

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 URMCLabs 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?
 - URMCLabs 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 URMCLabs 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, URMCLabs would need to evaluate the capacity of the PSC's being utilized for the study
- Does the study require Point of Care Testing (POCT - 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
- What biological tests does the study require URMCLabs to perform?
 - For a list of testing that URMCLabs 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)?
- Does the study have special requirements in addition to 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 supplies are required for the study?
 - Does the study require supplies that are needed for collection or shipping of samples? (Examples: Serum separator tube (SST), Lavender top with EDTA, Light blue sodium citrate tube)
 - Is the study sponsor providing the supplies/kits?
 - If URMCLabs is analyzing the samples, then URMCLabs could provide the supplies
 - If URMCLabs is not analyzing the samples, then you will need to order supplies:
 - 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/>
 - Fisher Scientific: <https://www.fishersci.com/us/en/home.html>
- URMCLabs 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:
 - Clinical Research Center (CRC)
<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 URMCLabs (Note: There is no centralized clinical trials department at UR)

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

- **Pricing:**
 - Submit the Research Test Price Quote Form to URMCLabs 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 Research Study Setup Request Form to URMCLabs approximately 10-14 days before the requisition is needed. This form can be found on the website: <https://www.urmedicine.org/services/ur-labs/physicians/researchers.cfm>
 - The setup process takes time to complete the billing and ward setup for reporting (done by Clinical Labs System Support - CLSS), 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