. **Other Services** *Protocol pg#_____ Manual pg#_____*

If other services, not described above, are needed for this study, please describe and attach separately, as applicable. Please indicate where in the protocol or lab manual details can be found regarding requested services.

The Estimate for Services to be provided by the UAB Tissue Biorepository will be based upon the following: (details refer to the information provided in the above sections #1-6)

- Time and effort that will be required by UAB-TBR personnel
- Work to be performed
- Supplies TBR is to provide
- Storage of samples (long term vs. short term)
- Histology Services
- Shipping of Specimens
- Protocol Administration requirements

In addition to processing fees, review fees will be assessed to cover time and effort expended by TBR personnel to review protocol, lab manual, and other supporting documents to prepare a Statement of Work (SOW) unique to this study. An **Administrative fee will be assessed per patient (***to cover, e.g., coordination with the study coordinator, completing requisition forms, responding to questions, troubleshooting as necessary, etc.)*

A Management Fee/hour will be assessed, as needed, if time is required by TBR management/leadership to troubleshoot issues or solve problems that may arise.

Please see separate Clinical Trial Fee Schedules for Non-Industry Sponsored vs. Industry-Sponsored trials.

Instructions and Explanations of Terms

Archival (Diagnostic)

Archival tissue refers to specimens which are collected during routine patient procedures (referred to as "**Standard of Care" or SOC**).

A typical **SOC tissue**, biopsy or resected tissue is submitted to Surgical Pathology where the sample is fixed in 10% **N**eutral **B**uffered **F**ormalin **(NBF**), then processed to a paraffin (wax) block, referred to as **F**ormalin **F**ixed **P**araffin **E**mbedded (**FFPE**) tissue. From that block, slides are prepared, stained with a standard **H**ematoxylin and **E**osin (**H&E**) stain, then provided to a pathologist who looks at the slide under a microscope and renders a diagnosis.

Many of the clinical trials will request archival FFPE blocks/ however, these SOC/archival FFPE blocks are required to be retained in Surgical Pathology for a number of years. Therefore, it is the policy of UAB Surgical Pathology NOT to release archival FFPE blocks. From these blocks, however, slides can be provided. Typically, unstained slides are requested, but occasionally a clinical trial may request unstained slides and a stained (e.g., H&E stained) slide. Those CAN be provided.

When/IF a clinical trial asks ONLY for slides from archival material (as described above), those requests do not need to go through the TBR. Requests for slides from archival material should be forwarded directly to Surgical Pathology Customer Service Supervisor in the UAB Hospital Lab. (Current contact: Adrienne Stokes, astokes@uabmc.edu [205-975-5542]).

Research Only

Tissue being removed "for research only" is above and beyond SOC. ANY time tissue is collected for **RESEARCH ONLY**, patient consent for the removal of that tissue IS REQUIRED and must be incorporated into the patient's informed consent document.

For the collection of biopsy:
If a patient has a **biopsy** performed for the express purpose of providing tissue for a clinical trial, that is considered "research only". In some situations, patients may have numerous biopsies removed, some of which are submitted to Pathology for diagnosis (SOC) and some of which are intended for research purposes. If tissue is removed for RESEARCH ONLY, the TBR staff can fix that research only tissue and process it to a paraffin (FFPE) block for submission to the study.

For the collection of the excess (remnant) tissue from resection:
If the excess (remnant) tissue is requested from a surgical **resection** (e.g. mastectomy of breast), the availability of such tissue should be determined by the Pathology staff. With Pathology's permission, TBR staff can collect the excess (remnant) tissue for the clinical trial. That tissue can be processed/prepared however needed for the clinical trial (e.g., frozen, fixed, FFPE).

Preparation of Tissue

It is critical that the TBR know how the clinical trial wants the tissue specimens prepared. Common Preparation Methods that may be requested include:

- **FFPE** – Refers to **F**ormalin **F**ixed **P**araffin **E**mbedded blocks
- **Wet Fixed** – Tissue is placed in formalin and shipped to the sponsor "wet" in the formalin. The study may request that tissue be fixed in NBF for a certain # of hours, then transferred to **70% ETOH** prior to shipping because transfer to ETOH stops the fixation process and keeps the tissue from becoming over fixed.
- **Frozen** – Tissue is snap frozen and is usually stored in a -70^{o} C freezer, on dry ice, or in a liquid nitrogen dewar or freezer.
- **OCT Frozen** – Tissue is placed into a mold and surrounded by a gel-like substance, referred to as "OCT", then frozen. Usually, slides cannot be cut from frozen tissue. However, slides, referred to as "Frozen Sections" (because they are sections of cut from frozen tissue) can be created from tissue frozen in OCT.

Studies may request numerous preparation methods, or may prioritize preparation methods (*e.g.*, 1st biopsy fixed, 2nd biopsy snap frozen, 3rd biopsy fixed).