**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****) ,**
* **Elise ODea (****Elise\_ODea@URMC.Rochester.edu****)**
* **For Strong Memorial Hospital and UR Central Labs, email this completed form to:** **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**