

Important Information about COVID-19 and Research Participation

August 2, 2021

At AdventHealth, our primary focus related to research is to protect the safety of our research participants.

COVID-19 refers to the Coronavirus that is being spread across people in our communities. We need to provide you with important information about COVID-19, and to tell you about ways your study participation might change because of COVID-19 related risk.

If you are considering joining a study at this time or are currently enrolled in a study, it is important that you consider the following information to determine if study participation is right for you at this time. It's up to you whether or not to participate in a research study.

How is COVID-19 spread? COVID-19 is a respiratory virus spread by respiratory droplets, mainly from person-to-person. This can happen between people who are in close contact with one another (less than 6 feet). It is also possible that a person can get COVID-19 by touching a surface or object (such as a doorknob or counter surface) that has the virus on it, then touching their mouth, nose or eyes.

Can COVID-19 be prevented? Current ways to minimize the risk of exposure to COVID-19 include receiving a COVID-19 vaccine (available to those over age 12) and, wearing masks in addition to “social distancing” which is a practice to decrease the potential for direct exposure to others who may have been exposed to COVID-19, for example by avoiding large gatherings or refraining from shaking hands with others. It is important to understand that since study participation may include increased travel outside of your home and increased exposure to others within a clinical care environment or research site it may increase your exposure to COVID-19.

What are the risks of COVID-19? For most people, the new coronavirus causes only mild or moderate symptoms, such as fever and cough. For some, especially older adults and people with existing health problems, it can cause more severe illness, including pneumonia. We are still learning information every day about this virus.

Who is most at risk? Individuals over 60 and anyone with chronic conditions such as cancer, diabetes and lung disease have the highest rates of severe disease from the infection. Please check the latest, up-to-date information about COVID-19 on the Center for Disease Control website at <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html>

How could your participation in this research change as a result of COVID-19? There are several ways we try to minimize your risk. If possible, we limit the number of times you have to come to a clinical care or research site. At different time points in the study, we ask every research participant if they have the symptoms of COVID-19 or have been in close contact with anyone who has or had COVID-19. During your research visits, we try to reduce the time you are exposed to other people as much as possible. If you are suspected to be positive for COVID-19, there may be last minute changes to how research procedures are performed [such as a change from an in-person visit to a telephone call] or cancellations of research tests or procedures to ensure your safety. It is even possible that your research procedures will be put on hold or stopped because of COVID-19.

All CDC and State of Florida COVID-19 and AdventHealth related safety procedures will remain in place. Those may include limiting the number of people in a room, practicing social distancing when possible, and using personal protective equipment (PPEs) like masks and gloves. We ask that you do your part in keeping yourself and the study staff safe. Please tell the study staff if you have been feeling ill with COVID-19 symptoms or have tested positive for COVID-19.

The leaders at AdventHealth are monitoring these risks and deciding how these risks should change our research. If you have questions about COVID-19 and your participation in research, please talk to your study team.

If at any time you feel uncomfortable with the research process, please let the study staff or study doctor know immediately so that proper action can be taken. As with any research protocol, you have the right to withdraw your participation. If you have any other research concerns, you may always contact the Institutional Review Board (IRB) at 407-200-2677