**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** **and** **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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