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**Clinical Research Study Setup for Pathology and Laboratory Services Request Form**

**Complete this form and e-mail to** **LabSRSS@urmc.rochester.edu**

**Allow 10-14 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**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Requester Name:** |  | **Department:** |  | **Date of Request:** |  |
| **Requester Phone #** |  | **Requester Email:** |  | **Intra-Mural Mail Box #:** |  |
| **Requester Fax #:** |  |
| **Protocol #:** |  | **Version Date:** |  | **Sponsor:** |  |
| **Protocol Full Name:** |  |
| **Is the Study Federally Funded?** |  **Yes** [ ]  **No** [ ]  |

1. **Contact information:**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Position** | **Name** | **Title** | **Department** | **Phone** | **Fax** | **Email** |
| Principal Investigator |  |  |  |  |  |  |
| Study Coordinator |  |  |  |  |  |  |
| Billing Contact |  |  |  |  |  |  |
| Other |  |  |  |  |  |  |

1. **Billing Information:**

**-All information must be accurate and complete in order to comply with Workday**

* Account Number for lab work MUST include all of the following:

|  |  |
| --- | --- |
| Company: CM ### | 0 |
| Ledger Account: | 65300 |
| FAO/Grant: (2 letters, 6 digits) Ex: (GR######, OP######) |  |

* + **Spend category**:

Is this a federally funded study? [ ]  YES (SC48500) [ ]  NO (SC48450)

* Account Number Expiration Date:      /    /
1. **Study Size, Duration, Patient Demographics:**
	1. Is this one of many sites participating in a larger multicenter study? [ ]  Yes [ ]  No
	2. First expected visit date:          Expected study duration:
	3. Subjects: [ ]  Human; Age and Gender:          [ ]  Animal
	4. Number of Subjects:          # Lab visits per subject:
2. **Reporting Requirements:**
	1. Preferred report delivery method (check one)

[ ]  FAX FAX Number:

[ ]  Intramural Mail Intramural Box#:

[ ]  Networked Printer Make/Model:

 IP Address:

 Printer Room#:

[ ]  None (will retrieve through e-record)

* If patient name and MRN is used patient may need to be opted out of e-record to prevent my chart access of lab results.
	1. The report should be delivered to the attention of:
	2. How will samples be labeled: [ ]  Subject name, MRN

 [ ]  De-identified, subject ID

* If de-identified, provide the subject ID format (e.g. last name: study name, first name: 3 digit code)
* *Note: Only lab orders under patient names will appear in eRecord*
1. **Lab Services - Please check all that apply:**

[ ]  Phlebotomy (complete section F)

 [ ]  Point of Care (complete section G)

[ ]  Sample analysis at URMC Lab (complete section I)

[ ]  Microbiology (complete section I)

[ ]  Anatomic Pathology (complete the applicable section(s) below**)**

[ ]  Other:

1. **Phlebotomy:**

Will you use the URMC LABS’ Patient Service Centers to draw blood? [ ]  Yes [ ]  No

* + - If yes, indicate Patient Service Centers that will be utilized:
		- Will the study sponsor provide kits? [ ]  Yes [ ]  No
		- Will you need URMC to provide any supplies? [ ]  Yes [ ]  No
			* If yes, list all supplies needed:
		- Special instructions for phlebotomy staff : [ ]  Yes [ ]  No
			* Please provide detailed instructions: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
1. **Point of Care (POC) Testing:**

Are you doing any Point of Care Testing for this study (e.g. urine pregnancy)?

 [ ]  Yes [ ]  No

* + - If yes, please list POC test names :
		- Is the study sponsor providing POC testing supplies? [ ]  Yes [ ]  No
		- If yes, please list test kit names :
		- Do you currently perform any POC testing in your area for other studies?

[ ]  Yes [ ]  No

1. **Archived Material (previous case material):**

 [ ]  **Block** Note: UR Medicine Labs does not routinely release tissue blocks on

 SOC cases. If there is an alternative, such as slides, please request the

 alternative instead. If the requirement is for a block and there is no other

 acceptable alternative, submit the request and it will be considered on a

 case-by-case basis, upon pathologist review of the case, and provide

 block selection criteria: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 [ ]  **Slides** [ ]  Unstained: Number of slides: \_\_\_\_\_\_\_\_\_\*\*\*

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

 [ ]  Charged slides [ ]  Uncharged slides

 [ ]  Stained: Type of Stain: \_\_\_\_\_\_\_\_\_\_\_\_ (ex: H&E)

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

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

 [ ]  Charged slides [ ]  Uncharged slides

**\*\*\*Please answer**: What is the **minimum** number of slides acceptable to the sponsor should the tissue be insufficient to provide the requested amount? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[ ]  **Core punch from tissue block:** How many: \_\_\_\_\_\_\_\_\_

 Size: \_\_\_\_\_\_\_\_\_\_\_\_\_\_

 [ ]  **Sections/scrolls/shavings (in microtubes):** How many: \_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

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

**[ ]** Standard-of-care (billed to insurance) [ ]  Non-SOC (billed to study ledger)

 Body site/Disease: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Type of Biopsy: [ ]  Core needle biopsy

[ ]  Bone marrow biopsy/aspirate

[ ]  Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Department where procedure will occur:

 [ ]  IR (Interventional Radiology)

[ ]  Cancer Center

[ ]  Surgery

[ ]  Other: \_\_\_\_\_\_\_\_\_\_

Department responsible for transporting the specimen to Pathology: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Processing/services needed:

 [ ]  FFPE Tissue Block only

[ ]  Snap freezing only (if specific instructions are not provided, pathology will snap freeze according to URMC standards)

 [ ]  Routine processing of tissue sample with pathologist diagnosis

 [ ]  Routine processing of tissue sample with special instructions/diagnosis:

 (i.e.: r/o malignancy only, for fibrosis/cirrhosis)

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

[ ]  Special handling of tissue sample: (i.e.: place biopsy in tissue cassette of 10% formalin for 8-24 hours, then transfer cassette to 70% ethanol)

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

[ ]  Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. **Supplies:** Provided by study: [ ]  Yes [ ]  No

 If yes, please list: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. **Labeling (of slides/block/tubes):** Usually labeled with pathology accession/case # and the study coordinator affixes 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: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. **Shipping:** [ ]  Yes [ ]  No

 If yes, to be done by: [ ]  Study Coordinator [ ]  Clinical Trials

1. **Storage:** [ ]  Yes [ ]  No

 If yes, please explain: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. **Specimen Storage:**

**Unless otherwise specified, all samples analyzed at UR Medicine Labs will be stored according to normal lab practices depending on what tests are ordered and discarded after several days. For more information call Clinical Trials at 585-758-0525.**

After analysis, is Short Term Specimen Storage Required: (Less than 1 week) [ ]  Yes [ ]  No

* + If yes, indicate required storage temperature(s):

[ ]  -20° Freezer [ ]  Ambient

[ ]  -80° Freezer [ ]  Other requirements:

[ ]  Refrigerator [ ]  Special specimen storage request

1. **Test Menu:** (List all tests that will be tested and reported by UR Medicine labs):

**Be Specific:** If unsure, refer to the URMC LABS Test index: <https://www.testmenu.com/rochester>

|  |  |  |  |  |  |  |  |  |  |
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1. **Lab Requisitions**
	* Requisition proof approver name and email:
	* The approved requisition will be sent to you as a pdf

**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.**