**STEP 3: Use of Clinical Laboratory and/or Anatomic Pathology Services or Specimens for Research**

Submit completed form electronically to:

pathologygroup@downstate.edu

This is **STEP 3** of a three-step process:

**STEP 1:**

* Complete ‘**STEP 1 Pathology Research Approval Form**,’ and submit to the Pathology Research Approval Committee (pathologygroup@downstate.edu). A committee member will review and schedule a meeting to discuss if needed.

**STEP 2:** Apply for and receive IRB, Biosafety, and/or IACUC approval, as applicable.

**STEP 3:**

* Complete the **‘STEP 3 Pathology Research Approval Form**,’ and submit to the Pathology Research Approval Committee (pathologygroup@downstate.edu).
* A Pathology Study Approval number will be issued upon approval of this form.

**Note: Do not complete STEP 3 until you have completed the first two steps of the process.**

## Principal Investigator

Name: Click or tap here to enter text.

Position: Click or tap here to enter text.

Department: Click or tap here to enter text.

Phone number: Click or tap here to enter text.

Email: Click or tap here to enter text.

## Study Title: Click or tap here to enter text.

Is this a Clinical Trial? [ ] Yes [ ]  No

**Grant Number/Research Foundation Account Number/Funding Source:**

Click or tap here to enter text.

**Approvals (as applicable) and Expiration Date(s)**

|  |  |  |
| --- | --- | --- |
|  | **Approval Number** | **Expiration Date** |
| IRB | Click or tap here to enter text. | Click or tap to enter a date. |
| IACUC | Click or tap here to enter text. | Click or tap to enter a date. |
| Biosafety | Click or tap here to enter text. | Click or tap to enter a date. |

[ ] 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. (see B on page 2 for Anatomic Pathology – tissue procurement)*

1. Names and titles of individuals interacting with Laboratories:

Click or tap here to enter text.

1. Specimen Source:

[ ] Human

[ ] Animal

*If animal, what is the species?* Click or tap here to enter text.

1. Tests requested:

Click or tap here to enter text.

1. Frequency of submission and number of samples to be tested (eg. One time/week; samples each): Click or tap here to enter text.
2. Total Number of samples/year: Click or tap here to enter text.

For **Human Samples**:

1. Target Patient Population (i.e. Patients with what type of disease or history):

Click or tap here to enter text.

1. 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.

1. Will specimens be de-identified?

[ ]  Yes

[ ]  No

[ ] B. Use of **Anatomic Pathology Facilities**

*Tissue samples, slide preparation, and staining including immunohistochemistry stains.*

 1. Names and titles of individuals interacting with Laboratory:

Click or tap here to enter text.

 2. Specimen Source (select one):

 [ ] Human

 [ ] Animal

 [ ] Cell Line

 **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

[ ] Sample from fresh surgical pathology specimen(s) obtained for clinical care [Involvement of Attending Pathologist required]:

* + What is the size (measurement) of sample to be taken?

Click or tap here to enter text.

* + What are the sample inclusion and exclusion criteria? (e.g. minimum tumor size?)

 Click or tap here to enter text.

1. Patient Population (i.e. type of disease or clinical history in patients)

Click or tap here to enter text.

1. Tests requested:

Click or tap here to enter text.

1. Frequency of submission and number of samples to be tested (eg. One time /week; samples each)

Click or tap here to enter text.

1. Total number of samples/year:

Click or tap here to enter text.

**C. Billing**

**How are you setting up the billing account?** (select one):

[ ] Hospital finance

[ ] Pathology directly

[ ] N/A [only check if taking excess material without requiring services]

**FOR PATHOLOGY DEPARTMENT USE ONLY**

**D. Approval**

I have reviewed the information above, and approve this study to proceed.

**E. Pathology Study Identification Number** (issued by Pathology Department)

**Pathology Study ID #:** Click or tap here to enter text.