# 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.gottesm**](mailto:susan.gottesman@downstate.edu)[**an@downstate.edu**](mailto:an@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**

## Principal Investigator

Name:

Position:

Department:

Phone number:

Email:

## Study Title:

1. **Is this a Clinical Trial?** Yes No

## Grant Number/ Research Foundation Account number/ Funding Source

1. **Approvals (as applicable) & Expiration Date**

|  |  |
| --- | --- |
| **Approval number** | **Expiration date** |
| IRB IACUC  Biosafety |  |

1. **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):

## Specimen

* 1. ☐Human ☐Animal ☐N/A (cell lines)

If animal, please list species:

If animal, skip to question 10

* 1. **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?)
  1. **Specimen type:** (e.g. urine, whole blood, serum, tissue…)
  2. **Targeted Population:** (e.g. Neonates, breast cancer, etc)

## Will the specimens be handled differently from current pathology practice?

* Yes ☐ No ☐N/A (animal, cell lines)

## If yes, please describe.

1. **Proposed plan of sample collection from patient**

(eg. Who is doing the phlebotomy, collecting the tissue, etc.?).

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

## 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)**:**

## Expected total number of specimens /year:

1. **Frequency and volume of tests being requested**

(i.e. one time/week; 5 samples each):

## 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):