MOP SAFETY APPENDIX: GUIDELINES FOR THE ADULT CLINICAL CENTERS IN RESPONSE TO COVID-19 – Highly Active Participants

Disclaimer. The current version of the COVID-19 safety appendix for MoTrPAC (version 2.0, dated 2020-09-30) provides risk mitigation recommendations against the virus. It takes into consideration the study design and the unique features of the clinical sites that conduct aerosol-generating study visits (i.e., exercise). This document is not intended to be applicable to all exercise testing approaches or all environments in which testing is conducted. Moreover, the material in this document is based largely on expert opinion because limited scientific data were available specific to this topic. Because the management of COVID-19 is highly dependent upon local environments, available resources, and level of community spread, local policies should supersede generic guidelines.

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I. Introduction

The primary aim of this appendix is to describe the guidelines that the adult clinical centers, with the support of the MoTrPAC Steering Committee, are required to adopt as a means of managing the research environment in response to COVID-19. This document applies to the highly active participants only. Prior to reinitiating any testing or training, site PIs will be required to complete a safety checklist verifying that the steps they are taking to manage COVID-19 is consistent with these guidelines. This document states that sites are not allowed to restart and will be instructed to temporarily suspend research activities if the community spread exceeds an average across 14-days of ≤30 new cases/day per 100,000 persons in the county/counties from which they recruit.

II. Ongoing Procedures for Monitoring Symptomatology & Exposure

1. Procedures and plans for monitoring participants and staff

   • Clinical Sites are to follow CDC and institutional guidelines for screening research participants and staff.
   • All participants and staff should be strongly encouraged to have their yearly flu shot prior to their first clinic visit.
   • Research participants and staff are to remain vigilant for signs/symptoms of COVID-19 (e.g., fever, chills, cough, shortness of breath, difficulty breathing, sore throat, myalgias, malaise, headache, new loss of taste or smell, congestion, rhinorrhea, nausea, vomiting). Participants and staff should receive a plan for whom to contact if they develop fever or respiratory symptoms.
   • Research participants are to communicate with the research staff 24 to 72 hours prior to a study visit and just prior to entering the research facilities to ensure that signs/symptoms of COVID-19 are not present, screen for possible contacts and recent travel outside of the local area over the past 14 days, and to provide preparatory instructions for the visit. The mode of communication may include telephone calls, texting, secured email or other electronic means of communication.
   • All sites must perform temperature checks just prior to entering a clinical research facility.
   • See Section IV regarding use of PPE during contact with research participants.

2. Considerations for SARS-CoV-2 testing

   • Any research participant or staff member who develops symptoms of COVID-19 should not enter the clinical research facility.
   • When a research participant or staff member develops symptoms of COVID-19, the local medical team should facilitate immediate testing through whatever means is available to the participant or site in question.
• Clinical sites may consider additional SARS-CoV-2 testing of asymptomatic research participants and staff prior to and during participation in MoTrPAC, as determined by the local medical team and the procedures adopted by each clinic.

3. Steps for managing COVID-19 infections within the research environment
• Any currently active MoTrPAC participant who becomes positive for SARS-CoV-2 should be withdrawn from the study to avoid possible transmission to other participants and staff. Clinical research activities are to be halted until the clinical research area is sanitized according to local procedures.
• Contact tracing will be carried; anyone exposed to the individual with a positive SARS-CoV-2 test should be immediately referred for testing as per local guidance.

III. General Procedures for Staff/Participants Related to Clinic Visits
The following procedures are to be followed for MoTrPAC clinic visits. Specific requirements for each clinic visit are detailed below under sections 1-5, which include a summary of the PPE required to conduct each visit.
• In-person interactions will be minimized. Study procedures and assessments, able to be completed remotely, will be conducted virtually in a standardized manner across the clinical sites.
• Health status/symptom screening for COVID-19, cold or flu will be assessed the day before all clinic visits via telephone call, texting, secured email or other electronic means of communication. If participants have symptoms or have been around someone who has tested positive, the visit will be rescheduled.
• Every participant and research study staff will be screened upon arrival to the facility, including symptom and exposure screening and temperature check. For anyone with a positive symptom screen or fever, or who has been in contact with someone who has tested positive for SARS-CoV-2, will not be allowed to enter the clinic of facility. SARS-CoV-2 positive participants will be dropped from the study and SARS-CoV-2 positive staff may only re-enter the clinic or facility once they are cleared to have “patient” contact by the institutional employee health office.
• Upon entering the clinic or facility, all research staff and investigators will be required to wash their hands and wear a mask. Any staff member who has in-person contact with participants must follow relevant institutional PPE requirements.
• Face masks must be worn by all staff working with participants. During aerosol-generating procedures, including CPET, familiarizations, and acute tests, staff should wear an N95 mask or equivalent, eye protection, gloves, and gowns.
- Use of surgical masks is mandatory for all research participants during face-to-face clinic visits, except while doing a CPET, strength testing, familiarizations, and acute tests.
- Hand hygiene is a cornerstone of COVID-19 prevention. Perform hand hygiene:
  - before and after any direct contact with participants
  - immediately after removal of gloves
  - after contact with inanimate objects in the immediate vicinity of the participant
  - after using the lavatory.

For additional information on hand hygiene, see CDC guidelines on handwashing in healthcare settings at: https://www.cdc.gov/handhygiene/providers/guideline.html

1. General guidance on the use of Personal Protective Equipment
   - **Face masks**: At a minimum, staff and participants will wear a surgical mask at all times. If the mask gets wet or dirty with secretions, it must be changed immediately. All masks should be discarded after a single use.
   - **N95 masks/respirators**: When performing CPET, strength testing, familiarizations, and acute tests, staff should wear an N95 mask or equivalent.
   - **Gloves**: Staff should wear gloves when having direct contact with participants. Apply standard infection prevention and control practices for glove use (e.g., changing gloves between participants). The use of gloves does not eliminate the need to perform hand hygiene.
   - **Gowns**: Use of gowns is mandatory for aerosol-generating procedures and for activities that involve close contact with the participant.
   - **Eye protection**: Eye protection is mandatory for aerosol-generating procedures and for activities that involve close contact with the participant. Reusable eye protective equipment can be used (e.g. goggles or face shield) but may pose a risk of cross-infection if not cleaned and disinfected properly after each use according to the manufacturer’s instructions. Ensure that equipment is thoroughly cleaned before disinfection. Perform hand hygiene after disposal or cleaning of eye protection equipment that may be contaminated with splash or spray. Do not use conventional glasses as eye protection, because they are not designed to protect against splashes to the eye mucosa.

2. Requirements of staff/environment for biospecimen collection/processing
   - Staff or appropriately trained sanitation employees will wipe down all the surfaces in the treatment room before and after completing a participant evaluation according to institutional cleaning guidelines. Everything
should be removed from open shelves and linens are to be changed between participants.

- Disposable items may be discarded in regular trashcans.
- Any disposable item holding >20 ml blood or body fluid must be properly discarded following local guidelines.
- Room set-up: space out the room and minimize staff to maintain 6-foot social distancing. Staff processing and collection room set-up should take into consideration social distancing when arranging the room. Limit the room to essential staff only for performing collection and processing measures.
- Staff protection: staff responsible for biospecimen collection or processing will wear surgical masks, face shield, protective coat/gown, and gloves.

3. Guidelines for CPET testing, strength testing, acute test familiarization sessions, and the acute exercise tests

The CPET, strength tests, familiarization sessions for the acute tests, and the acute tests will be conducted in accordance with the following mitigation procedures:

- These procedures will be conducted individually;
- symptom, high-risk contact screening, and temperature check will be done at least 72 hours prior to these exercise sessions and again on the day of the test. Persons failing this screen will not be tested;
- testing will be conducted in an environment with adequate ventilation and a closed door;
- staff will wear fitted N95 respirators or equivalent, eye protection (e.g. face-shields), gown, and gloves;
- participants will wear a surgical mask except while performing the test;
- bacterial-viral filters will be used on inspiratory and expiratory tubing when possible;
- fittings that touch participant’s skin or mucus membranes will be sterile, disinfected, or single use (e.g. facemask, mouthpiece, nose clips, sweatbands, EKG leads);
- surfaces and testing equipment will be cleaned with an approved disinfectant after each test;
- equipment will be disinfected according to the manufacturer’s recommendations;
- staff will be trained and certified on donning/doffing procedures, hand hygiene, and cleaning procedures;
- a log will be kept of the time, location, exposed staff, along with participant name and contact information for all exercise test procedures.
4. Requirements of staff for clinic visits in which no physical testing occurs
   - Staff protection: as a minimal requirement staff responsible for conducting study visits will wear surgical masks.
   - Participant protection: face masks are required.
   - Maintain physical distance of 6 feet.

IV. Sanitation of Equipment/Research Environments

1. CPET, familiarization, and acute tests
   - In addition to MoTrPAC requirements, sites are to follow all local recommendations, guidelines, and policies that are pertinent to these procedures.
   - Priority should be given to the safety of both study participants and staff during these procedures.
   - Staff Considerations:
     a. Efforts should be made to minimize the number of staff members in areas where the CPET, EE Familiarization Sessions, strength testing, and the Acute EE Test are conducted.
     b. Staff should stand at least 6 feet away from each other and the study participant whenever possible. Closer interactions should be as brief as possible.
     c. Staff should not stand in the direct path of expired air from the participant.
     d. Staff are to wear N95 masks (or equivalent), eye protection, gowns and gloves.
     e. Sites should have their staff function in designated teams. This may allow operations to continue should there be a suspected COVID-19 exposure requiring staff to self-isolate without the need to fully suspend research operations.
   - Lode Ergometer Considerations
     a. The cycle will be wiped with an approved SARS-CoV-2 CDC disinfectant solution at the completion of each test.
     b. The cycle will be wiped with a SARS-CoV-2 CDC approved disinfectant solution and allowed adequate drying time just prior to conducting each test.
   - Testing Room
     a. The room will be cleaned and sanitized between each test according to local guidelines.
     b. Follow institutional environmental health office guidelines regarding the amount of time that is to pass before that area can be used again for a different participant.
     c. Follow institutional environmental health office regarding optimal ventilation and use of fans.
     d. Sites can consider using an air purifying system with a HEPA filter to assist with air purification of the testing area.
• Metabolic Carts: disinfecting **common pieces across metabolic carts**. It is recognized that sites use different metabolic carts. Sites should disinfect their specific metabolic cart while following the recommendations of the manufacturer and while also following local sterilization recommendations and guidelines. Specific details on the Carefusion/Vyaire Vmax Metabolic Cart and the ParvoMedics Metabolic Cart (the most common carts being used) following the current section on disinfecting common pieces across metabolic carts.

  a. Mouthpieces

  • Disinfect after each use with a high-level disinfection such as Cidex OPA Solution High Level Disinfectant, Sporicidin Sterilizing and Disinfecting Solution, Revital-Ox Resert High Level Disinfectant, or other disinfectant approved by the manufacturer or local institution.

  • Sites may consider additional options that include the following:

    o Purchase a mouthpiece for each MoTrPAC participant that is used only by that person, with disinfection occurring between each use. After disinfecting this can be placed in a resealable plastic bag that is identified by participant acrostic and/or ID number.

    o Purchase sufficient numbers of mouthpieces that allow for a one-time use with disposal of the mouthpiece after each use.

  b. Noseclips

  • These are disinfected after each use using 70% alcohol, a high-level disinfection solution (e.g., Cidex OPA Solution High Level Disinfectant, Sporicidin Sterilizing and Disinfecting Solution, Revital-Ox Resert High Level Disinfectant), or a disinfectant approved by the manufacturer or local institution.

  • Sites may consider additional options that include the following:

    o Purchase a noseclip for each MoTrPAC participant that is used only by that person, with disinfection occurring between each use. After disinfecting this can be placed in a resealable plastic bag that is identified by participant acrostic and/or ID number.

    o Purchase sufficient noseclips that allow for a one-time use with disposal of the noseclip after each use. Sites can consider the plastic disposable noseclips (e.g., Snuffer), however, these tend to allow air to leak through the nose and can slip off the nose during exercise testing.

  c. Headgear

  • Plastic headpiece should be wiped with disinfectant cloths.

  • Other plastic or metal pieces can be cleaned with disinfectant cloths or washed with soap and warm water for 20 seconds. It is important to keep in mind that disinfectant wipes may degrade some of the plastic over multiple exposures for certain brands of headgear.

  d. Sweatbands

  • Sites may consider the following:

    o Wash the sweatbands according to institutional guidelines or purchase a sweatband for each MoTrPAC participant that is
used only by this person, with disinfection occurring between each use. After disinfection and adequate drying time, this can be placed in the resealable plastic bag that is identified for the participant.
  - Use a gauze wrap rather than a sweatband that can be disposed of between each use.

- **Carefusion/Vyaire Vmax Metabolic Cart** (see Exhibit A for components; note that a bacterial filter cannot be used on this system for CPET or acute exercise tests)
  a. **Flow Sensor**
   - The flow sensor is disinfected after each use with one of the following high-level disinfecting solutions:
     - Cidex OPA Solution High Level Disinfectant
     - Sporicidin Sterilizing and Disinfecting Solution
     - Revital-Ox Resert High Level Disinfectant
   - The flow sensor should be rinsed following disinfection to remove the high-level disinfecting solution prior to participant use.
   - Maintain sterilization (e.g., place in an individual resealable plastic bag) after cleaning and prior to subsequent use.
  b. **Sampling and Pressure Lines**
   - Connected to the flow sensor are both a sampling line and a pressure sensor line. These pull small samples of air from the flow sensor into the metabolic cart, so the flow of air in the tubes is one way and does not mix with the air that the participant is breathing.
   - These lines are to be removed after each test to allowed to dry (these can be reused up to 3 months depending on the number of tests), with disinfected or new lines placed onto the system prior to each test.
     - Sites can consider replacing these lines more often.
     - Caution should be taken if procedures to disinfect these lines that do not follow the recommendations of the manufacture are used, as this may cause damage to these lines that make them non-usable.
  c. **Other components**
   - Other components are to be disinfected and cleaned using manufacturer and local recommendations.
   - Sites may select to dispose of these parts between each use.
  d. **Surface Disinfection**
   - All other surfaces of the metabolic cart and computer are to be disinfected between each use. Disinfectant wipes can be used for this purpose.
     - Some internal components of the metabolic cart components can be damage with certain cleaners. The use of bleach solutions, glutaraldehyde solutions >2.6%, and alcohol (Isopropyl 70% or higher) should be avoided on these internal components (see equipment manual).

- **ParvoMedics Metabolic Cart** (see Exhibit B for components)
  a. **Housing unit**
   - The housing unit (all hard-plastic pieces, along with the membranes) is disinfected after each use with one of the following
high-level disinfecting solutions: Cidex OPA Solution High Level Disinfectant, Sporicidin Sterilizing and Disinfecting Solution, or Revital-Ox Resert High Level Disinfectant.

- Rinse the housing unit after completing disinfectant procedures to ensure thorough removal of the high-level disinfectant solution.

b. Maintain sanitation (e.g., place in an individual resealable plastic bag) after cleaning and prior to subsequent use. The resealable plastic bag should be identified by participant acrostic and/or ID number.

b. Breathing Tube: the breathing tube is soaked in a 70% alcohol bath for a minimum of 1 minute.

- The breathing tube must be filled and submerged in 70% alcohol to ensure proper disinfection.
  - Sites are encouraged to purchase a breathing tube for each MoTrPAC participant that only they will use during their time in the study, with disinfecting occurring between each use. After disinfection and adequate drying time, this can be placed in the resealable plastic bag that is identified for the participant.
  - It is encouraged that the breathing tube is discarded after participant’s completion of MoTrPAC.

c. Inline Filter

- A new inline filter should be purchased for each MoTrPAC participant.
  - The assigned inline filter is stored in participant’s resealable plastic bag.
  - The inline filter is discarded after participant’s completion of MoTrPAC.

d. Pneumotach: sites may consider the following:

- Disassemble and rinse the pneumotach at the end of each testing day or site determined interval (too frequent disassembling can result in damage to the pneumotach).
  - Use soapy water and then rinse to disinfect the device.
  - The pneumotach can then be dipped in 70% alcohol and rinsed again.
  - The pneumotach must be dry before each test.

e. Mixing Chamber

- If the mixing chamber holds condensation, consider using Cavicide or Metacide to clean.
  - Do not use alcohol or bleach on the mixing chamber.
  - The mixing chamber must be dry before each test.

e. Rinse the mixing chamber with water to flush out condensation produced by the participant’s expired gases. The mixing chamber must be dry before each test.

f. PermaPure sampling and Drying Lines should be changed every 3-4 months according to maintenance guidelines. The filter on the line, along with the negative pressure flow from the mixing chamber to the analyzer box, should prevent the air the participant is breathing from contaminating the lines; however, sites can consider replacing these lines more often.

- In summary, the recommendation is changing out the one-way filters, tubing, headband for headpiece, nose clips, in line filter and
mouthpiece for each test; however, at their discretion, sites may elect not to replace the more expensive components for each test and take appropriate steps for disinfecting these.

- **Electrocardiogram (ECG)**
  - **CPET and Acute Test**
    - The ECG wires connected to electrodes are to be disinfected between each use.
    - Razors that are used to remove surface hair and all ancillary equipment are either to be disposed of or disinfected between each use.
    - Staff are to wear appropriate PPE when placing electrodes on a study participant and should limit direct contact with the participant as soon as possible.
    - Tables/chairs that are used to position the participant for resting or recovery ECG collection are to be disinfected and allowed adequate drying time between each use.
    - Electrodes are to be disposed of after each use.

- **Zephyr Heart Rate Monitoring during EE Familiarization Sessions and Acute Test**
  - a. If possible, assign a Zephyr strap to an individual participant that is only used by that participant throughout their duration of the study (all EE Familiarization Sessions, Acute EE Sessions, and EE training Sessions).
  - b. Clean the Zephyr strap between each use as recommended by the manufacturer which includes the following (from the Zephyr BioHarness™ Manual).
    - h. Detach the BioHarness™ module.
    - i. Rinse the strap in fresh water after use to prevent salt buildup from perspiration.
    - j. Hand Wash, or Machine-wash on a Cold, Delicate setting after 30 days of use.
      - o Firmly attach the Velcro® fastenings together and do not wash with other garments which may be damaged by these fastenings.
      - o Use a washing pouch if possible.
      - o Use soap or mild detergent, but NOT sterilizing tablets.
      - o Maximum recommended wash temperature: 40°C / 104°F
      - o Do Not spin or tumble dry
      - o Hang to dry, out of direct sunlight.
      - o Do not bleach. Do not iron.
      - o Zephyr guarantees performance for a minimum of 80 machine washes of the chest strap.

- **Blood Pressure Cuffs and Stethoscopes**
  - a. Blood pressure cuffs are to be disinfected with disinfectant wipes between each use.
  - b. Stethoscopes should be disinfected with 70% alcohol between each use. It is preferred that each staff have their own stethoscope that is sanitized between use on different participants.

- **Considerations for testing procedures**
  - a. Electrocardiogram (ECG) for CPET
a. At baseline, consider performing the resting ECG on the day of the CPET only to minimize contact between the study participant and the staff.
b. Blood pressure assessment
   - CPET
     - Take seated resting blood pressure prior to the CPET.
     - Take blood pressure at minute 4 (and at minute 8 if feasible) and at termination of the CPET, and as deemed clinically appropriate during recovery. For participant safety, more frequent blood pressure measures may be taken at staff discretion.
   - Familiarization Sessions
     - Given that these are submaximal, only monitor blood pressure if deemed to be clinically necessary. This can be determined at the local site.
   - Acute Test
     - Given that this is submaximal, only monitor blood pressure if deemed to be clinically necessary. This can be determined at the local site.
c. Metabolic Testing
   - Familiarization
     - Maximize social distancing to minimize potential transmission between participants and staff.
   - Acute Testing
     - Maximize social distancing to minimize potential transmission between participants and staff. A potential alternative is to collect metabolic data only during the final 5-minute collection period using a mouthpiece and nose clips.

2. Sanitation of dynamometers and exercise equipment
   - The Exercise Equipment, including equipment necessary for the CPET, muscle fitness testing (isokinetic dynamometer and grip strength dynamometer), Acute Testing, and delivery of the Intervention poses a risk of infection to both staff and participants. The required PPE for staff and participants when using this equipment is as follows:
     a. Use a clean face mask (cloth face coverings or surgical mask), gloves and protective lab coat when disinfecting equipment.
     b. Staff members who encounter bodily fluids such as blood, urine, or saliva, the employee will be required to wear protective goggles or face shield, mask, protective lab coat, and gloves.
     c. Lab coats can be used multiple days unless soiled but should be kept in the laboratory.
     d. Soiled PPE should be disposed of or disinfected.
   - Hand Hygiene:
     a. Employees responsible for cleaning equipment must wash hands often with soap and water for at least 20 seconds before applying PPE and immediately after removal of PPE once equipment is disinfected.
b. Following hand washing with soap and water, use of a hand sanitizer that contains at least 60% alcohol is encouraged.
c. All employees should avoid touching eyes, nose, and mouth with unwashed hands.
d. All laboratories will have soap and hydroalcoholic solutions provided for employees to use.

- **Sanitization of Exercise Equipment:**
  a. All exercise equipment must be sanitized after each use using the cleaning wipes and disinfectants provided in those areas. The preferred disinfecting process is a 2 step protocol: 1) disinfect with a sanitizing wipe (Cavi-wipe, Sani-wipe Plus, 2XL Gym Wipes, etc) that is effective against COVID-19 and allow to dry, and 2) disinfect with an alcohol solution (at least 60%) allow to dry completely. Other options for disinfectants (i.e. glutaraldehyde) are admissible that comply with the CDC guidelines and effectively inactivate COVID-19.
  b. Examples of equipment that requires disinfecting includes: Treadmill (all parts), Bike (all parts), Resistance Training Equipment, Hand Dynamometer, Isokinetic Dynamometer (including all straps, seat and lever arm etc.), Chairs, Medical Tables, EKG monitoring Equipment, Heart Rate Monitors, Headgear, Blood Pressure Cuffs, Stethoscopes, Body Weight Scales, and any other item a participant touches or touches their skin
    - For some disinfectants, the surface should remain wet for approximately 2 minutes to achieve disinfection levels that are adequate.
    - All equipment such as laptop computers, metabolic carts, and other such items will be also be sanitized each morning and evening. Preferably, participants will not touch door handles or other random surfaces; however, these surfaces will be disinfected regularly in addition to the equipment.
    - The time between participants will be determined by individual sites depending on airflow in the exercise areas and time to disinfect the equipment to minimize exposure between participants and participant to staff exposure.

3. **Sanitation of DXA**
   - PPE should include use a face mask (cloth face coverings or surgical mask), gloves and protective lab coat when in contact with study participants.
     a. Lab coats can be used multiple days unless soiled but should be kept in the laboratory.
     b. Soiled PPE should be disposed of or disinfected.
   - **Sanitization of DXA and Imaging Suite:**
     a. All high touch areas in the Imaging Suite must be sanitized after each use using the provided cleaning wipes and disinfectants provided in those areas. Preferred disinfectant for the GE iDXA is Metricide or Cidex (2% glutaraldehyde) and the preferred disinfectant for the
Hologic is the Clorox Health Care Bleach Germicidal Wipes (0.5% sodium hypochlorite). However, other options are admissible that comply with the CDC guidelines and effectively inactivate Sars-CoV2.

b. All laboratories will be provided with disinfecting wipes, and disinfecting solutions to use according the CDC recommended guidelines.

V. Sanitation of Training and Workspace

- Ensure appropriate training of staff and participants on basic, COVID19-related hygiene measures (i.e. frequent hand washing).
- Following hand washing with soap and water, use of a hand sanitizer that contains at least 60% alcohol is encouraged. All surface of employee’s hands must be covered and rubbed together until they feel dry.
- Ensure availability of hygiene supplies, such as alcohol-based hand rub (60-95%), soaps at sinks, and no touch trash cans.
- Ensure daily sanitation of the workspace and frequently touched areas using facility-approved agents against SARS-CoV-2.
Exhibit A: Carefusion/Vyaire Metabolic Cart Components

- Flow Sensor
- Connecting Cable
- Drying and Pressure Sensing Tubing
Exhibit B. Parvo Medics Components

Parvo Mouthpiece Assembly: Entire Housing
Parvo Mouthpiece Assembly: Sterrad Parts
Parvo Mouthpiece Assembly: Steam Parts