

Approved Protocol Number: _____

Informed Consent Addendum:
COVID-19 information sheet for research participants experiencing in person research interactions

The “you” referenced in this information sheet either refers to the participant, “your child”, or the individual you are providing consent on behalf of as a legal authorized representative, as applicable.

This sheet provides you with necessary information about COVID-19 and the research study you are being asked to participate in or are already participating in. This information is in addition to the information you’ve been provided in the main study consent form. Unless specifically stated otherwise in the following paragraphs, all information contained in that original Consent Form is still true and remains in effect. Your participation continues to be voluntary. You may choose not to participate or may withdraw your consent to participate at any time, and for any reason.

WHAT SHOULD I KNOW ABOUT COVID-19?

COVID-19 is a new virus that has been declared a pandemic because of its global spread, ability to spread easily from person to person, and potential to make people very sick or possibly die. COVID-19 is caused by the new SARS COV-2 virus which is different than viruses typically found in people that usually cause mild illness, like the common cold.

Many countries, states, and local governments have tried to limit the spread of the disease by restricting certain activities such as close personal contact, public gatherings, large gatherings, travel, etc. If your community has any restrictions or limits in-person interaction, please tell the study team. We want to make sure you follow your community’s requirements.

Physical distancing is the main way that we are trying to prevent the spread of COVID-19. Physical distancing means people increase the space between one another and avoid gatherings and crowds. Public Health authorities say that people should maintain a distance of at least six feet from others when possible. They also recommend that people wear face masks or other face coverings when possible.

If you choose to continue your participation in research at American University, the research team will do their best to make sure you understand the risks of COVID-19 and to follow the recommendations described in this information sheet to try to keep you both safe from infection with COVID-19. Despite everyone’s efforts, there is still a risk that you may already have COVID-19 or may become infected with COVID-19 and may then infect others.

What are the symptoms and risks of COVID-19?

The virus that causes COVID-19 most commonly spreads between people who are in close contact with one another (within about 6 feet, or 2 arm lengths).

It spreads through respiratory droplets or small particles, such as those in aerosols, produced when an infected person coughs, sneezes, sings, talks, or breathes.

- These particles can be inhaled into the nose, mouth, airways, and lungs and cause infection. This is thought to be the main way the virus spreads.
- Droplets can also land on surfaces and objects and be transferred by touch. A person may get COVID-19 by touching the surface or object that has the virus on it and then touching their own mouth, nose, or eyes. Spread from touching surfaces is not thought to be the main way the virus spreads.

Symptoms may include but are not limited to:

- Cough
- Shortness of breath or difficulty breathing
- Fever
- Chills, especially repeated shaking chills
- Muscle pain
- Sore throat
- New loss of taste or smell
- Vomiting and diarrhea

Symptoms may appear 2-14 days after exposure to the virus, and some people may be infectious even if they don't show any symptoms.

The above list may not include all possible symptoms of COVID-19. Please contact your medical provider if you are experiencing symptoms that are concerning to you.

Additionally, we know that some people are at higher risk for severe illness from COVID-19. These people are:

- a. People 65 years and older
- b. People who live in a nursing home or long-term care facility
- c. People of all ages with underlying medical conditions, particularly if not well controlled, including:
 - i. People with chronic lung disease or moderate to severe asthma
 - ii. People who have serious heart conditions
 - iii. 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
 - iv. People with severe obesity (body mass index [BMI] of 40 or higher)

- v. People with diabetes or pre-diabetes
 - vi. People with chronic kidney disease undergoing dialysis
 - vii. People with liver disease
- d. Based on available information, pregnant people seem to have the same risk of COVID-19 as people who are not pregnant.

If you fall into one of the above categories, you may be at risk for developing severe illness should you contract COVID-19. You should be aware that participation in this research requires in-person interaction which may result in contracting COVID-19. The researchers will take precautions to prevent you from catching COVID-19, however, you may want to take additional personal precautions.

Children who have had COVID-19 may be at higher risk for a condition called Multisystem Inflammatory Syndrome (MIS-C). MIS-C is a condition in children where different body parts can become inflamed, including the heart, lungs, kidneys, brain, skin, eyes, or gastrointestinal organs. MIS-C can be serious, even deadly, but most children who have been diagnosed with this condition have gotten better with medical care.

If your child exhibits these symptoms, contact your child's doctor, nurse, or clinic right away:

- Fever
- Abdominal (stomach) pain
- Vomiting
- Diarrhea
- Neck pain
- Rash
- Bloodshot eyes
- Feeling extra tired

Pandemics can be stressful for everyone. Fear and anxiety about a disease can be overwhelming and cause strong emotions in both adults and children. Please talk with the study team if you are experiencing COVID-19 symptoms, fear or anxiety.

What steps are the research team and AU taking to prevent the spread of COVID-19?

The research team will talk with you about the research activities and your health to determine how at risk you are related to COVID-19. If you and the research team decide that participating in the research is a good idea for you, then you may participate in the research.

If you would like to participate but are in a high-risk group, the research team will discuss with you whether or not study activities can be safely delayed or if participation should continue.

The research team and AU will take the following steps to help prevent the spread of

COVID-19:

1. All AU and local/national health authority guidelines for safety will be followed.
2. You will also be screened when you arrive on campus for a study visit. Your temperature may be taken. Any participant who cannot affirm the health screening should not come onto campus or university premises.
3. You and the research team will maintain physical distancing (more than 6 feet apart) between people including researchers and human subjects whenever possible.
4. You and the research team will wear a mask or other face covering whenever possible. Researchers should wear face coverings at all times when interacting with you.
5. When appropriate for the research tasks, in addition to masks, other personal protective equipment (PPE) such as gloves and face shields may be used. You will be provided with appropriate PPE for the research. PPE will not be reused, or if is reused, it will be or appropriately sanitized between uses.
6. You and the researcher must wash your hands with soap and water before direct contact with each other or contact with equipment and high touch surfaces. Alcohol based hand sanitizer can be used in place of hand washing.
7. All highly touched surfaces, or equipment that is reused by participants will be cleaned before and after use by the research team.
8. Some locations may have additional safety procedures. If your visit is at such a location, the study team will describe what to expect when they call to confirm your study visit.
9. Public health authorities may contact you if there is a chance of COVID-19 exposure. We will not disclose any details of your research participation, but will be obliged to provide your contact information.

If you feel as though the above precautions are not being followed please either talk with the study staff, or contact the AU Office of Research Integrity at 202-885-3447.

Please discuss with the research team, ask all questions you may have, and confirm whether you would like to continue your participation. The research team may also withdraw you from the study or request to delay study activities if you or they have concerns about safety.

If you have had your questions answered and would like to continue your participation in the research with the knowledge that you are free to withdraw at any time, please sign and date below:

Signature

Date