Study Coordinators Organization for Research & Education (SCORE)

Utilizing URMC Laboratory Resources for Collecting and Processing Biological Research Samples

Presented by:
URMC Labs
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Debbie Street & Sarah Miscavage, Clinical Trials Project Assistants
and
Kelly Callahan, Sr. Health Project Coordinator,
Division of Allergy/Immunology & Rheumatology

Learning Objectives:
1. Describe the services available to researchers from the URMC Clinical Laboratory Services and how to navigate through the Clinical Laboratory Service website.
2. Describe the (NEW!)URMC Clinical Laboratory Biological Sample Management Tool.
3. Describe the two necessary lab forms for obtaining pricing and services from URMC Labs.
4. Demonstrate processes for shipping biological samples.

Thursday, March 10, 2016
Helen Wood Hall, 1W-502
Presentation: 12:00pm – 1:00pm
Coordinators’ Chat: 1:00pm – 1:30pm
Feel free to bring your lunch!

The next SCORE meeting will be held on
Thursday, April 14, 2016, SRB 1416

SCORE is sponsored by the CTSI as a coordinator-run forum to create opportunities for sharing, learning, and connecting with peer research coordinators.

For questions about SCORE, contact SCORE@urmc.rochester.edu.

If ASL interpreter services are needed for this meeting, please email SCORE@urmc.rochester.edu. This request must be submitted no later than 3 business days before the meeting. Thank you.
Research Study Setup 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

<table>
<thead>
<tr>
<th>Requester name:</th>
<th>Date requested:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Department:</td>
<td>Protocol #:</td>
</tr>
<tr>
<td>Phone number:</td>
<td>Full Study Name:</td>
</tr>
<tr>
<td>Intra-mural Mail Box:</td>
<td>FAX:</td>
</tr>
<tr>
<td>Email:</td>
<td>Study Sponsor:</td>
</tr>
</tbody>
</table>

A. Contact information:
- Principal Investigator: Title: | Department: | Phone: | Email: |
- Study Coordinator: Department: | Phone: | Email: |
- Billing Contact: Department: | Phone: | Email: |
- Other: Department: Phone: Email:

B. 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: ___ ___ ___
  - Ledger account: 65300
  - FAO/Grant: ___ ___ ___ ___ ___ ___ ___ ___
  - Spend category:
    - Is this a federally funded study? ☐ YES (SC48500) ☐ NO (SC48450)
    - Account Number Expiration Date: / / 

C. Study Size, Duration, Patient Demographics:
- a) Is this one of many sites participating in a larger multicenter study? ☐ Yes ☐ No
- b) Will this study be characterized as a Medicare qualifying study? ☐ Yes ☐ No
- c) How will samples be processed:
  ☐ Collected/prepared for transport to Central Lab (please provide processing instructions)
  ☐ Tested and/or stored at URMC Labs
  ☐ Both
Other (please explain)

d) First expected visit date: Expected study duration:
e) Subjects: □ Human; Age and Gender: □ Animal
f) Number of Subjects: # Lab visits per subject:

D. Reporting Requirements:
a) 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.

b) The report should be delivered to the attention of:

c) 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

E. Lab Services - Please check all that apply:

   □ Phlebotomy (complete section F)
   □ Point of Care (complete section G)
   □ Specimen Storage, Processing, Packaging and Shipping (complete section H)
   □ Sample analysis at URMC Lab (complete section I)
   □ Microbiology (complete section I)
   □ Anatomic Pathology (complete the Anatomic Pathology Addendum form)
   □ Other:

F. 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:
G. **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

H. **Specimen Storage, Processing, Packaging, Shipping (Optional):**

Unless otherwise specified all samples analyzed at URMC 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

After analysis, is Long Term Specimen Storage Required: (More than 1 week)  
☐ Yes ☐ No
- If yes, indicate required storage temperature(s):
  - ☐ -20° Freezer ☐ Ambient
  - ☐ -80° Freezer ☐ Other requirements:
  - ☐ Refrigerator ☐ Special specimen storage request

Will URMC labs be required to ship samples with an external courier, e.g. FedEx or UPS?  
☐ Yes ☐ No  If yes, list which courier is needed:

Will the study sponsor provide kits?  
☐ Yes ☐ No

Please list if there are any special packaging/shipping requests (e.g. dry ice)

I. **Test Menu** (List all tests that will be tested and reported by URMC labs:)

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

<table>
<thead>
<tr>
<th>Test 1</th>
<th>Test 2</th>
<th>Test 3</th>
<th>Test 4</th>
<th>Test 5</th>
<th>Test 6</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
</tbody>
</table>

J. **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.**
Research Test Price Quote Form

Need help? Call (585) 758-0525

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<tr>
<td>Phone number:</td>
<td>Ledger Acct#:</td>
</tr>
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<td>FAX:</td>
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</tr>
</tbody>
</table>

Is the study federally funded?  Yes ☐  No ☐

Tests

- ☐ Basic Metabolic Profile
  (Glucose, Sodium, Potassium, Chloride, CO2, BUN, Creatinine, Calcium, Anion Gap, GFR)
- ☐ CBC & Platelet
- ☐ CBC, Platelet & Differential
- ☐ Comprehensive Metabolic Profile
  (Glucose, Sodium, Potassium, Chloride, CO2, BUN, Creatinine, Calcium, Anion Gap, GFR, Total Protein, Albumin, Globulin, Total Bilirubin, AST, ALT, Alk Phos)
- ☐ Glucose
- ☐ Lipid Profile
  (Cholesterol, Triglycerides, HDL, LDL Calc., Cholesterol/HDL ratio)
- ☐ Liver Function Panel
  (Total Protein, Albumin, Globulin, Total Bilirubin, Direct Bilirubin, Indirect Bilirubin, AST, ALT, Alk Phos)
- ☐ Protime/INR
- ☐ PTT
- ☐ Serum Pregnancy
- ☐ Triglycerides
- ☐ Uric Acid
- ☐ Urine Pregnancy (point-of-care? ☐yes ☐no ☐both)
- ☐ Urinalysis with Reflex to Microscopic
- ☐ Urinalysis with Microscopic

List any other testing, be specific:

Your completed request will be returned via email within 5 business days
Send completed request form via email to LabSRSS@urmc.rochester.edu

Research prices for federally funded studies are subject to change per the University patient care rate agreement with the US Department of Health and Human Services. Prices may be adjusted annually based on the medical consumer price index or other changes, such as test methodology.
RESEARCHER BIOSPECIMEN PLANNING TOOL

For those writing a grant or looking to become a site for an approved study, this tool could help determine what services are needed from URMC Labs or direct you to another department that may be better suited for your study in terms of services and cost.

CONSIDERATIONS:

- Does the study require a consultation with the lab?
  - URMC Clinical Trials Lab main phone number: 585-758-0525
  - Can help to determine the feasibility and capability of providing the required services
- Does the study require a CLIA Lab?
  - The Centers for Medicare & Medicaid Services (CMS) regulates all laboratory testing (except research) performed on humans in the U.S. through the Clinical Laboratory Improvement Amendments (CLIA). The objective of the CLIA program is to ensure quality laboratory testing. Although all clinical laboratories must be properly certified to receive Medicare or Medicaid payments, CLIA has no direct Medicare or Medicaid program responsibilities.
- Does the study require URMC Phlebotomy services?
  - To locate UR Patient Service Centers (PSC's): https://www.urmedicine.org/services/ur-labs/
  - Volume of testing – if more than 10 patient encounters per month, URMC labs would need to evaluate the capacity of the PSC’s being utilized for the study
- Does the study require (POCT) Point of Care Testing (testing that is performed at bedside or near the site of patient care)?
  - There are regulations around this type of testing which have to be followed
  - POCT department contact number: 585-275-0229
- Does the study have special requirements other than testing? Such as:
  - Sample processing – specific instructions to spin (rpm’s, refrigerated centrifuge) and aliquot
  - Shipping samples to another facility
  - Sample storage – ambient, refrigerated or frozen
- What biological tests does the study require URMC Labs to perform?
  - For a list of testing that URMC Labs performs, refer to the UR Test Index: https://www.testmenu.com/rochester
  - What is the anticipated volume of tests (number of subjects and visits)?
  - What is the duration of the study?
  - Will the samples be sent in real-time or in batches?
  - Are there any volume restrictions (such as the study was only approved to draw 10mL of blood from the subjects)?
- What supplies are required for the study?
  - Does the study require supplies that are needed for collection or shipping of samples? (Examples: SST (Serum separator tube), Lavender top with EDTA, Light blue sodium citrate tube)
    - If URMC labs is analyzing the samples, then we would provide the supplies
    - Is the study sponsor providing the supplies/kits?
  - If supplies are needed, such as tubes if your department is performing the draws, the research team would need to order them
    - One reference is the Medline website: http://www.medline.com/home.jsp
If supplies such as cryovials or cryo storage boxes are needed (for samples that need to be frozen), two resources are:

- VWR: https://us.vwr.com/store/

URMC Labs may not be the best department to accommodate the needs of the study and may not be the most cost-effective

- Other UR resources may include, but are not limited to:
  - CRC – Clinical Research Center
    https://www.urmc.rochester.edu/crc/; Phone number: 585-275-2907
  - Chris Lane, Infectious Disease – phone number: 585-275-5822
  - Sally Quataert, Center for Vaccine Biology – phone number: 585-273-2454
  - If you are working with an outside institution, you may not need to go through URMC labs – There is no centralized clinical trials dept. at UR

TIMELINES for URMC lab testing – Once it has been decided that URMC Labs can provide the study with the services required, other considerations are:

- Pricing:
  - Submit the research test price quote form to URMC Labs approximately 5 days before it is needed to build the budget. This form is found on the website: https://www.urmedicine.org/services/ur-labs/physicians/researchers.cfm
  - The quote may take longer than 5 days if the testing is not on the fee schedule or involves microbiology or anatomic pathology testing (may require faculty review of study protocol and/or additional research)

- Study Setup:
  - Submit the study setup request form to URMC Labs approximately 10-14 days before the requisition is needed. This form can be found on the website: https://www.urmedicine.org/services/urlabs/physicians/researchers.cfm
  - The setup process takes time to complete the billing and ward setup for reporting (done by CLSS – Clinical Labs System Support), as well as the creation of the requisition which may need approvals from specific lab departments

- Results:
  - When are results needed for the study?
  - The turnaround time (TAT) for results may depend on several factors, such as:
    - Where the test is being performed (example: if UR sends the sample to a reference lab)
    - If the testing is only performed on certain days of the week
    - The courier transportation schedules
**Short Study Name:** Example  

**SMH-SMS:** Batch track samples to RR for processing  

**Study Contact Name:** John Coordinator  
**Contact number:** 275-5555  

**Study Ward:** A7OCM  
**Soft Ins:** RR596  
**Ordering Physician:** SKJGA (Jesse Schallek, PhD)  

<table>
<thead>
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<th>Last name</th>
<th>First Name</th>
<th>Gender</th>
<th>DOB</th>
<th>CollDate</th>
<th>CollTime</th>
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<th>Box</th>
<th>Row</th>
<th>Column</th>
<th>SoftLab#</th>
<th>Comment</th>
<th>Pour-Off Label</th>
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<tbody>
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<td>1</td>
<td>6</td>
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</tr>
</tbody>
</table>

**RR-SL staff:** After registration, scan this manifest to the PM's at: labsrss@urmc.rochester.edu  
**URMC Clinical Trials Central Lab 585-758-0525**
**PHLEBOTOMY STAFF: PLEASE CALL URMC Labs Clinical Trials at 758-0525 with ANY questions**

**Lab Staff ONLY** Apply "Requisition Label":

SEND ADDITIONAL COPIES TO:

- [ ] Fax To: _________________________
- [ ] Call To: _________________________

**STUDY:**
Short study name

**Flowcast Registration Information:**
WARD: [7XXX]
Plan Code: L590
Client Code: [RRXXX]

**Contact name:** Susie Coordinator
**Department:** Infectious Disease
**Box #:** 234
**Telephone:** 555-5555

**Gender:** M
**Birth Date:** 01/01/1980

**Ordering Physician:** (XXXXX) Physician name, MD

**Print Last Name:** SMITH
**Print First Name:** JOHN

**Specimens received:**
- GRN
- GRY
- LAV
- LB
- R
- SST
- SSTU (unspun spun at: __________)
- SWAB
- U

**URMC Clinical Trials Central Labs (585) 758-0525**

**Specimens received:**
- PTT
- PROTIME
- CBC, PLT/DIFF
- PLATELET COUNT
- SEDIMENTATION RATE
- CREATININE, UR
- PROTEIN, UR
- URINALYSIS WITH REFLEX TO MICRO
- URINALYSIS WITH MICRO
<table>
<thead>
<tr>
<th>Collection Date and Time:</th>
<th>Collectors Initials:</th>
<th><strong>lab use only</strong> X-MRN#:</th>
<th>Visit Number</th>
</tr>
</thead>
</table>

**STUDY:** Example  
Contact Name: Susie Coordinator  
Department: Cancer Center  
Box #: 123  
Phone: 275-5555

**Soft Registration Information:** *Do NOT use patient name*  
WARD: [A7XXX]  
Soft Ins: [RRXXX]  
**ATTN Lab Staff:** Please Reg/Log this req separate from any additional reqs**

<table>
<thead>
<tr>
<th>STUDY COORDINATOR – CHOOSE FROM THE OPTIONS BELOW:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>RESVP</strong> ☐ <strong>VENIPUNCTURE FEE FOR RESEARCH</strong></td>
</tr>
<tr>
<td><strong>SPINS</strong> ☐ <strong>SPECIAL LAB INSTRUCTIONS</strong></td>
</tr>
</tbody>
</table>

**PHLEBOTOMY**

1. Study will provide tube(s) for the subject draw. Label all tubes with RESVP barcodes.
2. Place SOFT header label on req. and send with batch.
3. Give copy of the req. to study staff with tubes.
4. If study staff is unavailable to retrieve samples, collect and track all tests in SOFT per normal procedure.
5. Place all tubes and URMC requisition in a specimen bag. Place a RESVP barcode on the outside of the bag and send with next pickup.

**SMH SMS:**

Receive samples in Soft and place specimen bag on black Baker’s rack (room temperature).  
Call the study contact listed above to notify them that a sample is waiting for them to pick up.

***LAB STAFF: PLEASE CALL URMC Labs Clinical Trials at 758-0525 with ANY questions***

<table>
<thead>
<tr>
<th>specimens received:</th>
<th>-GRN</th>
<th>-GRY</th>
<th>-LAV</th>
<th>-LB</th>
<th>-R</th>
<th>-SST</th>
<th>-SSTU (unspun spun at:_______)</th>
<th>-SWAB</th>
<th>-U</th>
</tr>
</thead>
</table>

VER. 02Mar2016

URMC Clinical Trials Central Labs (585) 758-0525
# Order of Draw for Multiple Tube Collections

## Designed for Your Safety

<table>
<thead>
<tr>
<th>Closure Color</th>
<th>Collection Tube</th>
<th>Mix by Inverting</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Blood Cultures</td>
<td>8 to 10 times</td>
</tr>
<tr>
<td></td>
<td>Serum (glass tube)</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>Citrate</td>
<td>3 to 4 times</td>
</tr>
<tr>
<td></td>
<td>BD SST™ Gel Separator Tube</td>
<td>5 times</td>
</tr>
<tr>
<td></td>
<td>BD SST Gel Separator Tube</td>
<td>&quot;</td>
</tr>
<tr>
<td></td>
<td>Serum (plastic tube)</td>
<td>&quot;</td>
</tr>
<tr>
<td></td>
<td>Heparin</td>
<td>8 to 10 times</td>
</tr>
<tr>
<td></td>
<td>BD PST™ Gel Separator Tube With Heparin</td>
<td>&quot;</td>
</tr>
<tr>
<td></td>
<td>EDTA</td>
<td>8 to 10 times</td>
</tr>
<tr>
<td></td>
<td>Fluoride (glucose tube)</td>
<td>8 to 10 times</td>
</tr>
</tbody>
</table>

**Note:** Always follow your facility’s protocol for order of draw

Handle all biologic samples and blood collection “sharps” (lancets, needles, luer adapters and blood collection sets) according to the policies and procedures of your facility. Obtain appropriate medical attention in the event of any exposure to biologic samples (for example, through a puncture injury) since they may transmit viral hepatitis, HIV (AIDS), or other infectious diseases. Utilize any built-in used needle protector if the blood collection device provides one. BD does not recommend reshielding used needles, but the policies and procedures of your facility may differ and must always be followed. Discard any blood collection “sharps” in biohazard containers approved for their disposal.
How to Prepare a Quality Sample Using BD Vacutainer® SST™ Tubes

Invert

5 Times

- Gently invert 5 times to mix clot activator with blood.

Clot

30 Minutes

- Allow blood to clot for a minimum of 30 minutes in a vertical position.
- Observe a dense clot.

Spin

10 Minutes

- Centrifuge at FULL SPEED (between 1100 and 1300 g) for 10 minutes for swing-head units or 15 minutes for fixed angle units (balance tube in centrifuge).
- Barrier will form, separating serum specimen from clot.
- Transport spun tube to laboratory.
## Plastic SST™ Tubes

<table>
<thead>
<tr>
<th>Reorder Number</th>
<th>Tube Size (mm)</th>
<th>Closure/Stopper</th>
<th>Stopper Color</th>
<th>Type of Label</th>
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<tr>
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<td>13 x 75</td>
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<td>Gold</td>
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<td>Red/Gray</td>
<td>Paper</td>
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*Double Gel Transport Tubes
“The Samples” How to Package Biological Specimens for Shipment

REQUIREMENTS

- IATA training and certificate – training required for packaging (and transport) of samples:
  - Enroll through Blackboard:
    - https://secure1.rochester.edu/safety/restricted/shipping/ShippingBiologicalsDryIceTrainingSelfEnrollment.pdf
- Transporting samples in your vehicle:
  - https://secure1.rochester.edu/safety/restricted/shipping/Shipping_AppendixII.pdf
- Contact Biosafety Officer at Environmental Health & Safety with your shipping questions 275-3014

RESOURCES, EQUIPMENT and SUPPLIES

- Study specific lab manual(s) – provided by the study sponsor
- Stock of kits (plus bulk supply) – manage expiration dates and timing/flow of kit/supply ordering – automatic resupply? Extra tubes for separate tests.
- Shipping container types: frozen, ambient, combo. Follow triple packaging concept.
- Labeling: use carrier air bill and classify package appropriately: Examples: Infectious Biological substance Category B, UN3373, class 6; Non-Infectious GMOs, UN3245, class 9; Dry Ice UN1845, class 9
- Dry ice – order prior to shipping date (not too far ahead or it will sublimate, turn to a gas) – coordinate with your labs so dry ice for study visit samples doesn’t get used up for another project. Don’t forget your account number for ordering.
- Identify freezer space for storing samples if necessary, as well as short term storage of dry ice. Follow temperature monitoring regulations.
- Record Keeping – document and retain copies of shipment information
- Access to centrifuge
  - Calibration certificate: http://www.phoenixequip.com/
  - Balancing scale
  - Protective equipment
  - Sharps containers etc.

OTHER DETERMINATIONS: Processes for:

- Lab results review and sign-off (emailed, faxed, mailed)
- Handling critical values (safety)
- Putting research labs into eRecord (scanning)
- Sending results to Primary Care Physician (following release of info policies)