Pathology approval number:_____

STEP 3:

Protocol of UHB Laboratory Use/Patient specimens for Research Projects: Clinical, Histology, and Surgical Pathology Labs

*** Submit the completed form electronically to:**
susan.gottesman@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. Gottesman or Dr. Otto 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**
  - **A pathology approval number will be issued upon successful completion of this form.**
  - **Do not complete step 3 form until you have completed the first 2 steps of the process**

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		

6. **Personnel interacting with Laboratory**
   (list all, additional space can be found at the end of this form)

   Name:
   Position:
   Contact Information:
   IRB approval of personnel (if human material):
   Details of planned Laboratory interaction (e.g. titrating antibody):

7. Specimen

A. ☐Human ☐Animal ☐N/A (cell lines)

If animal, please list species:
If animal, skip to question 10

B. For Human Studies: (Check appropriate box for source of human specimen)

☐Existing collection (Tissue blocks only)

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

If additional specimen, what is the proposed plan of sample collection from patient (eg. Who is doing the phlebotomy, collecting the tissue, etc.?).

☐Excess material from Clinical Laboratory Samples (e.g. Chemistry, hematology, microbiology, etc.)

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

- Who is taking the sample from the fresh specimen?
- What size of sample will be taken?
- What are the sample inclusion and exclusion criteria? (e.g. minimum tumor size?)

C. Specimen type: (e.g. urine, whole blood, serum, tissue…)

D. Targeted Population: (e.g. Neonates, breast cancer, etc)

8. Will the specimens be handled differently from current pathology practice?

☐Yes ☐ No ☐N/A (animal, cell lines)

If yes, please describe.

9. **Proposed plan of sample collection from patient**
   (eg. Who is doing the phlebotomy, collecting the tissue, etc.?).

10. **Will the specimens be de-identified?** ☐Yes ☐ No

11. **Does this project require services from the pathology department?** ☐Yes ☐No

    If yes, please list the tests, procedures, and/or services requested (e.g. immunohistochemistry, standard chemistry or hematology tests)**:**

12. **Expected total number of specimens /year:**

13. **Frequency and volume of tests being requested**
    (i.e. one time/week; 5 samples each):

14. **How are you planning on setting up the billing account?**
    ☐Hospital finance
    ☐Pathology directly
    ☐n/a

NOTE

Remember to establish the appropriate billing account

Personnel interacting with Laboratory (continued)

Name:
Position:
Contact Information:
IRB approval of personnel (if human material):
Details of planned Laboratory interaction (e.g. titrating antibody): .

Name:
Position:
Contact Information:
IRB approval of personnel (if human material):
Details of planned Laboratory interaction (e.g. titrating antibody):

Name:
Position:
Contact Information:
IRB approval of personnel (if human material):
Details of planned Laboratory interaction (e.g. titrating antibody):

Name:
Position:
Contact Information:
IRB approval of personnel (if human material):
Details of planned Laboratory interaction (e.g. titrating antibody):

Name:
Position:
Contact Information:
IRB approval of personnel (if human material):
Details of planned Laboratory interaction (e.g. titrating antibody):

Name:
Position:
Contact Information:
IRB approval of personnel (if human material):
Details of planned Laboratory interaction (e.g. titrating antibody):