

Guiding Principles for Restarting Human Subject Research (HSR)

The COVID-19 pandemic has introduced unique challenges to research studies involving human subjects. This document is not meant to supersede the Guiding Principles and Best Practices included in the [RII Research Restart Plan](#). Rather, the purpose of this plan is to provide additional guidance for a range of research involving human subjects from behavioral studies to therapeutic and interventional clinical trials, in order to protect the health and safety of researchers, research participants, and students. The plan incorporates [CDC recommendations](#) and general guidance included in the [RII Research Restart Plan](#). Understanding that a one-size fits-all set of guidelines may not capture the risks and benefits across all types of human subject research, individual colleges, departments, and laboratories may need to tailor their plans for mitigating risk to fit the specific circumstances and scope of their research activities. Since human subject and clinical research may be conducted off-campus or within affiliated medical units, research teams should also be familiar with and follow the guidelines, procedures and timelines developed by those entities. As new information about COVID-19 becomes available and its prevalence within our environment changes, these guidelines will be periodically re-evaluated and adjusted, and researchers may need to modify their safety plans.

Visit the [RII Research Restart Website](#) for the RII Research Restart Plan, COVID-19 Re-Entry Checklist, Participant Wellness Screen, IRB-approved materials, and other related information.

1. **All investigators** are required to complete the COVID-19 Re-Entry Checklist for Commencing Research prior to restarting studies, regardless of whether or not an RII Essential Research Waiver has already been obtained.
2. Researchers should use the table below to determine the highest *potential* level of COVID-19 exposure risk for both research personnel and participants.
3. The table provides guidance on the *minimum required strategies* for mitigating risk for each level of COVID-19 exposure risk. Some situations may require additional mitigation strategies (such as COVID-19 testing), which should be assessed by the principle investigator and research unit.
4. For studies that include participants or research staff with elevated risk for COVID-19, additional safeguards should be considered. Based on current [CDC guidelines](#), elevated risk is defined as all persons age 65 or older, or persons of any age with a medical condition including lung disease or moderate-severe asthma, serious heart condition, immune system compromise, obesity (BMI >39), diabetes, or chronic kidney or liver disease.
5. Whenever possible, research involving human subjects should be conducted using methods that remove or diminish contact between researchers and participants.
6. Some studies may require more than one research participant to be present in the study area at a given time. For participants who reside together (e.g., a parent accompanying a child, or spouses), no additional precautions are necessary. For participants who do not reside together, social distancing at a minimum of 6 ft between participants must be strictly maintained and participants should wear a face covering at all times.
7. Studies requiring more than one research visit may use mitigation strategies that are appropriate to each visit. For example, the requirements for behavioral testing may be different than a visit for blood draw and/or MRI.
8. Adequate social distancing (minimum 6 ft) between all participants and research personnel should be maintained unless person-to-person contact is necessary for a study (see examples in the table below). Plans for maintaining social distancing should consider additional factors, such how participants will travel to and from the research setting, ingress/egress from the laboratory and building, use of waiting areas, and scheduling additional time between visits to allow for disinfecting of spaces.
9. All research staff should review [CDC guidance on handwashing](#) and the use of hand sanitizer. Researchers should wash their hands before/after each research visit, and immediately before/after any direct physical contact with a research participant.
10. All research staff should self-screen daily using the University of Arizona COVID-19 screening tool available on the [RII Research Restart website](#). Researchers who are experiencing COVID-19 symptoms or have been exposed to individuals with COVID-19 should refrain from engaging in face-to-face human research activities for 14 days.

11. Participants should be screened by phone using the Participant Wellness Screen prior to attending a face-to-face research visit. Additionally, the Participant Wellness Screen should be repeated in-person at the beginning of each research visit. Participants who are experiencing COVID-19 symptoms or have been exposed to individuals with COVID-19 should be rescheduled at least 14 days later. The exception is research focusing on participants with a diagnosis of COVID-19 confirmed or under investigation, as described in the Level 5 risk category in the table below.
12. Participants must be fully informed of the COVID-19 risks and the mitigation strategies that will be employed during the study, utilizing the information sheet and script provided by IRB (available on the [RII Research Restart website](#)). Use of the IRB approved materials does NOT require separate IRB approval. Researchers should document that each participant has indicated that they understand the information and accept the risk.
13. Training for personnel engaged in research in Levels 3, 4, or 5 of COVID-19 exposure risk categories (see table below) should include detailed training on the correct procedures for hand washing, donning and doffing PPE, as well as adequate cleaning and disinfecting protocols. It is strongly encouraged that laboratories use a “buddy system” to ensure that correct PPE procedures and disinfecting protocols are followed by all personnel.
14. Community-based studies or studies that take place at affiliated facilities should follow these same guidelines with the addition of any guidance and/or rules imposed by the community partners and/or other facilities. These include, among others, Banner-University Medical Center, Banner Alzheimer’s Institute, Banner Sun Health Research Institute, University of Arizona Cancer Center, and Sarver Heart Center.

CV-19 Exposure Risk	Study Activities and Examples	Mitigation Strategies
Level 1	<ul style="list-style-type: none"> Studies conducted using fully online/distance methods or remote activities <p>Example Activities: Online surveys, web-based experimental tasks, virtual interviews and focus groups, phone interviews, telehealth, remote chart review</p>	N/A
Level 2	<ul style="list-style-type: none"> In-person interactions and procedures that <u>require no physical contact</u> and that can maintain social distancing, minimum 6 ft, between all individuals Can be conducted with limited number of research team members (max 2) <p>Example Activities: Behavioral experiments or clinical interventions without physical contact, computerized tasks, onsite chart review</p>	<ul style="list-style-type: none"> Personnel training on handwashing, face coverings, disinfection COVID-19 symptom screening for researchers and participants Social distancing plan to maintain minimum 6 ft between all individuals Face coverings for researchers Increased cleaning/disinfecting
Level 3	<ul style="list-style-type: none"> In-person non-invasive interactions and procedures that <u>require minimal physical contact</u> but can otherwise maintain social distancing Physical contact with the participant limited to one research team member Can be conducted with limited number of research team members (max 2) <p>Example Activities: Instrument setup including MRI, TMS, ERP, DEXA, eye tracking, physical examinations such as balance testing and neurological exam, blood pressure measurements, sleep evaluations, audiology assessment, studies with infants and young children that are not anxiety-provoking</p>	<ul style="list-style-type: none"> Personnel training on handwashing, wearing PPE, disinfection COVID-19 symptom screening for researchers and participants Social distancing plan to minimize physical contact and otherwise maintain 6 ft between all individuals Surgical grade mask, gloves for researchers Increased cleaning/disinfecting
Level 4	<ul style="list-style-type: none"> In-person interactions, interventional activities and procedures that <u>require physical contact less than 15 mins and involve collection of biofluid samples through non-aerosolizing methods</u> <p>Example Activities: Collection of blood, urine, saliva samples, contact with mucosa</p>	<ul style="list-style-type: none"> Personnel training on handwashing, wearing PPE, disinfection Personnel training on procedures for safe handling of biofluid samples COVID-19 symptom screening for researchers and participants Social distancing plan to minimize physical contact time Surgical grade mask, gloves for researchers Additional PPE, including gown and eye protection, and the use of a biosafety cabinet may be required for post-collection processing of biofluid samples Increased cleaning/disinfecting
Level 5	<ul style="list-style-type: none"> Activities and procedures that <u>require direct or close physical contact lasting more than 15 mins that do not produce aerosols</u> In-person interactions, interventional activities and procedures that <u>may or may not require physical contact but likely produce aerosols</u>¹ COVID-19 studies involving patients with current diagnosis, under investigation, or those with active symptoms consistent with COVID-19¹ <p>Example Activities: Studies involving exercise, cardiovascular stress testing, pulmonary function tests, infant-child studies that may induce crying, medical procedures including but not limited to intubation, anesthesia, interventional and basic research studies involving COVID-19 patients</p>	<ul style="list-style-type: none"> Personnel training on handwashing, donning/doffing full PPE, disinfection Procedures for safe handling of biofluid samples where required COVID-19 symptom screening for researchers and participants Social distancing plans to minimize physical contact time Full PPE for researchers including N-95 grade mask, gloves, gown, eye protection Increased cleaning/disinfecting Consider COVID-19 testing of study participants prior to intervention Adequate ventilation¹

¹**Adequate ventilation:** Procedures or research that are likely to produce aerosols should be conducted in spaces with negative-pressure ventilation. If negative-pressure ventilation is not available, pauses between participants should be included to allow for adequate air circulation, air replacement, and disinfecting. Guidance can be obtained through Facilities Management. Revised July 29, 2020