

Remote Lab Procedures

COVID-19: Specimen Collection Questions for Sponsors when developing a Continuity of Care Plan

1. Can safety labs normally performed at central lab be moved to a local lab?
2. Provide guidance on what labs to obtain vs. what can be skipped (safety labs vs. research only (PK) vs. those stored for future research)
3. Is it possible to send the lab collection kits to participant's home to have them take to local lab to have drawn remotely at an affiliated site?
 - a. Labs would then be picked up by a courier and transported to MUHA for processing
 - b. Will shipping supplies required to ship specimen collection supplies to the participant's home be provided by the sponsor?
 - i. Will need sponsor courier (FedEx, UPS, etc.) account number
4. Can testing be performed at home?
 - a. Can pregnancy testing kits be shipped to a participant's home?
 - b. Can the sponsor ship a collection kit (such as Mitra) directly to the participant and the participant ship to central lab?
 - i. Will need sponsor courier (FedEx, UPS, etc.) account number

MUSC Laboratory Contact information:

MUHA Clinical Lab: **Lab Client Services 843-792-0707**
Fast Flow Lab, Room EH318

NEXUS Research Lab: **Amy Gandy 843-792-2595**
Research Lab located on 2nd floor of CSB, Room 216B

The following is guidance for research teams: Conducting Clinical Safety and Research Labs Outside of MUSC's Main Campus

Clinical Safety Labs

To be performed at MUSC affiliated site. Specimen collection at sponsor contracted labs (such as LabCorp, Quest, etc.) should be coordinated with the sponsor.

April 9, 2020

1. It is preferable for an Epic order for clinical labs to be collected at off-site laboratory to be entered using the approved study SmartSet. Alternatively, the PI can enter the lab order and associate to the research study.
 - a. If a clinical lab was previously performed centrally and will now be performed locally and will be paid for by research, an amendment to the study billing plan will be required in order to route the lab charge to the research study in Epic.
2. Instruct participant to go to an MUSC affiliated site to have blood drawn.
 - a. A list of affiliated sites can be found here: <https://muschealth.org/patients-visitors/about-us/affiliation> and <https://muschealth.org/medical-services/labs>
 - b. When selecting the affiliated site, keep in mind participant's residence, and whether research labs will need to be transported by MUSC courier to MUHA (see Research Only Labs section below).
 - c. It is suggested to have the clinical safety labs done the day prior to the study visit.
3. Once specimens have been collected, the off-site laboratory will perform the testing or the scheduled courier will pick up the sample and transport to MUHA lab.
4. If the sample was not tested at the off-site laboratory, MUHA will perform the testing.
5. Results will be available in the Epic medical record.
6. Ensure lab charges are routed to the research study through Epic billing review.

Research Only Labs

Please note that if an Epic order for a clinical lab is not present, the venipuncture charge must be selected on the Billing Sheet and included with the specimen collection supplies in order for research labs to be drawn.

1. Coordinator will need to place empty, properly labeled (as defined by sponsor) blood collection tubes for research samples in a biohazard bag and label the bag with the research study member name and contact information.
 - a. If research labs will be processed by MUHA, a Billing Sheet and Processing or Shipping for Grants form must accompany the blood samples. **Research specimens processed by the MUHA clinical lab must be picked up by a member of the study team the next day.**
 - b. The empty blood collection tubes and associated paperwork may be shipped to participant's home ahead of time if approved by Sponsor.
 - c. Alternatively, the study coordinator may need to provide the participant with the appropriate specimen collection supplies in person prior to scheduled specimen collection.
 - i. This may include requiring subjects to come to campus or providing the sample collection supplies curbside.
2. Instruct participant to take specimen collection bag to off-site laboratory for research sample collection.

- a. A list of affiliated sites which offer blood draw services can be found here:
<https://muschealth.org/medical-services/labs>
3. Once the specimens have been collected at the off-site laboratory, the specimens will be picked up by the scheduled courier and transported to the MUHA lab.
 - a. The courier pick-up should be scheduled by a member of the study team through OneStop on the MUSC intranet.
 - i. Navigate to MUSC intranet:
<https://www.musc.edu/medcenter/index.htm>
 - ii. Under “frequently used resources” select “OneStop”
4. The MUHA lab will process the samples according to the provided Processing or Shipping for Grants instructions or contact a member of the study team to pick up the specimens, which will then be transported to the appropriate on-site research laboratory for processing/storage/shipment.
 - a. If arranged ahead of time with MUHA and the Nexus Research Laboratory, samples can be transported to the Nexus Research Laboratory via Tube 119 for processing/storage/shipping. If samples are to be transferred to the Research Nexus Laboratory, the secondary specimen container must be clearly flagged to indicate instructions for MUHA to send samples via Tube 119.
 - i. Please note that urine samples must be in a sealed container, no snap top urine cups.
5. Protocol requirements for time-sensitive processing may prohibit collection at affiliated sites and should be discussed with the Sponsor.

Home Testing by Participant

If approved by Sponsor, pregnancy testing may be performed at home by the participant. Additionally, several blood collection kits are commercially available (such as the Mitra), for which participants would collect their own blood and ship directly to the central laboratory. Any home testing by the participant should be discussed with the Sponsor and IRB before implementation.