Guidance for the Resumption of Human Subjects Research Activities

Updated August 21, 2020

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.

<table>
<thead>
<tr>
<th>Code/Timing</th>
<th>Type of Human Subjects Research Allowed</th>
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<tbody>
<tr>
<td>Code Orange</td>
<td>Research that has the potential to mitigate the COVID-19 pandemic and HSR that must be conducted for the participants’ health and well-being.</td>
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<tr>
<td>Code Yellow: Phase 1</td>
<td>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.</td>
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<tr>
<td>Code Yellow: Phase 1 plus 14 days</td>
<td>All HSR that involves close contact can resume or be initiated.</td>
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<tr>
<td>Code Green</td>
<td>Normal research operations.</td>
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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
tscreened positive:
  o 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.
  o 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.
  o 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.
  o 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”.
  o 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:
  o 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.
  o 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).
  o 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.
  o COVID-19 research participant screenings are to include the following elements:
    ▪ 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.
• Research teams may use UAB Medicine COVID screening form.

o 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, following a repeat COVID-19 test negative.
    ▪ 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 tests positive for COVID, the participant must be re-tested (either by the primary care physician if he or she conducted the original COVID test OR by UAB Research COVID testing if UAB conducted the original COVID test) prior to participation in any in-person research protocols.
    ▪ The COVID re-testing must be conducted after at least a) 14 days have passed since the original COVID RNA test, and b) 8 days of being symptom free.
  ▪ Research personnel will inform the participant that they can be remotely re-screened following a confirmed negative COVID test result and 8 symptom-free days.
    ▪ 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.

o Upon completion of the in-person screening:
• If a participant (and support person, if applicable) screens negative and is afebrile (<100.4°F), 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 sit empty for at least one hour and Environmental Services (or a similarly qualified group if the research is occurring off-campus) must be notified to perform a cleaning due to a COVID-19 exposure.
  - 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 testing as describe above prior to re-engaging the participant for future screenings.
  - If participant is tested and there is positive test result, the participant must be informed that they need to self-quarantine for 14 days until negative test results are returned AND the participant must screen negative for 8 additional days following the negative test before proceeding with additional screening for research. 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).
  - Participants who screen positive but then test negative must screen negative for 8 additional days following the negative test, followed by negative remote and on-site screenings before proceeding with the study visit.

• Some research or medical procedures may require personnel to work within the 6-foot social distancing guidelines. 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 (e.g. common areas such as passing in the hall, laboratories, 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.”

• 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.
  - Encourage participants to 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 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.
If both above are present, 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 requiring both negative COVID-19 symptom screen and negative pre-visit COVID test prior to 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.)**

- In person monitoring and site visits are deferred at this time. These visits are to occur remotely through phone, Zoom, or teleconference software.
- 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. If there is an urgent need to perform an in-person monitoring visit, contact Mark Marchant 205-934-2098 or mmarchant@uabmc.edu with a request.
- Studies that require a sponsor representative present in the hospital (e.g., device) require pre-approval from the investigator’s School/Department/Unit leadership and, if relevant, appropriate hospital/service line leadership.
• Facilities Considerations
  o Investigators must follow his/her Unit-approved R2Ops operational plan for their own and shared HSR spaces, including floor plans.
  o Research visits occurring in the hospital or ambulatory clinic setting will follow the policies and guidance in place for those areas.
  o 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.
  o Ensure your research space utilizes signage sharing current guidance and restrictions
    ▪ Signage can be downloaded from https://www.uab.edu/coronavirus/media-graphics
    ▪ Contact your school or department for assistance in obtaining additional signage.
  o 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.
  o 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.
  o Hand sanitizer must be freely available in all waiting and research areas.
  o Attention must be given to following the UAB Disinfection and Cleaning Protocol particularly after the presence of an individual known or suspected of being COVID-19 positive.