**Study Setup Form for Pathology and Laboratory Services**

**For Testing at Strong Memorial Hospital (SMH) and UR Central Lab ONLY**

* **Highland Hospital (HH) will not accept this form for Pathology and Lab Services. Please contact:**
* **Julio Brito (**[**Julio\_Brito@URMC.Rochester.edu**](mailto:Julio_Brito@URMC.Rochester.edu)**) ,**
* **Elise ODea (**[**Elise\_ODea@URMC.Rochester.edu**](mailto:Elise_ODea@URMC.Rochester.edu)**)**
* **For Strong Memorial Hospital and UR Central Labs, email this completed form to:** [**InternalURMCClinicalTrials@URMC.Rochester.edu**](mailto:InternalURMCClinicalTrials@URMC.Rochester.edu)
* **Allow 14 business days to complete routine study set-up.**
* **Complex projects may require additional study setup lead time. Incomplete information will delay the study setup process. Need help? Call (585) 758-0525**

1. **Protocol Information:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Protocol #:** |  | **Protocol Date:** |  |
| **Protocol Full Name:** |  | | |
| **Sponsor Name:** |  | | |
| **Is the Study Federally Funded?** | **Yes**  **No** | **Setup Request Date:** |  |

1. **Contact information:**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Position** | **Name, Title** | **Department** | **Intra-Mural Box #** | **Phone** | **Fax** | **Email** |
| Principal Investigator |  |  |  |  |  |  |
| Study Coordinator |  |  |  |  |  |  |
| Invoice Recipient |  |  |  |  |  |  |
| Requester Information |  |  |  |  |  |  |

1. **Billing Account Information:**

|  |  |
| --- | --- |
| **Account Number Information (Fill in all fields to process request)** | |
| **Company: CM ###** |  |
| **Ledger Account: ##### *(Ex. 65300)*** |  |
| **FAO/Grant: (2 letters, 6 digits)**  ***Ex: (GR######, OP######)*** |  |
| **Spend Category (Check one)** | **Federal (SC48500)**  **Non-Federal (SC48450)** |
| **Account Expiration Date: DDMMMYYYY** |  |

1. **Study Size, Duration, Patient Demographics:**
   1. First expected visit date:
   2. Expected study duration:
   3. Subject Information: (check one)

Human

Animal

* 1. Number of Subjects:
  2. Number of lab visits per subject:

1. **Reporting Requirements:**
   1. Preferred report delivery method (check one)

FAX

FAX Number:

Intramural Mail

Intramural Box#:

Email

Email Address:

None (will retrieve through e-record)

**Note:** If patient name and MRN are used, the patient may need to be opted out of e-record to prevent MyChart access of lab results.

* 1. How will samples be labeled:

**Note:**Only lab orders under patient names will appear in eRecord

Subject name, MRN

De-identified, subject ID

If de-identified, provide the subject ID format (Ex: last name: study name, first name: 3 digit code)

1. **Lab Services - Please check all that apply:**

Point of Care Urine Pregnancy Test

Phlebotomy **(complete section G)**

Clinical Lab Tests (ex: CBC, Urinalysis, etc.) **(complete section H)**

Surgical Pathology **(complete section I)**

1. **Phlebotomy:** 
   * + Special instructions for requisition:  Yes  No

Please provide detailed instructions (if applicable): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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1. **Test Menu (required for clinical lab testing):**

**\*\***Any reflex/add-on tests may incur additional charges\*\*

**Be Specific:** If unsure, refer to the URMC LABS Test index: [**https://www.testmenu.com/rochester**](https://www.testmenu.com/rochester)

|  |  |  |
| --- | --- | --- |
| **Test number**  *(Ex: CBC)* | **Test name**  *(Ex: CBC with Platelet Count)* | **CPT Code-if available**  *(Ex: 85027)* |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

1. **Surgical Pathology (SMH):** *(Reminder: See page 1 for HH Contact Information)*
   1. Surgical Pathology Archived Material (previous case material):

**Block**

**Note:** SMH does not routinely release tissue blocks. Please consider requesting slides or punches if feasible. If a block is required, requests will be considered on a case-by-case basis upon pathologist review.

**Block selection criteria:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Slides:**

**Unstained:**

Charged slides  Uncharged slides

Number of slides: \_\_\_\_\_\_\_\_\_

Microns thickness: \_\_\_\_\_\_\_\_

**Stained:**

Charged slides  Uncharged slides

Type of Stain (Ex: H&E, CK7): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Number of slides: \_\_\_\_\_\_\_\_\_

Microns thickness: \_\_\_\_\_\_\_\_

**\*\*\***What is the **minimum** number of slides acceptable to the sponsor in the event the tissue is insufficient to provide the total requested amount? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Core punch from tissue block:**

How many: \_\_\_\_\_

Size in millimeters: \_\_\_\_

**Sections/scrolls/shavings (in microtubes):**

Section  Scrolls  Shavings

How many: \_\_\_\_\_\_\_\_\_\_\_\_\_\_

Microns thickness: \_\_\_\_\_\_\_\_

* 1. Surgical Pathology Fresh Tumor Biopsy (new case material):

**Billing Information: (Check one)**

Standard-of-care (billed to insurance)

Non-SOC (billed to study ledger)

**Body Site / Disease State:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Type of Biopsy: (Check below)**

Core needle biopsy

Bone marrow biopsy/aspirate

Excision

Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Department where procedure will occur: (Check below)**

Interventional Radiology (IR)

Wilmot Cancer Center

Surgery

Other: \_\_\_\_\_\_\_\_\_\_

**Processing/services needed:**

FFPE Tissue Block only

Routine processing of tissue sample with pathologist diagnosis

Snap freezing only

(if specific instructions are not provided, pathology will snap freeze according to URMC standards)

Routine processing of tissue sample with special instructions/diagnosis: (Ex: rule out malignancy only; assess for fibrosis/cirrhosis only)

Please explain: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Special handling of tissue sample:

(Ex: place biopsy in tissue cassette in 10% formalin for 8-24 hours, then transfer cassette to 70% ethanol)

Please explain: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. **Labeling of slides/block/tubes:**

**Default labeling:** Surgical pathology will labeled the case with pathology accession/case #. The study coordinator will affix study-specific label from kit once the materials have been picked up from Pathology.

**If different labeling is required, please specify:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. **Special Instructions:** (i.e.: cut first section and discard, then cut remaining sections OR when selecting the block for archived material, choose the block with at least 60% tumor content).

Please Explain: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**If your study requires additional lab services that are not listed on this form,**

**Please call 585-758-0525 at the time you submit this form to discuss**