

Guidance for the Resumption of Human Subjects Research Activities

Updated January 13, 2021

Note – The COVID-19 pandemic presents a complex and dynamic environment. This document provides the best information and guidance to date but is subject to change as conditions warrant.

During the COVID-19 pandemic, our guiding principles include the protection of the health and safety of our community, which includes our research participants and personnel. As the institution begins to resume normal operations, new and existing human subjects research (HSR) activities that must occur on-site and in-person may be allowed. However, research personnel and participants may be at increased risk for COVID-19 as these study visits may involve close contact. Therefore, the purpose of this document is to provide guidance specific to the resumption of HSR in the context of the UAB over-arching resumption of research operations.

Code/Timing	Type of Human Subjects Research Allowed
Code Orange	Research that has the potential to mitigate the COVID-19 pandemic and HSR that must be conducted for the participants' health and well-being.
Code Yellow: Phase 1	All HSR that does not involve close contact (within 6 feet of another person for at least 15 minutes) may resume or be initiated. UAB guidance must be followed. Investigators must follow their unit-approved R2Ops plans for individual and/or shared HSR spaces.
Code Yellow: Phase 1 plus 14 days	All HSR that involves close contact can resume or be initiated.
Code Green	Normal research operations.

General Information for All Research Personnel Involved in Human Subjects Research

- The R2Ops overarching guiding principles, allowable research activities, roles and responsibilities, laboratory and research space considerations, and operational plan template provide background guidance and are to be followed as they relate to the more detailed HSR guidance provided herein.
 - Each school/college defines the Unit (e.g., school/college, department, division, other) that will operationalize all guidelines on resuming research and approve plans developed by PIs.
- Self-screening of all research personnel must be conducted regularly as directed through the [COVID-19 Assessment Tool](#), a symptom and exposure tracker.
- All personnel conducting HSR must familiarize themselves with the [IRB's COVID-19 FAQs](#) and must abide by the IRB-approved protocol except when necessary to eliminate apparent immediate hazards to the subject.

Remote (Off-Site) Human Subjects Research

- Human subject research activities that can be conducted remotely must continue to be conducted remotely until the institution reaches Code Green. Considerations in conducting remote HSR research include:
 - The IRB-approved protocol must be followed, and any modifications must be approved by the IRB before changes are implemented. See IRB FAQ #10 for guidance on changes that require submission and approval of a Protocol Revision/Amendment Form (PRAF).
 - See IRB FAQ #27 for current guidance on consent discussions in a remote setting.
 - Study visits that are conducted virtually must utilize HIPAA compliant online software systems.
 - Transition study documents such as surveys and questionnaires to an online format if possible (e.g. RedCap).
 - Interventions (i.e., drugs, devices) or other study materials can be delivered to the participant's home per sponsor approval and guidance, if possible.
 - Remote data analysis must follow data security requirements of the IRB.

In-Person (On-Site) Human Subjects Research

- For in-person study visits for participants known to have COVID-19 or are persons under investigation (PUI) having screened positive:
 - The PI must follow UAB directives including the identification of stable supplies of PPE, handwashing protocols, and facility disinfection protocols that are required when working with participants with confirmed or suspected COVID-19.
 - Based on CDC and UAB Medicine guidelines for medical providers, it is recommended that frontline research personnel conducting human subjects research wear face shields with masks when coming in close contact with patients and visitors.
 - Patients under investigation (PUI) or COVID-19 positive research participants must have separate, individual waiting areas or preferably be taken directly to examination/procedure rooms.
 - Any human biospecimens that may be infected by SARS-CoV-2 must adhere to the requirements outlined in the document titled [UAB COVID-19 Containment Guidance for Researchers](#).
 - All work at UAB involving culturing of COVID-19+ patient samples or propagation/isolation of SARS-CoV-2 must be conducted at A/BSL3 in the SEBLAB. This work will require review and approval by the Institutional Biosafety Committee prior to initiation.

- For in-person study visits that are intended for participants NEITHER known nor suspected of having COVID-19:
 - COVID-19 screenings must be conducted remotely (via phone or teleconference) on participants (and their support person, if applicable) within 24 hours before each in-person study visit **AND** when the participant arrives on-site to their study visit (assuming they screen negative during the remote screening within 24 hours in advance).
 - The remote phone screening must take place within 24 hours of the visit, but can occur anytime within that time period, including the day of the visit so long as it is conducted prior to the participant entering UAB facilities.
 - During the remote 24-hour screening, research personnel must instruct participants to wear a mask or face covering to the study visit. If they do not have a mask or face covering, research personnel may provide a mask or face covering. If these are not available, the in-person screening and study visit cannot proceed.
 - Consider providing [“What to Expect”](#) document to the participant.
 - Screening of potential and on-going participants (and their support person, if applicable) for COVID-19 must be performed prior to the conduct of study procedures, including informed consent, unless the screening information is considered part of the research.
 - If the COVID-19 screening information is to be used for research, the screening protocol must be included in the study protocol and approved by the IRB before proceeding with study activities ([IRB FAQ #6](#)).
 - During the in-person screenings and study visits, both the research personnel and participant(s) and their support person (if applicable) must wear face masks or face coverings, and stringent handwashing and social distancing protocols must be followed. Personnel can wear gloves and a gown (if available) if the visit requires close contact due to necessary research procedures or facility constraints.
 - COVID-19 research participant screenings are to include the following elements:
 - Current diagnosis of COVID-19.
 - Subjective COVID-19 symptom assessment: cough, shortness of breath or difficulty breathing, fever, chills, muscle pain, new loss of taste or smell, GI symptoms (nausea, vomiting, diarrhea).
 - Body temperature (<100.4°)—assessed by the participant while off-site and by the research personnel when on-site.

- For 24-hour, remote COVID-19 pre-screenings, a temperature may be taken with a thermometer or noted subjectively by the participant (and support person, if applicable) to the research personnel.
 - For on-site COVID-19 screenings, a tympanic or forehead thermometer must be used for measuring body temperature.
- Upon completion of the *remote pre-screening*:
- If a participant (or support person, if applicable) screens positive for COVID-19 on any criteria, the in-person screening and research visit must be postponed.
 - Research personnel must communicate the positive screening results with the Principal Investigator and instruct the participant to contact their primary care provider for further screening and testing.
 - If the participant’s physician chooses not to proceed with COVID-19 testing, the UAB COVID-19 testing facility is available as described in the next bullet point. The PI will be responsible for ensuring COVID-19 testing is conducted prior to re-engaging the participant for future remote screenings.
 - When utilizing the UAB Research COVID-19 testing process, a member of the research study team must complete the testing registration e-form found here: [COVID Testing for Research Participant Registration](#). Upon completion of the e-form, a nurse from the COVID testing team will contact the research study team to register the research participant for COVID-19 testing. The COVID testing team nurse will also provide detailed instructions on the UAB testing location in addition to what to expect when they confirm the COVID-19 testing appointment. The results of the test will be communicated by the testing team nurse to the research participant and the research team within 24-48 hours. COVID-19 testing will be billed to the participant’s health insurance (without a deductible applied) OR will be covered through alternative means (such as through the CARES act funding or otherwise). Research participants will not be billed for testing directly and will not be billed for co-pays, unless the individual is part of an employer-sponsored plan that does not allow co-pays to be waived. If a participant is aware that her/his plan is employer-sponsored, we ask that they confirm co-pay responsibility. No co-pays will be collected at the time of testing. Likewise, sponsored research projects will not be billed for COVID-19 testing as the test results are related to required screening for participation and are not part of the human subjects research. In the event that COVID-19 testing is part of the human subjects research protocol, the COVID-19 testing may be billed to the sponsored research project. Please contact Cindy Joiner, PhD, MPH, RN with questions (205-934-7520, cirwin@uabmc.edu).
 - If the participant RNA tests positive for COVID-19, the participant must be re-tested (either by the primary care physician if he or she conducted the original COVID-19 test OR by UAB Research COVID-19 testing if UAB conducted the original COVID-19 test) prior to participation in any in-person research protocols using the time periods listed below. Note that these criteria for re-entry also pertain to study monitors and support personnel as well.
 - Participants cannot be re-considered for human subject research within the first 14-day period following a positive COVID-19 RNA test.
 - Between days 14 and 30 following a positive COVID-19 RNA test, participants can be re-considered for human subject research if a negative COVID-19 re-test is demonstrated and the participant is 8 days symptom free.
 - Participants can be re-considered for human subject research 31 days after the original COVID-19 positive test result if they are symptom free. However, a negative COVID-19 re-test is highly encouraged when possible to confirm that participant is indeed COVID-19 negative.
 - If participant (and support person, if applicable) screens negative for COVID-19 on all criteria, the in-person screening may continue within 24 hours of the remote screening. Participants can be provided study-specific

instructions, the [“What To Expect”](#) document, asked to wear a mask or face covering to the on-site visit, and be given detailed instructions regarding paperwork to bring to the appointment (if any) and precise study location.

- Upon completion of the *in-person screening*:
 - If a participant (and support person, if applicable) screens negative and is afebrile (<100.4°), he or she can be directed to a waiting area or directly to a research room (preferred, if possible) but will maintain social distance (6ft) with other non-family participants and personnel at all possible times, and continue to wear their mask or face covering.
 - If a participant (or support person, if applicable) screens positive for COVID-19, the participant (or support person, if applicable) will be asked to depart the research facility and instructed to contact their primary care provider for further screening and testing.
 - The research room/office/space/lab that the participant was present in must be cleaned per UAB Environmental Services guidelines (or a similarly qualified group if the research is occurring off-campus) must be notified to perform a [UAB COVID Cleaning and Disinfection Protocol](#) .
 - If the participant’s physician chooses not to proceed with COVID-19 testing, the PI will be responsible for ensuring COVID-19 testing through UAB Research COVID-19 testing as described above prior to re-engaging the participant for future screenings.
 - If participant is tested and there is a positive test result, the participant must be informed that they need to self-quarantine for 10-14 days. Repeat COVID testing will be completed by the originator of the first COVID RNA test (e.g., either the primary care physician or research personnel working with UAB COVID testing).
- Some research or medical procedures may require personnel to work within the 6-foot social distancing guidelines and for periods accumulating to more than 15 minutes over a 24-hour period. In those situations, it must be determined that there are no alternatives to keep personnel and participants separated by 6 feet. Note that there will inevitably be incidental contact within the 6-foot guideline of less than a total of 15 minutes over a 24 hour period (e.g. common areas such as passing in the hall, laboratories, and waiting rooms). It is critical to keep those incidental contacts to a minimum but realize that these kinds of interaction are probably not a major source of transmission. The [CDC currently defines a “close contact”](#) as being “within 6 feet of a COVID-19 case for a prolonged period of time” OR “having direct contact with infectious secretions of a COVID-19 case”. Since everyone is considered COVID-19 positive, anyone that works within 6 feet for 15 minutes is considered to have had “close contact.”
 - **Research protocols that are known to be associated with possible exposures (unmasking of research personnel or participants within a 6-foot proximity for 15 minutes or longer over a 24-hour period) must have IRB-approved language in the Informed Consent documentation informing the research participant that either party (to be specified in the Informed Consent) will need to be unmasked for the approximate period of time and that this could lead to a COVID-19 exposure. The consent should also discuss the efforts used to mitigate the risk of exposure.**
 - The OIRB has provided a template [addendum consent for this purpose](#). Investigators may choose to use this addendum consent along with the primary consent form, and/or may choose to include the exposure risks in the primary consent form in lieu of the addendum consent.
 - If the separate addendum consent is used to inform participants of exposure risks, the investigator must have every participant sign both documents.
 - For ongoing studies with repeat visits by research participants who have already provided consent, the investigator may inform research participants of these risks upon their next visit using either the

addendum consent form, or if adding exposure risks to the primary consent, re-consenting participants with the revised primary consent form.

- All consent forms and revisions to previously approved consent forms, including use of the template addendum consent form, must be reviewed and approved by the IRB prior to their use with participants. For ongoing studies, consent changes should be submitted via a Revision/Amendment submission in IRAP.
- If research personnel believe that a research participant or their support person has been exposed to COVID-19 through their involvement in on-site/in-person research, research personnel should immediately inform the study Principal Investigator. The Principal Investigator should immediately contact Cindy Joiner, PhD, MPH, RN to provide details of the exposure—including a review of screening information (for both research personnel and participants), distancing, and use of facial coverings (205-934-7520, cirwin@uabmc.edu). Dr. Joiner will work with the PI, R2Ops HSR task force, and others as needed to determine actions that may be required to resolve the situation including supplying the research team with [pre-approved scripts](#) that can be used if contacting research participants with recommendations for COVID-19 testing, as necessary.
 - **Note:** An exposure is currently defined as proximity within 6 feet of an individual with confirmed or suspected COVID-19 for 15 minutes or longer while at least one of the individuals is not wearing a facial covering. The timeframe for having contact with an individual includes the period 48 hours before the individual became symptomatic.
 - **Noncompliance with R2Ops guidance will be reported to the investigator’s Dean and Department Chair by the R2Ops HSR committee, and if associated with either research personnel or participants being placed at increased risk, this fact must also be reported to the IRB by the PI via submission of a Problem Report.**
- **Additional Research Participant Considerations**
 - Investigators must implement a pre-visit process for all participants that includes a remote screening 24 hours in advance, informed consent for new participants when possible (see [IRB FAQ #27](#)—remote consent), and information about UAB’s policies regarding COVID. If applicable consider using the following [telephone script](#) in communications with participants.
 - Participants will call research staff upon on-site arrival and be greeted/escorted into the facility by research personnel. Encourage accompanying family members/caregivers who are not needed at research appointments to stay home or in the car/outside the building (see “Visitors of Research Participants” below). If participants and researchers are physically able, encourage using stairs rather than elevators.
 - In addition to on-going remote (24 hour) and in-person screenings, participants receiving medically invasive (introduction of instruments or other objects into the body or bodily cavities) or aerosolized research or medical procedures must have COVID-19 testing and a negative result within 4 days prior to study activities at an FDA approved laboratory. NOTE: If an aerosolizing generating procedure (AGP) is performed at a UAB clinical facility (Operating Room, Kirklin, etc.), then the COVID test must be performed at a UAB or UAB-approved facility.
 - With a negative COVID-19 screening and test result, the team may proceed with aerosolizing procedures. Aerosolizing procedures include but are not limited to pulmonary function test, bronchoscopy, test involving the naso- or oropharynx, sputum induction, and any other procedure requiring endotracheal intubation and/or mechanical ventilation. These procedures must be conducted using enhanced respiratory precautions (N95, gown, and face shield). These can be reused by staff given assumed COVID negative status of the subject. As an alternate to respiratory enhanced PPE, an approved Personal Protection Booth (Oasis, Bento, etc.) could be used to isolate the subject from the staff during the aerosolizing procedure.
 - UAB refers to the CDC guidance and FAQs as they relate to AGPs. There are several FAQs posted by the CDC which address common AGPs [which are found here](#). Also note that outside of medical procedures, certain other protocols associated with research may be associated with the generation of aerosols (e.g., vigorous

exercise, stress tests). If you are uncertain about a specific procedure or protocol, please contact Cindy Joiner, PhD, MPH, RN with questions (205-934-7520, cirwin@uabmc.edu).

- COVID-19 RNA testing is not required on what is determined by the R2Ops HSR committee to be a minimally invasive medical or research procedure. For example, COVID-19 testing is not required prior to research study visits involving phlebotomy, lumbar punctures, or muscle biopsies unless the research participant screens positive for COVID-19. These examples are not intended to be all inclusive. For questions about exceptions, please contact Cindy Joiner, PhD, MPH, RN who will consult with the R2Ops HSR committee for clarifications (205-934-7520, cirwin@uabmc.edu).
 - If the COVID-19 symptom screen is positive on remote (24 hour) or in-person screening at the research facility, the visit must be canceled. See above for requirements for proceeding with research participation.
 - Participant visits must be scheduled to stagger visits and minimize waiting room occupancy. This will promote social distancing and allow time between visits to clean spaces appropriately.
- **Visitors of Research Participants**
 - For research involving children where parental permission is required from both parents, but only one parent is permitted in the facility due to COVID-19 restrictions, the investigator must obtain permission of the other parent via an alternative method. [See IRB FAQ #27](#). Visitor restriction from the facility alone is not reason to consider the other parent “not reasonably available.”
 - Participants are encouraged to come to the study visit alone. Exceptions may be allowed where a support person or persons’ presence improves the individual’s safety, emotional well-being, or physical care.
 - If a support person accompanies the participant, they must adhere to the same COVID screening requirements as the participant.
 - If a support person screens positive for COVID, the participant visit must be rescheduled.
- **Study Sponsor Visits (monitor visits, site initiation visits, etc.)**
 - Remote monitoring and site visits are preferred for non-UAB personnel. These visits are to occur through phone, Zoom, or teleconference software, when possible.
 - In-person monitoring and site visits may occur when needed, but require that study personnel follow the same screening procedures described in this document for research participants for both remote pre-screening within 24 hours ahead of the monitoring or site visit, and in-person screening on site prior to the monitoring or site visit initiation. For monitoring visits that span consecutive days, the study monitor must be screened in-person before proceeding with the monitoring visit each day.
 - If a study monitor screens positive for COVID-19 on any criteria (remotely or in-person), the in-person monitoring visit must be postponed.
 - Research personnel must communicate the positive screening of the study monitor to the Principal Investigator and instruct the study monitor to contact their primary care provider for further screening and testing.
 - If the study monitor’s physician chooses not to proceed with COVID-19 testing, the UAB COVID-19 testing facility is available as described elsewhere in this document. The PI will be responsible for ensuring COVID-19 testing is conducted prior to re-engaging the study monitor for future remote screenings.
 - If the study monitor is tested and there is a positive test result, study personnel must use the re-entry criteria based on days since initial positive COVID test, negative COVID-19 testing, and being free from symptoms for 8 days described above in this document for re-entry of participants. A negative test result is not required 30 days from the original test, as long as the study monitor is 8 days symptom free.

- Study monitors who screen positive but then PCR test negative must screen negative for 8 additional days following the negative PCR test, followed by negative remote and on-site screenings before proceeding with the study monitoring visit.
 - Monitoring visits that require the sponsor to view the Electronic Medical Record (EMR) can be accomplished by research personnel sharing the information via HIPAA-compliant Zoom. Access to the EMR can also be requested for remote monitor visits by contacting Mark Marchant at 205-934-2098 or mmarchant@uabmc.edu.
- **Facilities Considerations**
 - Investigators must follow his/her Unit-approved R2Ops operational plan for their own and shared HSR spaces, including floor plans.
 - Research visits occurring in the hospital or ambulatory clinic setting will follow the policies and guidance in place for those areas.
 - Research activities involving COVID-19 positive or presumed positive participants must be conducted at a UAB designated research facility that accommodates COVID-19 participants with suspected or known infection. Please contact Cindy Joiner, PhD, MPH, RN (205-934-7520, cirwin@uabmc.edu) regarding available space. Dr. Joiner's email confirmation should be included in the submission of any new or amended IRB protocols involving known or suspected COVID-19 participants.
 - Ensure your research space utilizes signage sharing current guidance and restrictions
 - Signage can be downloaded from <https://www.uab.edu/fightcovid19/media-resources>
 - Contact your school or department for assistance in obtaining additional signage.
 - Investigators must confirm that study-specific imaging, laboratories, and other research facilities used as part of conducting research protocols are open and have essential staff on-site to perform research activities, including COVID screenings.
 - If your research participants will visit a UAB facility in which neither you nor your research personnel provide oversight or work, you or your study personnel must still complete the remote 24-hour COVID screening with the research participant. The conduct of in-person COVID screening is required and will vary by facility or office on campus. Some facilities or offices conduct in-person COVID screenings at each entrance to the facility, and these research participants will typically be identified as screening negative by a sticker that is to be worn while in the facility or office (while on site at UAB). If this is the scenario, this screening process must be documented in the Principal Investigator's (PI) department and school approved R2Ops plans. Other facilities or offices may have no regular COVID screening procedures or personnel in place at facility or office entrances; if this is the case, the study personnel must conduct the remote 24-hour COVID screening AND ensure that personnel in the facilities or offices being used by research participants are trained to and will conduct in-person COVID screenings per the R2Ops HSR guidance. Documentation of this must be included in the PI's department and school approved R2Ops plans, and shared with all study personnel, as well as ancillary departments that perform services for the study.
 - Waiting areas must be arranged to allow for 6 feet of social distancing between seating. Seating can be marked off with signage promoting social distancing or a ribbon placed over the arms of the seat to prevent use.
 - Hand sanitizer must be freely available in all waiting and research areas.
 - Attention must be given to following the [UAB COVID Cleaning and Disinfection Protocol](#) particularly after the presence of an individual known or suspected of being COVID-19 positive.