**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**](mailto:susan.gottesman@downstate.edu) **and** [**caitlin.otto@downstate.edu**](mailto:caitlin.otto@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: Click here to enter text.

Position: Click here to enter text.

Department: Click here to enter text.

Phone number: Click here to enter text.

Email: Click here to enter text.

1. **Study Title:** Click here to enter text.
2. **Is this a Clinical Trial?** Yes No
3. **Grant Number/ Research Foundation Account number/ Funding Source**

Click here to enter text.

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

|  |  |  |
| --- | --- | --- |
|  | **Approval number** | **Expiration date** |
| IRB | Click here to enter text. | Click here to enter text. |
| IACUC | Click here to enter text. | Click here to enter text. |
| Biosafety | Click here to enter text. | Click here to enter text. |

1. **Personnel interacting with Laboratory**

(list all, additional space can be found at the end of this form)

Name: Click here to enter text.

Position: Click here to enter text.

Contact Information: Click here to enter text.

IRB approval of personnel (if human material): Click here to enter text.

Details of planned Laboratory interaction (e.g. titrating antibody): Click here to enter text.

Name: Click here to enter text.

Position: Click here to enter text.

Contact Information: Click here to enter text.

IRB approval of personnel (if human material): Click here to enter text.

Details of planned Laboratory interaction (e.g. titrating antibody): Click here to enter text.

1. **Specimen**

**A.** Human Animal N/A (cell lines)

If animal, please list species: Click here to enter text.

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.?).

Click here to enter text.

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? Click here to enter text.
  + What size of sample will be taken? Click here to enter text.
  + What are the sample inclusion and exclusion criteria? (e.g. minimum tumor size?) Click here to enter text.

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

Click here to enter text.

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

Click here to enter text.

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

Yes  No N/A (animal, cell lines)

**If yes, please describe.**

Click here to enter text.

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

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

Click here to enter text.

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

Click here to enter text.

1. **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)**:**

Click here to enter text.

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

Click here to enter text.

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

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

Click here to enter text.

1. **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: Click here to enter text.

Position: Click here to enter text.

Contact Information: Click here to enter text.

IRB approval of personnel (if human material): Click here to enter text.

Details of planned Laboratory interaction (e.g. titrating antibody): Click here to enter text.

Name: Click here to enter text.

Position: Click here to enter text.

Contact Information: Click here to enter text.

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Position: Click here to enter text.

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Details of planned Laboratory interaction (e.g. titrating antibody): Click here to enter text.

Name: Click here to enter text.

Position: Click here to enter text.

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