STEP 3:

Protocol of UHB Laboratory Use/Patient Specimens for Research:
Clinical and Anatomical Pathology Labs

Submit completed form electronically to: pathologygroup@downstate.edu

This is STEP 3 of a three step process.

- Step 1: Complete STEP 1: "Specimen use and Laboratory feasibility determination" form
  - Schedule to meet with Dr. Libien to discuss feasibility information provided in Step 1 form
- Step 2: IRB application, Biosafety, and/or IACUC, as applicable
- **Step 3: Complete STEP 3: "Protocol of UHB Laboratory Use/Patient specimens for Research projects" form**
  - **Do not complete step 3 form until you have completed the first 2 steps of the process**
  - **A pathology approval number will be issued upon successful completion of this form.**

1. Principal Investigator

Name:
Position:
Department:
Phone number:
Email:

2. Study Title:

3. Is this a Clinical Trial? ☐ Yes ☐ No

4. Grant Number/Research Foundation Account Number/Funding Source

5. Approvals (as applicable) & Expiration Date

	Approval Number	Expiration Date
IRB		
IACUC		
Biosafety		

A. Use of **Clinical Pathology Laboratories**: Samples and laboratory testing on blood, urine, fluids. Includes hematology, chemistry, coagulation, urine analysis, microbiology, virology and flow cytometry.

1. Names and Titles of Individuals Interacting with Laboratories (all individuals interacting with

the labs must be named and approved on IRB/IACUC applications):

2. Specimen Source:

Human ☐

Animal ☐ Species:

3. Tests requested:

4. Frequency of submission and Number of Samples to be tested (eg. One time /week; # samples each time)

5. Total number of samples/year:

For **Human Samples**:

6. Target Patient Population (e.g. SLE patients)

7. Check Appropriate Box:

☐Excess Material from Clinical Laboratory Samples [All specimens subject to Clinical Laboratory Protocols before use for research.]

☐Additional Specimen obtained for research purposes only.

8. Will Specimens be De-Identified?

☐Yes

☐No

B. Use of **Anatomical Pathology Facilities**: Tissue samples, slide preparation, and staining including immunohistochemistry stains.

1. Names and Titles of Individuals interacting with Laboratory (all individuals interacting with the labs must be named and approved on IRB/IACUC applications):

2. Specimen Source

☐Human

☐Animal

☐Cell Line

3. Tests requested:

4. Frequency of submission and Number of Samples to be tested (eg. One time /week; # samples each time)

5. Total number of samples/year:

For Human Studies:

6. Target Patient Population (e.g. TN Breast Cancer)

7. Source of Human Specimen

☐ Existing collection (Tissue blocks only)

☐ Additional specimen(s) to be obtained for Research Purposes Only

☐ Sample from fresh surgical pathology specimen(s) obtained for clinical care. If yes, please complete the following:

- What size of sample will be taken?
- What are the sample inclusion and exclusion criteria? (e.g. minimum tumor size?)

How are you setting up the billing account?

☐ Hospital finance

☐ Pathology directly

☐ n/a [only check if taking excess material without requiring services]