

## Research Participant Information Sheet

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

Yale University's primary responsibility is to protect the safety of our research participants. Because participating in a study may involve travel outside of your home and exposure to others while on campus, within a clinical care environment, research site, or other location, you should be aware that this may increase your exposure to COVID-19. Due to the risk, we therefore need to provide you with important information about COVID-19 and to tell you about ways your participation in a research study might change because of risks related to COVID-19.

If you are considering joining a study at this time or are currently enrolled in a study, please speak to the researcher, and review and consider the information below to determine if study participation is right for you at this time. You may also wish to speak with your primary care physician.

**What is COVID-19?** COVID-19 refers to the Coronavirus that is being spread in communities around the world. Due to the health risks associated with this virus, we want to provide you with some general information about COVID-19 and how your participation may be impacted.

**How is COVID-19 spread?** The virus is thought to spread mainly from person-to-person between people who are in close proximity to each other or through respiratory droplets when an infected person coughs, sneezes, or talks. (These droplets can land in the mouths or noses of people who are nearby or possibly be inhaled into the lungs.) The virus may also spread in other ways such as touching a surface or object that has the virus on it and then touching your mouth, nose, or possibly your eyes. For more information about the virus and how it is spread, please refer to the United States' Centers for Disease Control and Prevention (CDC) website "[How COVID-19 Spreads](#)".

**Can COVID-19 be prevented?** Although we are still learning about the virus, it is believed that wearing a cloth face cover or mask over your nose and mouth, washing your hands often with soap and water for at least 20 seconds (or using "a hand sanitizer that contains at least 60% alcohol" when soap and water are not available), routine cleaning and disinfecting of touched surfaces, and social distancing (staying about 6 feet [2 meters] or more away from others) are among the most effective ways to minimize the risk of virus transmission. See the CDC website for additional information regarding [How to Protect Yourself and Others](#). The CDC website also provides useful information regarding: how to wear, make, and care for [cloth face covers](#), [when to wear gloves](#), [cleaning your home](#), and [social distancing](#). At this time there is no vaccine to protect against COVID-19, and no approved drugs to treat COVID-19.

**What are the risks of COVID-19?** For many 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 conditions, it can cause more severe illness, including pneumonia. Some infected individuals have died as a result of COVID-19.

**Who is most at risk for severe illness from COVID-19?** COVID-19 is a new disease and there is limited information regarding risk factors for severe disease. According to the CDC, anyone can have mild to severe symptoms. However, based on currently available information and clinical expertise, older adults and people of any age who have serious underlying medical conditions seem to be at higher risk for severe illness from COVID-19. See CDC website, [Symptoms of Coronavirus](#) and [People Who Need to Take Extra Precautions](#).

**How could your participation in 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 campus or a clinical care or research site and/or the times a researcher may visit you. Prior to any in-person visit, you will be asked if you have had any symptoms of COVID-19 or have been in close contact with anyone who has or had COVID-19. During 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 and visits 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 and visits will be put on hold or stopped because of COVID-19. Based on the nature of the research, additional precautions may be required.

*The information regarding the risks and preventive measures related to COVID-19 changes frequently. Yale is continually monitoring COVID-19 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 or the researcher who has been in contact with you. If you suspect that you may have COVID-19 or have been in close physical contact with someone who has, please consult immediately with your primary health care provider, and remain isolated from other individuals until your treatment provider has provided further medical advice.*

## Responsibilities and Requests for Research Participants Involved in Yale Studies

As part of its responsibility to protect the safety of research participants, Yale University is taking many steps to reduce the possibility of COVID-19 transmission on campus, including in all campus sites where research takes place. Your researcher or study team can provide additional details about your specific site upon request. Yale's responsibility also applies to cases in which research takes place off campus (including outside of the state of Connecticut and internationally). Researchers working away from the Yale University campus will follow safety measures including wearing cloth face covers or masks and maintaining social distancing unless there are specific reasons that the research requires or allows otherwise.

Yale researchers conducting research on campus or away from campus are expected to contact you in advance to cancel or reschedule your participation if they are experiencing symptoms related to COVID-19, if they have been in close proximity with someone who has tested positive within 14 days, or if they have been in a COVID-19 hot spot within 14 days.

In turn, we request that you:

- Report any of the symptoms below that you may be experiencing to the researcher or research team prior to your scheduled visit so that the visit can be rescheduled. Please pay particular attention to the [symptoms of Coronavirus](#) below designated by the CDC which include:
  - Fever (temperature of 99° or higher) 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
- Report if you have been in close proximity to anyone who is experiencing symptoms, or has tested positive for COVID-19, within 14 days of your scheduled visit.
- If the research in which you are participating takes place *on the Yale campus or in Connecticut*, let the researcher who has contacted you know if you have traveled anywhere outside of Connecticut within 14 days of your scheduled visit. If the research is taking place *outside of the state of Connecticut (including internationally)*, report if you have travelled anywhere considered to be a COVID-19 hot spot within 14 days of your scheduled visit.
- Wear a cloth face covering or mask over your nose and mouth when you are on Yale's campus, in any Yale or affiliate location, or participating in any Yale-related research activities.
- Maintain social distancing (staying about 6 feet [2 meters] or more away from others) whenever possible. However, please be aware that full social distancing may not be possible to be maintained at all times depending on the type of activity that is scheduled for your research participation. If this is the case, the amount of time needed for such activities will be limited as much as possible to maintain as safe of an environment as possible.

*Depending on where the research in which you are participating is taking place (including outside of the state of Connecticut or internationally), you also may be asked to comply with additional safety measures such as temperature checks or other testing before entering a campus building, clinic, or other research location. You also may be asked to comply with additional health and safety requirements and guidelines, including those established by national, local, and institutional policies. In cases where these policies conflict, researchers should follow the more restrictive measures.*

**Yale appreciates your commitment to health and safety during research. Together we can do our parts to reduce the spread of COVID-19 and ensure that your participation in research is as safe as possible. Thank you!**

### References:

United States, Department of Health and Human Services, Centers for Disease Control and Prevention (CDC). *Coronavirus Disease 2019 (COVID-19), Your Health*. Retrieved July 15, 2020, from <https://www.cdc.gov/coronavirus/2019-ncov/your-health/index.html>.