



# VILLANOVA UNIVERSITY

INSTITUTIONAL REVIEW BOARD

## Guidance for Study Participants

### Important Information about COVID-19 and Research Participation

**IRB Number:**

**PI:** *Researcher: fill in the details for these three items*

**Study Team Contact Information:**

*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.*

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*At Villanova 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.*

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### 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 not socially or physically distanced from one another (within 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, it may increase your exposure to COVID-19.** Currently there are also vaccinations available to some groups that show promising reduction in 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. During your research visits, we will try to reduce the time you are exposed to other people as much as possible. In this study, you may have the following experiences in which social or physical distancing cannot be maintained (within six feet of another person) **Researcher: fill in the details of close contact including duration specific to this study.**

Please do not participate in this research study if you have any of the following symptoms of COVID-19 or have been around others with these symptoms: 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, OR if you are awaiting test results or if you have been exposed to someone who has tested positive.

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.

*You have a right to say “no” to participating in this research if you are not comfortable with the risks outlined above or in the main informed consent document.*

### How might my information be shared as a result of COVID-19?

Importantly, a public health mandate or health and safety justification may dictate that Villanova must reveal identities of study participants to University or government contact tracers. This action would supersede any confidentiality promised to you in the informed consent document for this study, although your study data would not be shared with officials, solely your identity and the contact information you provide on the contact tracing tracking sheet.

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*The information related to risks of COVID-19 changes every day. The situation 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 this research, please talk to your study team.*

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