UAB RESEARCH
The University of Alabama at Birmingham

Guidance for the Resumption of Human Subjects Research Activities
Updated July 1, 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.

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 it relates 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 should 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 should 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 should be delivered to the participant's home per sponsor approval and guidance, if possible'
  - Remote data analysis should 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 should 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.
  - Patients under investigation (PUI) or COVID-19 positive research participants should 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 outlines 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 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 should 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 is to 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) should wear face masks or face coverings, and stringent handwashing and social distancing protocols are to 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 should be used for measuring body temperature.
      - Research teams may use UAB Medicine COVID screening form.

- 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 should communicate the 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 PI will be responsible for ensuring COVID-19 testing is conducted prior to re-engaging the participant for future remote screenings.
    - Research personnel should 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 should 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 should maintain social distance (6ft) with other 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) should 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. UAB Facilities is developing disinfection and cleaning guidelines (LINK under construction).
    - If the participant's physician chooses not to proceed with COVID-19 testing, the PI will be responsible for ensuring COVID-19 testing is conducted prior to re-engaging the participant for future screenings.
    - If participant is tested and there is positive test result, the participant should be informed that they need to self-quarantine for 14 days until negative test results are returned AND the participant should screen negative for 8 additional days following the negative test before proceeding with additional screening for research.
    - Participants who screen positive but then test negative should 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 should 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 should 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 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.
  - **07/01/20 Start of Update** - 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 procedures should have COVID-19 testing and a negative result within 4 days prior to study activities at an FDA approved laboratory. NOTE: If aerosolizing procedure is performed at a UAB clinical facility (OR, Kirklin, etc.), then the COVID test should be performed at a UAB or UAB-approved facility.
    - If both above are present, the team may proceed with aerosolizing procedures. Aerosolizing procedures include 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 should 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, alternatively an approved Personal Protection Booth (Oasis, Bento, etc.) could be used to isolate the subject from the staff during the aerosolizing procedure.
    - If the COVID-19 symptom screen is positive on remote (24 hour) or in-person screening at the research facility, the visit will should be canceled and repeated ≥7 days, requiring both negative COVID-19 symptom screen and negative pre-visit COVID test. **07/01/20 End of Update.**
  - Participant visits should 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 should be rescheduled.

- **Study Sponsor Visits (monitor visits, site initiation visits, etc.)**
  - In person monitoring and site visits are deferred at this time. These visits should 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.
  - If there is an urgent need to perform an in-person monitoring visit, contact Mark Marchant 205-934-2098; 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 appropriate hospital/service line leadership.

- **Facilities Considerations**
  - Investigators should 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.
  - 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.
  - Investigators should 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.
  - Waiting areas should 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 should be freely available in all waiting and research areas.
  - Attention must be given to following the UAB Disinfection and Cleaning Protocol (LINK under construction) particularly after the presence of an individual known or suspected of being COVID-19 positive.