Instructions for Research Projects using UHB Pathology Laboratories and Pathology Specimens

(Clinical Laboratories & Histology Lab/Surgical Pathology)

This is a 3 STEP process:
Step 1: Complete Step 1 "Specimen use and Laboratory feasibility determination" form
Step 2: IRB, IACUC, Biosafety approval, as needed.
Step 3: Filing of "Protocol of UHB Laboratory Use for Research Projects: Clinical Laboratories & Histology Lab/Surgical Pathology" with the Pathology Department

Step 1: Feasibility Determination

1. Fill out STEP 1 form (STEP 1 Form can be found on the IRB website or the UBH website)

2. Please contact Dr. Susan Gottesman (Susan.Gottesman@downstate.edu) or Dr. Caitlin Otto (Caitlin.Otto@downstate.edu) who will direct you to the proper laboratory individuals and will start the process for application to the pathology labs.

3. Schedule a meeting with Dr. Gottesman or Dr. Otto to discuss the feasibility of the request, scheduling, ordering, availability of samples, fee schedule, etc. The Step 1 form and meeting must be done prior to IRB or IACUC approval. Any request for samples from fresh tissue submitted to the surgical pathology laboratory will require a review by a surgical pathology attending to ascertain that patient care will not be compromised.

4. Use "Use of Prospective Pathology Samples" instructions document to guide you as to what information we will need at the meeting should you be requesting specimens from us. The instructions document is located on the pathology website.

5. Following submission and approval of Step 1, a pathology representative will indicate approval to the IRB thus allowing your IRB application to proceed. NOTE: The IRB application will not be approved until a department representative has approved the Step 1, Feasibility form.

Step 2: Proceed with Biosafety/IRB/IACUC applications, as needed

Step 3: Protocol Filing

1. Once you have obtained IRB/BioSafety/IACUC approval, fill out STEP 3 form. The Step 3 form will require: your IRB/IACUC approval number and expiration date, your funding account so that billing can be set up, and a detailed protocol so that we can follow it in order to work with you.

2. We will issue you a **pathology approval number** which you will need to put on all specimen study requests. This number will include the month and year of expiration of IRB and IACUC approval and will also indicate if it is a clinical trial.

3. Create a billing account. Projects using Clinical Laboratories can either have accounts set up with

    a. Hospital Finance which will directly bill the Research Foundation (RF) account or
    b. Pathology department LIS division (maria.yudlowitz@downstate.edu)

    For choice 1, results will be in Healthbridge and will need to be identified specimens. For choice 2, the specimens can either be identified or de-identified. The results will remain in Cerner and will not be transferred to Healthbridge. The choice will be the PI's. In the case of pathology department billing accounts, the investigator will be billed monthly by Pathology and will need to request RF to reimburse the department.

    Projects involving Surgical Pathology including the histology laboratory must have accounts set up with Pathology Department administration. The investigator will be billed monthly or quarterly by Pathology.

4. Involved Research Personnel will be trained by laboratory staff for ordering, submitting and handling of samples. Involved Laboratory Staff will be instructed on handling of research specimens.

5. All investigators must forward annual renewal of IRB or IACUC approval. Only exempt studies do not require annual renewal. Lapse in documentation of approval will result in suspension of services.

6. Any change in involved research personnel requires notification of the laboratory administration and submission of proper documentation. Any changes in protocol that involve the pathology department must be reviewed first by pathology.

7. Delinquent accounts (> 6 months post billing) will result in suspension of services.

8. Laboratory administration should be notified at termination of a project.

9. IRB renewal process: If there are changes to the requested pathology department services, contact Dr. Gottesman or Dr. Otto for approval.

For Clinical Pathology Laboratory Services:

Charges will be based on processing required and on test requested. This will be discussed at meeting with pathology staff following submission of Protocol. Fee schedule is available.

Instruments may not be operated by individuals other than laboratory staff.

Please be advised that turnaround time will vary depending on test request and work volume.

For Use of Histology Laboratory Services:

Available for SUNY Downstate faculty projects only.
Specimens originating from outside the institution are not able to be processed at this time.
Please be advised that turnaround time will vary depending on work volume.
Fee schedule available.

All requests must be accompanied by the *Histology Requisition Form for Research*. The form must include the PATHOLOGY APPROVAL NUMBER assigned after submission and approval of the STEP 3 pathology approval forms. *Histology Requisition Forms for Research* are located in the histology laboratory (UH A2-466).

For studies requiring specimen processing:
- Coordination with staff is required each time prior to submission of specimen. This is to ensure that sufficient staff is available to handle the research specimens in addition to the priority hospital samples.

For Sectioning, Staining and Special Stains:
- Equipment may only be operated by Department of Pathology employees.

For studies requiring Pathologist review of slides and block selection:
Meeting with pathology attending is required.
This may apply to multicenter clinical trials.

For Use of Prospective Pathology Samples:

See “Use of Prospective Pathology Samples” instructions document located on the pathology website