CLINICAL RESEARCH SPECIFIC COVID-19 CAMPUS PLAN

Contents

Responsibilities and Expectations .................................................. 2
Process to Begin Human Participant Research .......................... 3
General Considerations for In-Person Human Research .......... 3
Required Training ........................................................................... 4
Phased Work Plan ......................................................................... 4
Facilities and Workspace Considerations ..................................... 4
  Physical Safety ........................................................................... 6
  Personal Protective Equipment (PPE) ........................................ 8
  Cleaning and Disinfecting Practices ........................................ 9
Scheduling of In-Person Research Assessments ....................... 10
Recordkeeping, Reporting and Compliance ............................... 10
Important links ............................................................................ 12
Appendix A .................................................................................. 13
Appendix B .................................................................................. 14
Appendix C .................................................................................. 16
Appendix D .................................................................................. 17
Appendix E .................................................................................. 19
Appendix F .................................................................................. 20
Appendix G .................................................................................. 21

*in-person refers to an in-person, face-to-face research activity
CHS COVID-19 Guidebook to Resume Human Participant In-Person Clinical Research

Purpose

This guidebook outlines the practices set forth by CHS to allow faculty, staff and students to resume human participant in-person* clinical research. The goal is to ramp up research thoughtfully and deliberately while protecting our faculty, staff, students and visitors by following the most current published guidelines provided by ASU and the CDC. Faculty, staff and students should be educated regarding the policies and practices below, and be informed about changes that will occur over time. This form must be completed and signed by the faculty lead for a research team, i.e., PI, as a condition for restarting or start of their research.

Responsibilities and Expectations

A. Responsibilities of faculty, managers, research coordinators - those who are responsible for the conduct of research
   1. Must be familiar with the information contained within this guidebook, remain up to date as new guidelines are released and be ready to answer questions.
   2. Principal Investigators (PIs) must remain responsible for providing direction and oversight knowledge of their projects, labs, and/or research sites, and personnel including graduate students, postdoctoral fellows, and staff.
   3. Must set a good example by following the guidebook at all times.
   4. Must encourage the same behavior in students and employees and remind individuals when they see incorrect practices.

B. Responsibilities of faculty, staff and students - those engaging in research
   1. Read and fully comply with the policies, protocols and guidelines outlined in this guidebook, and the official ASU policies for returning to work. Repeated failure to do so may result in corrective action.
   2. Ask faculty, managers or research coordinators for help if needed or for any questions you have concerning the stated policies.

*in-person refers to an in-person, face-to-face research activity. If conducting HP research remotely no action is needed.
Process to Resume Human Participant Research

To ramp up on-campus research activities, responsible faculty members will:

A. Using this guidebook as a template, create a human participant research safety plan for your research space.

B. Submit a research re-start or start request by completing the CHS Clinical and Translational Science Research startup request form through ASU docusign. The startup request form is study specific to each protocol however only one PI will need to submit for each study.

C. Await approval notification from unitleadership.

D. Submit approvals and protocol modifications outlining safety plans to IRB for approval.

E. Faculty investigators and essential personnel must notify managers, clinical research coordinators, their staff and students with plans for resuming work.

F. Faculty investigators, managers, and research coordinators must next prepare the research space for each study based on information in their lab safety plan.

General Considerations for Returning to In-Person Human Research

On-campus or community-based research involving human participants can proceed only to the extent that visits can be executed safely and in a manner that protects the health of the participants, researchers, students and research staff.

A. ASU Knowledge Enterprise has created a guideline for implementing human participants research that must be addressed in the research safety plan submitted by allinvestigators

B. All university policies and requirements, as well as all local, state and federal regulatory requirements remain in place and must be followed, unless there is written guidance or documentation that they have been modified or suspended.

C. ASU follows Maricopa County Public Health Department protocols related to isolation and treatment of individuals who exhibit COVID-19 symptoms or test positive. Refer to section Recordkeeping, Reporting and Compliance below for reporting possible exposure to COVID-19.

D. Researchers must establish plans for ramping up and potentially respond to new outbreaks by ramping down on short notice if this becomes necessary.

E. Efforts should be made to use remote (online, mailed, telephone) consent and interview formats prior to the research participant’s arrival in order to enforce social distancing guidelines and minimize one-on-one close proximity.

F. As part of the risk/benefit assessment that each investigator should consider before restarting research, it may be necessary for an investigator to modify the nature of the participant population, or the inclusion/exclusion criteria, to reduce the number of high-risk participants. This should be done in consultation with the medical director, or licensed medical personnel associated with the study, and might require a revision by the responsible IRB. If there are questions or concerns about participant inclusion, please contact the CHS Director for Clinical and Translational Science and/or CHS Medical Director.

*in-person refers to an in-person, face-to-face research activity. If conducting HP research remotely no action is needed.

Ver3.1 07/27/2020
Required Training

A. ASU safety training that applies to your area must be current. Refer to the [https://cfo.asu.edu/ehs-training](https://cfo.asu.edu/ehs-training) for a list of training recommendations
   1. ASU Fire Safety
   2. ASU Biosafety and Bloodborne Pathogens (if you work directly with human participants.)
   3. ASU Hazardous Waste Training
B. [2021 Community of Care Training](#) for Employees through Career Edge.
C. All students are required to participate in our Community of Care: Coming to Campus training. This training includes important information about our expectations for students while on campus, including safety protocols students must follow related to COVID-19.
D. PPE: [PPE video demonstration link](#).
E. Donning/Doffing Safety Glasses: [Donning/doffing safety glasses video demonstration link](#).
F. Donning/Doffing Gloves: [Donning/doffing gloves video demonstration link](#).
G. Review clinical research SOPs for your work, specific SOPs from faculty and review all SDS for chemicals. List the location of the SOPs and SDS manuals for each research space.

Return to Campus

A. ASU seeks to balance public health concerns with the operational needs of returning employees to our campuses. Units may elect to use phased work plans, keep their entire staff, or a significant majority, working remotely until further notice during the return process. This decision requires dean or vice president-level approval.
B. Establish a staffing rotation plan in accordance with ASU Return to Campus Guidelines and aligned with ASU’s campus facilities plan.
C. Avoid performing non-clinical research work, such as data analysis, literature reviews and writing assignments in the clinical research or office area when it can be done at home. This will free up the schedule to accommodate all faculty, staff and student’s needs.
D. Alternating workdays: Use alternating work schedules if you have space limitations and to reduce the number of people in a single space per day. For example, have part of your returned staff work on campus on Monday, Wednesday and Friday and have another group work on Tuesday and Thursday. Alternating weeks between two groups can also be an option. Saturday or Sunday as workdays and 4-day workweeks may be other options. You may also have a morning shift and an afternoon shift.
E. Staggered start and stop times: The beginning and end of the workday typically bring many people together at common entry/exit points of buildings. You may want to consider staggering the workday, changing starting and departing times to prevent congestion at entry and exit doors.

Facilities and Workspace Considerations

A. Entering and exiting buildings
   1. All faculty, staff, students, and visitors are expected to follow signage posted on building entry doors and in walking areas regarding limited points of entry and traffic flow control patterns.

*in-person refers to an in-person, face-to-face research activity. If conducting HP research remotely no action is needed.

Ver3.1 07/27/2020
2. Only study participants will be permitted to enter into the building. If the study participant is a minor and/or has a disability, only one parent or guardian may accompany the participant inside the building. An accompanying parent or guardian must also follow CDC guidelines, such as social distancing, wearing a face covering, and show no signs of illness. They must also pass the screening questionnaire. Exceptions for this rule may be considered on a case-by-case basis in consultation with the PI, CHS Director for Clinical and Translational Science and CHS Medical Director.

3. Personal Belongings. Participants will be encouraged to limit the number of personal belongings they are bringing with them to an appointment. Upon arrival, belongings will be secured in a plastic bag. If a participant must remove their mask for an assessment, proper donning and doffing procedures will be followed.

B. Modified workspace
   1. Assign dedicated workspaces, label chairs and workstations clearly with study staff or students names to minimize contact with others.
   2. Workspaces and clinical research areas must be modified to enforce social distancing requirements. Do not move furniture or equipment once modifications are in place.
   3. Faculty will work within their assigned space and submit a request to schedule shared clinical research space and equipment through online calendars.

C. Disinfection of individual and shared workspaces
   1. ASU and UA (ABC1) will disinfect all lobby spaces, shared spaces, offices, computer labs and clinical research spaces in accordance with ASU Facilities COVID 19 guide: ASU Facilities COVID-19 Guide.
   2. Each faculty is responsible for cleaning their personal and clinical research workspace at least twice per day (enter and exit) when in use. This includes, but is not limited to keyboards/mouse, phones, doorknobs and other high touch surfaces. Refer to instructions and list of disinfectants below for effective cleaning.
   3. Shared computer items (e.g., keyboard, mouse, desktops, computer monitors) must be wipe down with approved, computer-safe, EPA-registered disinfectant after every user. Paper towels, wipes or cloths should be sprayed with disinfectant and then used to wipe surfaces. Personnel must ensure that the surfaces are damp but do not saturate the electronics. Allow surfaces to air dry. Wash or sanitize your hands after removing gloves and carefully remove them as to not touch the exterior surfaces of the gloves.
   4. A disposable keyboard cover such as plastic press-N-seal is recommended in shared spaces and on equipment utilized with research participants.
   5. Building occupants will be asked to remove extraneous items from individual areas, kitchenettes and other shared spaces to enhance custodial cleaning and disinfection.
   6. If working with human participants, the work space and any materials and equipment used must be disinfected before and after the interaction with the participant.

C. Occupancy Limits
   1. Occupancy limits and space controls are required to be posted in each room.
   2. Determine the maximum occupancy in your work area, common work areas, and equipment rooms based on research space square footage. Occupancy limits will enforce reduce

*In-person refers to an in-person, face-to-face research activity. If conducting HP research remotely no action is needed.

Ver3.1 07/27/2020
occupancy and social distancing guidelines, determine scheduling and may affect additional PPE considerations.

3. Occupancy limits for shared healthy Lifestyles Recharge Center (HLRC) space in the ABC1 building can be found in Appendix A.

D. Elevators
1. Occupancy limit signs posted in all ASU and UA elevators must be adhered to.
2. ASU will have a maximum occupancy of four occupants per ride.
3. ABC1 elevators have a maximum occupancy of two occupants per ride.
4. Masks are required in elevators.
5. Individuals should sanitize their hands before and after touching elevator buttons.

E. Break rooms should be used only for cleaning dishes, getting water, preparing food, and similar activities. Wash hands before and after using the kitchen. Wear a face covering and maintain a physical distance of 6 feet from others in break areas and kitchen spaces. Individuals are encouraged to eat at their desk or another area where they can maintain physical distancing.

F. Interactions in hallways and corridors should be as brief as possible. Face covering is required in all buildings, elevators, open areas, and parking lots. Avoid congregating in common areas or walkways and be mindful of increased risks of virus transmission when in confined indoor spaces. This includes engaging in conversations in close proximity, loitering in break rooms, and gathering for meals.

G. Meetings will be held via zoom or phone whenever possible. If in-person meeting is required, follow CDC guidelines maintaining appropriate social distancing of at least six feet and use of face coverings.

H. Vendors
1. Non-essential visitors and vendors are prohibited.
2. Essential visitors/vendors must follow ASU and CDC guidelines such as social distancing, wearing face coverings and answering screening questions, showing no signs of illness.
3. Visitors and vendors will be scheduled on the research calendar and a clinical research coordinator notified before they are allowed in the building and other appropriate PPE is required (see PPE table Appendix B).

Physical Safety

A. Universal Face Coverings (cloth face covering or surgical mask)
1. Effective June 12, 2020, all staff, faculty, students, research study volunteer and visitors are required to wear a face covering (cloth face covering or surgical mask) when in ASU buildings, collaborative research space and when conducting in-person* research. Face coverings will also be required in outdoor community spaces where social distancing is not possible.
2. Research study volunteers will be asked to bring their own face covering. If a study volunteer does not have a face covering, one will be provided.
3. Maintain appropriate social distancing of at least six feet. When it is not possible to maintain that distance, a face covering consistent with CDC guidance, and other appropriate PPEs must be worn. (See PPE Table Appendix B).
4. A face covering is not required when working alone in a confined office.

*in-person refers to an in-person, face-to-face research activity. If conducting HP research remotely no action is needed.

Ver3.1 07/27/2020
B. Health Self-Assessment (Faculty, Staff and Students)

1. Before coming to an ASU Facility each faculty member, staff member or student must complete the ASU daily health check. It is recommended to complete this screening via the ASU Mobile App (expected to be available August 7).
   a. All students should not attend class in person or be around others if feeling sick or if exhibiting any symptoms related to COVID-19.
   b. Staff that are not well will notify their supervisor. Any staff member that is suspected confirmed or being tested for COVID-19 must follow the ASU procedures for reporting.
   c. ASU COVID-19 Saliva Testing: All staff, faculty and students working in a research setting where they engage in close human interaction (research participants or with co-workers) are strongly encouraged to undergo frequent COVID-19 testing provided for free through ASU. Reservations are required.

2. Health Self-Assessment (Research Study Participants)
   a. Pre-Screening: Faculty, staff, and student workers/volunteers need to contact all research participants 24 hours prior to an in-person research visit to conduct pre-screening questions and provide participants with information to comply with ASU social distancing/safety/health screening guidelines as well as CDC and State guidance. Pre-screening questions will include but not be limited to:
      i. In the last 24 hours, have you had a sore throat, dry cough, fever, muscle and body aches, fatigue, or been exposed to anyone with a respiratory illness in the past 14 days?
      ii. In the last 14 days, have you or a family member traveled out of state?
      iii. If yes, to any of the above, they must be rescheduled and advised to contact their health care provider. This will be communicated to patients via email communication and verbally via telephone.
   b. Participant Arrival to research site
      Upon arrival to the research building, each research participant will be escorted to a dedicated space to have their temperature taken and answer screening questions using a Screening form (Example: Appendix C). Temperature and the screening form will be maintained by the PI.
      i. If they meet any of the following, they will NOT be permitted to continue the study assessment, and should be referred back to their primary care provider who will determine the need for COVID-19 testing:
         a. If the participant’s temperature is 100.4 or above
         b. If they report a cough, shortness of breath, or otherwise feel unwell
         c. If they report having been exposed to someone with known COVID-19 in the past 14 days
         d. If they report having traveled out of state within the last 14 days
   c. IRB Compliance regarding the addition of COVID-19 screenings:
      Please review the IRB compliance section in the KE Human Subjects Guidance document for information regarding reporting modifications to IRB. NOTE: IRB approval for human

*in-person refers to an in-person, face-to-face research activity. If conducting HP research remotely no action is needed.

Ver3.1 07/27/2020
participant’s research is separate from the Dean/Chair/Director and Oversight Committee approvals in this Guidance.

C. Social Distancing
1. Maintain appropriate social distancing of at least six feet.
2. Know and observe spacing requirements for your assigned office and clinical research area.
3. Use touchless technology where possible.
4. Use technology for teaching research techniques, procedures and during oversight of -visits whenever possible.
5. If in-person training is required- use a face covering plus a face shield or plexiglass or plastic sheet barrier when in close contact less than six feet of distance.

D. Good Respiratory Hygiene
1. Cover nose and mouth with tissue when sneezing or coughing or cover mouth with elbow away from direction of people.
2. Throw away used tissues in the trash immediately after using.
3. Wash hands with soap and water or apply hand sanitizer after.

E. Hand Washing
1. Wash hands before and after procedures or visits and frequently when contact with commonly accessed touch points have occurred (door knobs, handles, copy machine, etc.) for 20-40 seconds.
2. Hand sanitizer is an acceptable option if sinks are not available.
3. Avoid touching eyes, nose and mouth with unwashed hands. Wash your hands immediately after touching your eyes, nose, or mouth.

Personal Protective Equipment (PPE)
It is the responsibility of each researcher to obtain the proper PPE based on his or her research protocol. If the recommended PPE (see examples of PPE -Appendix C) is not available at any point, research will need to be halted until required protective gear is available. If you are unable to obtain personal protective equipment or cleaning supplies through normal purchasing methods, contact Ginger Hook (Ginger.Hook@asu.edu) for assistance. PPE extended-use or reuse strategies as outlined by CDC must be implemented and must be disposed of per CDC guidelines using biohazard protocol (per EHS).

A. Face Coverings
1. Cloth facial coverings or surgical type masks, consistent with CDC guidance, must be worn by all individuals when minimum safe distancing of 6 feet cannot be assured.
2. **ASU Environmental Health and Safety (EHS) recommends that a surgical mask be worn by research staff when interacting in close proximity with human participants. A personal cloth face covering is not recommended.**
3. Refer to ASU guidelines in Appendix D below for the correct use of face coverings.
4. Wash hands before and after each procedure.
5. Paper face coverings can be reused if not wet or soiled and can be stored for reuse. Carefully place the face cover into a clean bag, labeled with the user’s name. Avoid compressing the face cover. Do not seal the bag.
6. Paper face coverings will be discarded at the end of each day or upon becoming soiled.
7. Clinical research coordinator will review the storage process during orientation.

*In-person refers to an in-person, face-to-face research activity. If conducting HP research remotely no action is needed.*

Ver3.1 07/27/2020
8. Cloth face coverings should be laundered in warm water with soap frequently or when contamination is visible or suspected. Cloth face coverings should be dried in a dryer or in the hot sun.

9. Use of a filtering face-piece respirator, such as the N-95 disposable particulate mask, must be requested through ASU Environmental Health and Safety (EHS) in accordance with ASU Respiratory Protection Program. For information on fit testing and training contact Catherine.Mancini@asu.edu

10. Follow CHS standard operating procedures for labeling, reuse, storage and disinfection of filtering face-piece respirators or dust masks such as N-95 or KN95.

B. Gloves
Gloves must be worn for all clinical research procedures, cleaning, disinfection and study assessments that require direct human contact. Refer to ASU guidelines in Appendix F below for the correct method to don and doff gloves.

C. Lab coats
1. Wear lab coats as required by ASU for all phlebotomy procedures, wet lab, sample processing, medication preparation and processing activities.
2. Use the ASU Lab Coat program to launder coats weekly at a minimum.
3. Disposable gowns will be required for certain activities (See PPE Table- Appendix B). Gowns may be reused if they are not soiled and did not come in contact with a research participant or other individual. Contact clinical research coordinator for questions.

D. Safety glasses and Face Shields
1. Protective eyewear (safety glasses or face shield) are required for procedures that involve close encounters with a participant. Personal eyeglasses are not an acceptable form of protective eyewear.
2. Face shields will also be required when close work with another person is performed in the same clinical research or lab space.
3. Refer to ASU guidelines in Appendix E below for the correct method to don and doff safety glasses. The same precautions outlined in Appendix E below are advised for use of a face shield. Individual training by the clinical research coordinator will be provided if face shields are required.

Cleaning and Disinfecting Practices

Wear PPE (surgical mask, gloves and eye protection) when cleaning and disinfecting. SDS safety sheets for all disinfectants are located in the SDS folder. Be aware of the hazards of the material you are using.

A. All equipment and instruments will be disinfected using SARS-CoV-2 effective disinfectants between each research participant.
B. Clipboards, pens and other supplies used by a study participant for completing paperwork will be disinfected after each use.
C. Computer labs and shared computer stations will be disinfected between users. Personnel computers will be disinfected daily by the users using electronic safe disinfectants. Copy machines and scanners will be disinfected at the end of each day. ASU Disinfection Guidelines for Computer Labs.
D. Safe disinfectants should be verified for effectiveness for SARS-CoV-2 (link provided below). Suggestions for disinfectants include:

*in-person refers to an in-person, face-to-face research activity. If conducting HP research remotely no action is needed.
1. 70% Isopropyl alcohol (IPA) solution
2. Clorox Wipes
3. Lysol Wipes
4. Protex Wipes
5. Covidien™ or other approved Alcohol Prep pads
6. CaviWipes and CaviWipes 1™
7. Total Solutions® Disinfectant Wipes

E. Paper records provided by research participants will be scanned by study staff wearing gloves.
F. Use Lysol disinfectant spray to spray soft surfaces that cannot be wiped down.
G. For surface decontamination, cleaning and disinfecting facilities where persons suspected or confirmed to have COVID-19 were present please follow the procedures outlined in the ASU Guidance to Prevent the Spread of Respiratory Virus.

Scheduling of In-Person Research Assessments

Scheduling of research faculty shared clinical research space through an online study calendar will be required to maintain occupancy limits.

A. In order to disinfect clinic equipment and the space appropriately and to practice social distancing, scheduling of assessments will be limited and following the following guidelines:
   1. Appointment times will be staggered to ensure no more than one research participant is waiting in the lobby or waiting areas at a given time.
   2. Signage on building and clinical research entrances will indicate the CDC guidelines; all study participants will need to call the study coordinator or clinical research staff when they arrive and will be escorted directly to the assessment room to ensure social distancing.
   3. Rooms, clinical research space and equipment occupied or used to conduct and assessment of a participant will not be used on another research participant for 15 minutes after disinfection.

B. Only study participants will be permitted to enter into the building. If the study participant is a minor and/or has a disability, only one parent or guardian may accompany the participant inside the building. An accompanying parent or guardian must also follow CDC guidelines, such as social distancing, wearing a face covering, and show no signs of illness. Exceptions for this rule may be considered on a case-by-case basis in consultation with the PI, CHS Director for Clinical and Translational Science and CHS Medical Director.

C. In order to comply with occupancy limits students, vendors, participants, and employees who arrive prior to their appointment time may be asked to leave the building and return at their scheduled time, those who arrive late may be asked to reschedule.

Recordkeeping, Reporting and Compliance

A. Disinfection Log
   1. Each research space, common area and shared equipment will have a Disinfecting Log Sheet. See Appendix G.
   2. Initial document with date and time when disinfection is completed. This is required at least twice daily.

B. Building Sign In/Out Procedure

*In-person refers to an in-person, face-to-face research activity. If conducting HP research remotely no action is needed.

Ver3.1 07/27/2020
All individuals (ASU and guests) will be required to follow ASU and UA(ABC1) daily sign in/out procedures in their lab space - and building.

C. Employee Reporting of COVID-19 Exposure, link: Reporting of COVID-19 Exposure

If an employee is made aware that they have had significant contact with an individual that has a positive diagnosis of COVID-19 or that employee has received a diagnosis, they should follow the following process:

1. Employee immediately notifies supervisor
   a. Provided links to FAQs and HR addressing COVID leave policies
   b. Allow remote work if employee is able
   c. Employee must self-isolate for 14 days
   d. Refer to medical provider for testing
   e. Employee privacy must be maintained
2. Supervisor notifies Phil Carrano by phone at 602-496-2151
3. Supervisor notifies Elizabeth Badalamenti by phone 480-727-6517
   a. Provide employee contact information
   b. Let her know if cleaning is needed
4. Elizabeth will contact the employee for follow up
   a. Gathers details for ASU
   b. Conducts contact tracing
5. If an employee is located at a non-ASU site (Mayo, ABC, TGEN). Phil Carrano to notify appropriate representative for cleaning
   a. David Heineking, Heinekin@arizona.edu, ABC
   b. James Mercer, merrcerjames@mayo.edu, Mayo
   c. Courtney Smith, Courtney.smith@theplazaco.com, TGEN

D. Compliance

1. Faculty investigator is responsible for monitoring compliance of the guidelines by all staff and students working in their clinical research spaces.
2. The faculty investigator may designate a study team member(s) to monitor ASU COVID-19 communication, perform record keeping functions and monitor compliance. This individual(s) must be listed on the KE ques. Staff changes and reassignment of this role must be communicated by email to Theresa Jorgensen and Scott Leischow.
3. Walkthrough by faculty investigators, managers and clinical research coordinators will occur throughout the day to monitor and ensure policies and processes are followed.
4. Managers and clinical research coordinators will work with individuals in the CHS clinical research spaces to develop and implement work routines for their specific studies and monitor proper conduct of these guidelines.
5. Non-adherence to the guidelines will be brought to the attention of supervisors, faculty and unit directors.
6. Continued non-compliance may result in temporary discontinuation of research.

*in-person refers to an in-person, face-to-face research activity. If conducting HP research remotely no action is needed.

Ver3.1 07/27/2020
*in-person refers to an in-person, face-to-face research activity. If conducting HP research remotely no action is needed.*
### Appendix A

**Occupancy Limits Shared Space and HLRC spaces ABC1**

<table>
<thead>
<tr>
<th>Building-Room Number/Description</th>
<th>Maximum Occupancy</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABC1- Screening Area</td>
<td>2</td>
<td>To be used to conduct temperature &amp; health screening</td>
</tr>
<tr>
<td>ABC1-166/ HLRC Main Exercise Lab</td>
<td>6</td>
<td>Only 1 participant assessment at a time is permitted in the main lab</td>
</tr>
<tr>
<td>ABC1-166A and B/ HLRC Procedural Room</td>
<td>2</td>
<td>There are 2 separate procedural rooms available with a maximum of 2 per room</td>
</tr>
<tr>
<td>ABC 1-156/Research Metabolic Kitchen</td>
<td>2</td>
<td>This refers to the kitchen and prep area and does not include the dining area</td>
</tr>
<tr>
<td>ABC1-250/Dexa Room</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>ABC1-259</td>
<td>3</td>
<td>A portion of the room will be blocked off to enable consenting in the lobby area and allow access to room 259A</td>
</tr>
<tr>
<td>ABC1-259A/Clinical Procedure Area</td>
<td>4</td>
<td>Enter from room 259’s north door</td>
</tr>
<tr>
<td>ABC1-259A-1/Clinical Station</td>
<td>2</td>
<td>One person at each computer station, six feet apart.</td>
</tr>
<tr>
<td>ABC1-259A-2/Procedure Area</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>ABC1-271/Wet Lab</td>
<td>9</td>
<td>Must work at least six feet apart. A temporary partitioned consent area will be created near the east entrance door.</td>
</tr>
</tbody>
</table>

*in-person refers to an in-person, face-to-face research activity. If conducting HP research remotely no action is needed.*

Ver3.1 07/27/2020
Appendix B

PPE Recommendations for common procedures. Please consult with research managers and/or EHS if needed for recommendations on procedures not covered in this table.

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Hand Washing</th>
<th>Gloves</th>
<th>Cloth face covering</th>
<th>Surgical Mask</th>
<th>N95 or KN95</th>
<th>Safety Glasses or Face Shield</th>
<th>Lab Coat</th>
<th>Isolation Gown</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consent process/interview*</td>
<td>X</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anthropometrics</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Applying wearables</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aerosol generating procedures</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Blood pressure</td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BMR</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Breath testing</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Cardiac ultrasound</td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>CGM insertion</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>CO monitoring</td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Dynamometer</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>DXA</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>EEG</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>EKG</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Exercise HIIT training</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Fingerstick</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>FMD</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Food delivery to participant home</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Food pickup in ABC</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Food preparation in Metabolic Kitchen</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Nutritional consultation</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>OGTT/meal tests</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Phlebotomy/IV line insertion</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Physical Exam</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Pulse wave analysis</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Sample processing</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Sub-max (without cart)</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Urine collection</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>VO2 Max Metabolic Testing</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Wingate</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Questionnaires- computer or paper</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Walk test (6 min)</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
</tbody>
</table>

*in-person refers to an in-person, face-to-face research activity. If conducting HP research remotely no action is needed.

Ver3.1 07/27/2020
## SHS Clinic PPE Recommendations

<table>
<thead>
<tr>
<th></th>
<th>Hand Washing</th>
<th>Gloves</th>
<th>Safety Glasses/Face Shield</th>
<th>Surgical Mask</th>
<th>N95 or KN95</th>
<th>Sneeze Guard</th>
<th>Isolation Gown</th>
<th>Earphone Covers</th>
<th>Includes Otoscopy</th>
</tr>
</thead>
<tbody>
<tr>
<td>SLP Individual Treatment-Adult</td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SLP Group Treatment-Adult</td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SLP Individual Treatment-Pediatric</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SLP Group Treatment-Pediatric</td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SLP Diagnostic Evaluation-Standard</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SLP Diagnostic Evaluation-Aerosol</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>AuD-Otoscopy</td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
<td>X**</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AuD-Evaluation</td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
<td>X**</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AuD-Immittance</td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
<td>X**</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AuD-Consultation</td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
<td>X**</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AuD-ABR</td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
<td>X**</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AuD-VNG</td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
<td>X**</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AuD-Ear Impressions</td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
<td>X**</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AuD-Hearing Aid Fitting</td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
<td>X**</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AuD-Hearing Aid Check/Repair</td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
<td>X**</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AuD-Cochlear Implant</td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
<td>X**</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Questionnaire/Paperwork*</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>COVID-19 Screening</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Check in/out</td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* online format is recommended
**surgical mask required, KN95 recommended

*in-person refers to an in-person, face-to-face research activity. If conducting HP research remotely no action is needed.

Ver3.1 07/27/2020
Appendix C

Health Screening Form

Name: ___________________________ Study Name/ID: ___________________________

Principle Investigator: ___________________________ Temperature: ___________

In the last 48 hours, have you had any of the following NEW symptoms:

<table>
<thead>
<tr>
<th>Symptom</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fever of 100.4 F (37.8°C) or above</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Possible fever symptoms like headache, alternating chills and sweating</td>
<td></td>
<td></td>
</tr>
<tr>
<td>New Cough</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nausea, vomiting or diarrhea</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Symptoms described as NEW</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trouble breathing, shortness of breath</td>
</tr>
<tr>
<td>Muscle aches</td>
</tr>
<tr>
<td>Sore throat</td>
</tr>
<tr>
<td>Loss of smell or taste, a change in taste</td>
</tr>
</tbody>
</table>

CIRCUMSTANCES:

<table>
<thead>
<tr>
<th>Question</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Have you had contact with anyone who was diagnosed with or under investigation for the Coronavirus (Covid-19) in the last 14-days?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you traveled in the past 14-days? (including within the US)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

If the person does NOT have a temperature, has NO symptoms AND answered NO to the circumstance question above:

No monitoring is required

If the person has had contact with someone who was diagnosed with or under investigation for the coronavirus (Covid-19) in the last 14-days OR has traveled to an affected geographical area within 14-days AND NO temperature AND NO symptoms:

Inform the participant it will be necessary to reschedule & have person contact their primary care provider

If the person has a temperature above 100.4F OR has symptoms listed above AND answered YES to circumstance questions:

Inform the participant it will be necessary to reschedule & have person contact their primary care provider

Screener name: ___________________________ Date: ___________

*In-person refers to an in-person, face-to-face research activity. If conducting HP research remotely no action is needed.

Ver3.1 07/27/2020
Appendix D

Donning a surgical mask

1. Wash hands with soap and water or apply hand sanitizer before donning a mask.
2. Place mask on face with ear loops over ears.
3. The mask should cover your nose and mouth with no gaps between the mask and your face.
4. Wash hands with soap and water or apply hand sanitizer.
5. Avoid touching the mask while wearing it.

Doffing a surgical mask

1. Wash hands with soap and water or apply hand sanitizer.
2. Use the ear loops to remove the mask, avoiding touching the front of the mask or your face.
3. If the mask is in good condition and not soiled, you may reuse it.
4. Carefully place the mask into a clean Ziploc bag, labeled with the user’s name. Avoid compressing the mask. Do not seal the bag.
5. Wash hands with soap and water or apply hand sanitizer.

Note: If the mask was worn during an encounter with another person who displayed signs of illness, discarding the mask in the trash.

*In-person refers to an in-person, face-to-face research activity. If conducting HP research remotely no action is needed.

Ver3.1 07/27/2020
Reusing the surgical Mask

If using a surgical mask and following social distancing practices, the likelihood of the mask being contaminated is very low.

1. Wash hands with soap and water or apply hand sanitizer.
2. Remove the mask by holding the ear loops.
3. After removing facemask, visually inspect for contamination, distortion in shape or form. Discard in trash if soiled, torn, or saturated.
4. Carefully store in an unsealed bag labeled with your name on it.
5. Wash hands with soap and water or apply hand sanitizer

*in-person refers to an in-person, face-to-face research activity. If conducting HP research remotely no action is needed.*
Appendix E

Procedures for donning safety glasses
1. Wash hands with soap and water or apply hand sanitizer before donning safety glasses.
2. Remove the safety glasses from package or storage container.
3. Place safety glasses directly on your face. Do not set the safety glasses on surfaces.

Procedures for doffing safety glasses
1. Wash hands with soap and water or apply hand sanitizer. If wearing gloves, remove gloves before removing safety glasses.
2. Remove safety glasses. Avoid touching your eyes and face.
3. Clean safety glasses with soap and water solution. Let dry before storing them.
4. Place safety glasses in a clean plastic container or Ziploc bag for reuse.

*In-person refers to an in-person, face-to-face research activity. If conducting HP research remotely no action is needed.

Ver3.1 07/27/2020
Appendix F

Procedures for donning gloves
1. Wash hands with soap and water or apply hand sanitizer before donning gloves.
2. Select properly sized gloves.
3. Don one glove per hand.
4. Inspect gloves for any tears or holes and replace gloves if defects are detected.

Procedures for doffing gloves
1. Grasp the outside edge near your wrist.
2. Peel away from your hand, turning the glove inside out.
3. Hold in opposite gloved hand.
4. Slide ungloved finger under the wrist of the remaining glove.
5. Peel off from inside, creating a bag for both gloves.
6. Discard gloves in the garbage.


*in-person refers to an in-person, face-to-face research activity. If conducting HP research remotely no action is needed.

Ver3.1 07/27/2020
Appendix G

**LAB DISINFECTING LOG**

<table>
<thead>
<tr>
<th>LOCATION:</th>
<th>MONTH:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>WEEK:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>MON</th>
<th>TUE</th>
<th>WED</th>
<th>THUR</th>
<th>FRI</th>
<th>SAT</th>
<th>SUN</th>
</tr>
</thead>
<tbody>
<tr>
<td>TIME</td>
<td>INIT</td>
<td>TIME</td>
<td>INIT</td>
<td>TIME</td>
<td>INIT</td>
<td>TIME</td>
</tr>
</tbody>
</table>

*In-person refers to an in-person, face-to-face research activity. If conducting HP research remotely no action is needed.*

Ver3.1 07/27/2020