

B-6a. Biorepository COVID-19 Safety Procedures and Restart Plan

This document was created to inform the OMB and IRB office of the plan that was created to minimize risk and exposure and safely restart participant sample collections.

Introduction

On March 11, 2020, the Registry paused Biorepository specimen collections to protect the health of the Biorepository participants and members of their household. The Biorepository staff canceled all collection appointments scheduled until further review of the pandemic. Restarting the Biorepository collections will require that precautions be put in place to ensure that staff and participants and their caretakers/household members are protected from COVID-19. This plan is based on interim CDC guidance for non-COVID public health activities that require face-to-face interaction during the COVID-19 pandemic and will be used to outline practices for conducting Biorepository project activities.

Changes in the Biorepository procedures are proposed to reduce or eliminate close contact (within 6 feet) between project staff and participants when possible to prevent the spread of COVID-19 during collection activities. The precautions and personal protective equipment (PPE) recommended in this plan will be reevaluated monthly and more often as needed to ensure they are still in line with CDC COVID-19 guidelines and may be revised to add or remove precautions as needed.

Objectives

- Minimize risk of exposure, illness, and spread of disease among staff working with the Biorepository;
- Minimize risk of exposure, illness, and spread of disease among Biorepository participants and members of their households; and
- Preserve essential functions of the Biorepository.

Schedule Considerations

Scheduling study activities, the Biorepository staff and Phlebotomy companies will consider before appointments are finalized:

- The level of local COVID-19 transmission (number of new cases, emergency department visits, and percent positive for testing in each community as available)
- Not scheduling appointments in areas with higher-than-average transmission
- State and local guidance/mandates

COVID-19 Safety Precautions for the National ALS Biorepository

Staffing: Biorepository staff will oversee the phlebotomists assigned to collect specimens at each location. The Biorepository staff will also oversee collection activities relating to the project operations office, specimen collections, and sample processing. The collections that take place by home healthcare workers and in physician's offices, the staff will follow the procedures already established by their offices or agencies. The Biorepository staff are not expected to provide in-person support for these activities.

All phlebotomists will be provided clear information about new procedures and PPE (Personal Protective Equipment) requirements by their employer (as described in table below). Phlebotomists will go through collection training and all PPE will be provided to staff prior to initiation of activities. Phlebotomists utilize full PPE, including long sleeves, long pants (or scrubs), closed-toe shoes, and gloves. In addition to the usual PPE used during collections, we are adding extra measures due to COVID-19 which include a cloth face covering or disposable face mask and a face shield that covers eyes, nose, and mouth.

Face coverings are required and meant to protect others in case you are infected. We recommend both the phlebotomists, the participants, and household members present for the specimen collection appointment, wear a cloth face covering or a disposable face mask during the in-home appointment. Cloth face coverings and disposable face masks should not be placed on anyone who has trouble breathing, or is unconscious, incapacitated or otherwise unable to remove the mask without assistance. If participants are unable to wear a cloth face covering or disposable face mask due to medical conditions, the phlebotomist will wear a disposable surgical mask. The Biorepository staff will include at least two disposable face masks in each collection kit that is shipped to the participant for the participant or their family members to wear during appointment.

Screening of Project Phlebotomists, Participants, and Household Members

Phlebotomist screening

Before entering the collection location, phlebotomists will be screened for symptoms associated with COVID-19. Phlebotomist will not be assigned to any collections if they answer yes to having any of the COVID-19 symptoms or traveled in violation of any federal, state, or local guidance or orders, or had close contact with an individual who has any symptoms or travelled in violation in the past 14 days.

Questions on COVID-19 symptoms will include asking about the presence of any of the following in the past 14 days:

- Fever or chills
- Cough
- Shortness of breath or difficulty breathing
- Fatigue
- Muscle or body aches
- Headache
- New loss of taste or smell
- Sore throat
- Congestion or runny nose
- Nausea or vomiting
- Diarrhea

If any phlebotomist develops any COVID-19 symptoms they will be instructed not to come to work, to inform their supervisor who will notify the Biorepository staff. If a phlebotomist develops symptoms consistent with COVID-19, Biorepository staff will pause that phlebotomists' collections. The

phlebotomist must subsequently test negative for COVID-19, before resuming collection activities. If the phlebotomist tests positive, Biorepository staff will notify any participants who have been in contact with the positive individual.

Participant and Household member screening

The Biorepository staff will ask the participant if in the past 14 days, they have experienced any of the symptoms above or have they had close (within 6 feet) prolonged (10 minutes or more) contact with someone who has had any of the symptoms. In the last 14 days have you traveled in violation of any federal, state, or local guidance or orders, or had close contact with an individual who has. The participants will be asked if they are comfortable scheduling their appointment once the screening questions have been answered. When appointments are scheduled, participants and household members will be informed of screening procedures and be required to wear a cloth face covering or disposable face mask during their appointment. They will also be instructed to notify Biorepository staff to cancel their appointment if they are experiencing COVID-19 symptoms (as defined in the list above). Participants will be asked about symptoms in a reminder call the day before their scheduled appointment.

Additional actions that will be enforced to reduce the potential for COVID-19 transmission include:

- Proper hand washing.
- Providing disposable face masks for participants who do not have their own face covering upon entry into the home or designated collection location.

Travel Guidelines

Biorepository staff are not normally present during the blood collection and do not interact with the participants during the collection visit. Phlebotomists are the only staff members that meet in person with the participants and other household members.

During travel Biorepository staff will be directed to the considerations to the CDC travel in the US guidelines at <https://www.cdc.gov/coronavirus/2019-ncov/travelers/travel-in-the-us.html>. Staff will also be provided with the guidance below.

Protect yourself and others during your trip:

- Clean your hands often.
 - o Wash your hands often with soap and water for at least 20 seconds especially after you have been in a public place, or after blowing your nose, coughing, or sneezing.
 - o If soap and water are not readily available, use a hand sanitizer that contains at least 60% alcohol. Cover all surfaces of your hands and rub your hands together until they feel dry.
- Avoid touching your eyes, nose, and mouth.
- Avoid close contact with others.
 - o Keep 6 feet of physical distance from others.
 - o Avoiding close contact is especially important if you are at higher risk of getting very sick from COVID-19.
- Wear a cloth face covering or face mask in public.

- Cover coughs and sneezes.
- Pick up food at drive-throughs, curbside restaurant service, or stores. Do not dine in restaurants if that is prohibited by state or local guidance.

Protective Measures

Specific project activities are shown in the table below with recommended PPE, and additional precautions. All PPE for project phlebotomists will be provided by their organization. See table below.

Activity	Description	PPE	Additional Precautions
Travel	Time spent in ride share/public transportation, in airport, on airplane, time spent in public venues while traveling	Disposable face mask	<ul style="list-style-type: none"> • Frequent handwashing_ • Cloth face coverings_ • General travel precautions_ • Ride sharing and public transportation
COVID-19 Screening	Talk to participants outside of their home or collection location, ask symptom screening questions	Disposable face mask, disposable gloves	<ul style="list-style-type: none"> • Confirm participants and care givers/family members are symptom and fever free before entering the collection location
Biological sample collection	Collect blood samples	Phlebotomists: Cloth face covering or face mask, disposable gloves, Phlebotomists will be utilizing full PPE (Personal Protective Equipment), including long sleeves, long pants (or scrubs), closed-toe shoes, gloves and face shields that cover eyes, nose, and mouth.	<ul style="list-style-type: none"> • Frequent handwashing_ • Blood and plasma collection precautions.