

# Uniform Guidance for Study Participants

## Important Information about COVID-19 and Research Participation

We know that this may be a difficult time to consider participating in research. We hope that the information provided below is helpful in your decision-making process.

At Stony Brook University, the protection of our research participants is of utmost importance, which is why this additional information regarding COVID-19 is being provided to you. COVID-19 refers to the Coronavirus that is being spread among people in our communities. We need to provide you with important information about COVID-19 and tell you about the ways that 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.

### + How is COVID-19 spread?

COVID-19 is a respiratory virus spread by respiratory droplets, mainly from one person-to another. 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 "social or physical 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 research environment may increase your exposure to COVID-19. At this time there is no vaccination to prevent COVID-19 infection.

### + What are the risks of COVID-19?

For most people, the 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. While we are still learning about this virus, the information we have right now suggests that about 3 of 100 people who are infected might die from the virus.

### Who is most at risk?

Individuals over 65 with chronic conditions such as heart disease, diabetes and lung disease have the highest rates of severe disease from the infection (Center for Disease Control, June 25, 2020).

#### +How could your participation in this research change as a result of COVID-19?

There are several ways that we try to minimize the risk to you and to the study team. If possible, we limit the number of times you are to come to a research site. During your research visits, we will try to reduce the time you are exposed to other people as much as possible. You will be asked questions about whether you have any symptoms or risk factors related to COVID-19, or have been in close contact with anyone who has or had COVID-19. If you are suspected to be positive for COVID-19 or are at risk for severe forms of the virus, there may be last minute changes to the research procedures being performed (such as a change from an in-person visit to a telephone call) or cancellation of research tests or procedures to ensure your safety and the safety of the study team. It is also possible that your research procedures will be put on hold or stopped to ensure your safety or the safety of others.

If you test positive for COVID-19 or develop typical symptoms within 14 days after an in-person visit, you must notify the study team immediately. Additionally, if you discover that you were exposed to COVID-19 prior to your in-person visit, you must notify the study team immediately. Team members will direct you to call a Health Information Line. Individuals from the Health Information Line will interview you and determine with whom you may have been in close contact.

The information related to risks of COVID-19 changes every day. This is being monitored so that the most current information is being provided to you through our study team members.

If you have specific questions or concerns about COVID-19 and your participation in research, please talk to your study team.

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