**STEP 1: Use of Clinical Laboratory and/or Anatomic Pathology Services or Specimens for Research**

Submit completed form electronically to:

[pathologygroup@downstate.edu](mailto:pathologygroup@downstate.edu)

This is **STEP 1** 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](mailto:pathologygroup@downstate.edu)). A committee member will review and schedule a meeting to discuss if needed.

**STEP 2:** Apply for and receive IRB, Biosafety Committee, 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](mailto:pathologygroup@downstate.edu)).
* A Pathology Study Approval number will be issued upon approval of this form.

## 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

A. Use of **Clinical Laboratory**:

*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 per submission): 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 **Anatomical 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. Pathology Department Approval**

I have reviewed the information above, and confirm that this study is feasible for the Pathology Department. **Note that this does NOT indicate approval by the IRB, Biosafety Committee, or IACUC. If indicated, approval must be obtained through separate application(s).**

