

 **University of North Alabama
COVID-19 Guidance for Research with Human Subjects**

*COVID-19 presents a new and evolving situation that potentially may adversely affect human participants. Principal Investigators conducting human subject research should stay informed of the most current guidance from the UNA IRB regarding the implications of Covid-19 for research. Guidance will be updated here as new information becomes available.*

**Investigators conducting human subjects research**must consider the risk(s) to participants and PI's within the current COVID-19 environment.  Risk of exposure to COVID-19 resulting from participation in human research may arise when research procedures include face-to-face interactions with participants, physical presence of participants on UNA's campus, or other scenarios.  Investigators are requested, as appropriate to meet research objectives, to consider replacing in-person activities with remote activities, technology-assisted participant interactions, or other methods to reduce the risk of participant exposure to COVID-19.

**Investigators with active IRB protocols and those that are submitting new applications to the IRB**may need to submit modifications to approved protocols and/or provide additional information related to the current COVID-19 environment.

**Frequently Asked Questions**

1. **If I have an active IRB protocol that does not involve risk of exposure to COVID-19, what should I do?**

Active IRB protocols in which exposure to COVID-19 would not result from participation in the research may proceed as previously approved by the IRB.
2. **If I have an active IRB protocol that involves the risk of exposure to COVID-19, but I plan to temporarily suspend the research, what should I do?**

Active IRB protocols where exposure to COVID-19 may result from participation in the research may be temporarily suspended by the Principal Investigator.  The PI may suspend all work on the protocol, or limit activities to those that do not involve interaction with human participants. The PI should notify the IRB of the temporary suspension by emailing IRB@una.edu the following information:
	* PI Name
	* Protocol Number
	* Protocol Title
	* A statement that exposure to COVID-19 may result from participation in the research.
	* A statement that the PI plans to temporarily suspend research activities.
	* A statement that all protocol activities will be suspended, or only activities that involve interaction with human participants will be suspended.
3. **If I have an active IRB protocol that involves the risk of exposure to COVID-19, and I would like to proceed with research activities at this time, what should I do?**

Principal Investigators with active IRB protocols that include studies in which exposure to COVID-19 may result from participation in the research must submit a Modification of Approved Protocol form to engage human participants in research activities. This form is available on the UNA IRB webpage. The Modification of Approved Protocol must include the following:

**If face-to-face interactions, physical presence, etc. are needed to meet the research objectives:**
(See the Resource and Guidance below for assistance with developing IRB submissions)
	* include a justification for procedures that may expose participants to COVID-19,
	* include detailed information needed to assess the risk of COVID-19
	* include any additional precautions to reduce the risk of exposure to COVID-19 for both participants and research personnel, and
	* include new or updated consent documents, scripts, or other materials as needed to address the requested modification

**If remote activities or other methods may be substituted for face-to-face interactions, physical presence, etc.:**

* + describe the requested change to the approved protocol,
	+ include a description of the new procedure, and
	+ include new or updated consent documents, scripts, or other materials as needed to address the requested modification
1. **If I am submitting a new protocol application to the IRB, what should I do?**

Principal Investigators submitting protocol applications to the IRB must consider if the risk of exposure to COVID-19 could result from participation in the research.  If it is determined that exposure to COVID-19 is a potential risk to research participants based on the proposed procedures, the following items will need to be included in the protocol application:

(See Resource and Guidance below for assistance with developing IRB submissions):
	* list exposure to COVID-19 as a potential risk to participants,
	* justify the use of procedures which may result in risk of participant exposure to COVID-19,
	* include detailed information needed to assess the risk of COVID-19,
	* describe precautions (see Precautions for risk of exposure to COVID-19 below for more information) to address the risk of participant exposure to COVID-19, and
	* describe the risk and precautions in the consent documents, scripts, and any other material.

**Covid-19 Resources and Guidance for Investigators**

**Notify Participants of Infection Risk**

Participants should be provided with information regarding the current COVID-19 epidemic, how risks may arise from participation in research, and the precautions that will be used to reduce the risk of infection. This information may be provided in multiple forms suited to the type of interaction, including website link or a telephone/Zoom script. Further, a description of the risk of exposure and potential infection from COVID-19, along with precautions implemented to reduce the risk, must be included in the consent documents. The IRB has provided the **Covid-19 Information for Research Participant** for PI’s to include with consent documents.

**Screen Participants Before Research Begins**

All research participants should be screened remotely (by phone or Zoom) for fever, cough and flu-like symptoms the day before participation, with repeat screening at the time of an in-person visit. Appropriate screening questions might include the following, which could be modified to fit your participant population and the location of in-person interactions:

1. Have you had any of the following symptoms in the past two weeks, even if they were mild?
* Fever or chills
* Cough
* Shortness of breath or difficulty breathing
* Fatigue
* Muscle or body aches
* Headache
* New loss of taste or smell
* Sore throat
* Congestion or runny nose
* Nausea or vomiting
* Diarrhea
1. In the past three weeks, have you visited another state, country, or facility with sustained (ongoing) occurrence of COVID-19?
2. Have you had close contact with a person that has tested positive for COVID-19 or who is under investigation for possible COVID-19?
3. Is there any additional information you would like to provide related to your possible exposure to COVID-19?

Although COVID-19 may present with multiple symptoms or no symptoms, any **YES** answer should be considered sufficient reason to postpone in-person visits or not enroll the individual in the study. Those who screen positive should be directed to contact their primary care provider.

Likewise, researchers should follow the [UNA Self-Screening Assessment](https://una.co1.qualtrics.com/jfe/form/SV_0UIsIbwa0u7yRPn) prior to coming to campus and/or conducting human research which involves direct contact with participants.

**Screening High-Risk Participants**

Before an in-person visit, research participants should be screened remotely (by phone or Zoom) for risk factors of severe illness from COVID-19. Decisions about in-person visits should be especially conservative for those at higher risk of complications related to Covid-19.

Appropriate screening questions might include the following, which could be modified to fit your participant population and the location of in-person interactions:

* Based on what we know now, those at high-risk for severe illness from COVID-19 are:
	+ People 65 years and older
	+ People who live in a nursing home or long-term care facility
* People of all ages with underlying medical conditions, particularly if not well controlled, including:
	+ People with chronic lung disease or moderate to severe asthma
	+ People who have serious heart conditions
	+ People who are immunocompromised
		- Many conditions can cause a person to be immunocompromised, including cancer treatment, smoking, bone marrow or organ transplantation, immune deficiencies, poorly controlled HIV or AIDS, and prolonged use of corticosteroids and other immune weakening medications
	+ People with severe obesity (body mass index [BMI] of 30 or higher)
	+ People with diabetes
	+ People with chronic kidney disease undergoing dialysis
	+ People with liver disease

**Personal Protective Equipment**
The following Personal Protective Equipment (PPE) may be used as appropriate depending on the risks involved with the study:

* **Surgical masks**
	+ Provides the wearer protection against large droplets from a sneeze or cough and protects others from the wearer’s respiratory emissions
	+ Does not provide the wearer or others protection against smaller respiratory aerosols
* **Cloth face coverings** (not considered PPE for the wearer, but does provides additional protection for anyone near the wearer)
	+ Protects others from wearer’s respiratory emissions
	+ Does not provide wearer or others protection against smaller respiratory aerosols
* **N95 respirator**
	+ Filters out large droplets and smaller respiratory aerosols
	+ Designed to protect the wearer from inhaling airborne particulate contaminants such as dusts, fumes, and infectious agents
	+ An N95 respirator with an exhalation valve does not protect others from the wearer’s respiratory emissions
* **Eye protection**
	+ Face shield or goggles are appropriate
	+ Must be cleaned with [EPA approved disinfectant](https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2) after each session
* **Gloves**
	+ Disposable type nitrile or natural rubber
* **Disposable lab coat**

**Determining PPE Needs**
The following provides guidance to investigators for determining the appropriate PPE for a given project:

If the research requires interaction with the participant **within 6 feet without any barrier** the following PPE is appropriate:
**Participant** - Cloth face covering (see the [CDC guidance on cloth face coverings](https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/diy-cloth-face-coverings.html) for reference)
**Research Personnel** – disposable lab coat, gloves, face shield or goggles, and a surgical mask

* If the research requires interaction with the participant **within 6 feet with an**[**effective barrier**](https://ncceh.ca/content/blog/physical-barriers-covid-19-infection-prevention-and-control-commercial-settings) the following PPE is appropriate:
**Participant** - Cloth face covering (see the [CDC guidance on cloth face coverings](https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/diy-cloth-face-coverings.html))

**Research Personnel** – Surgical Mask

* If the research requires interaction with the participant and can **maintain a minimum of 6 feet at all times**the following PPE is appropriate:
**Participant** - Cloth face covering (see the [CDC guidance on cloth face coverings](https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/diy-cloth-face-coverings.html))

**Research Personnel** – Cloth face covering (see the [CDC guidance on cloth face coverings](https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/diy-cloth-face-coverings.html))

Exclusions include (across all situations):

Participants completing requirements which necessitate alternate face coverings (i.e. respiratory mask) may omit required face covering while wearing an alternate face covering but should don appropriate face covering immediately before and after.

Participants completing strenuous physical activity as part of volunteering may omit face covering during activity but should don appropriate face covering immediately before and after.

**Sanitizing Sites and Materials**

Any physical item that participants need to make physical contact with should be decontaminated **BEFORE** and **AFTER** each participant. Ensure that research staff and participants have necessary supplies, such as hand sanitizer that contains at least 60% alcohol, tissues or paper towels, trash baskets, cleaners and disinfectants. Clean and disinfect all surfaces in the room that may have been contacted by participants.

Research personnel should follow the [UNA Covid-19 Recovery Guidance Plan](https://una.edu/university-communications/COVID-19%20Recovery%20Guidance%20Plan.pdf) for Cleaning and Disinfecting, which include the following:

Follow guidelines recommended by the CDC Guidelines for Cleaning and Disinfecting for proper use of materials and safety precautions.

Use only cleaning materials listed on the EPA’s List N, which is approved to kill SARS-coV-2, the virus that causes COVID-19. Manufacturers’ recommendations should be followed closely for dwell time and safety precautions taken.

It is recommended to use only the disinfectants supplied by UNA Facilities to ensure the proper dilution; however, common household cleaners that will be allowed are:

a . Clorox Disinfecting Wipes
b . Lysol Disinfecting Wipes
c . Clorox Multi-Surface Spray

* Communicate with the UNA Department of Environmental Health and Safety for approval to use any cleaner or disinfectant not listed above.
* Ensure hand sanitizer is placed in accessible locations.
* Promote frequent hand washing.