Trinity Health Of New England Institutional Review Board primary responsibility is to protect the safety of research participants. Participating in a study may involve travel outside of your home and exposure to others while within a clinical care setting, 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.

**What is COVID-19?** COVID-19 refers to the Coronavirus that is being spread in communities around the world. For many people, the new Coronavirus causes only mild or moderate symptoms, such as fever and cough. For some, it can cause more severe illness, including pneumonia and death. 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 near 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.

**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 need to come into 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. Trinity Health Of New England 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 Trinity Health Of New England Research Studies**

As part of its responsibility to protect the safety of research participants, Trinity Health Of New England is taking many steps to reduce the possibility of COVID-19 transmission in all sites where research takes place. Your researcher or study team can provide additional details about your specific site upon request. Trinity Health of New England’s responsibility also applies to cases in which research takes place in a different location (including outside of the state in which you live and/or internationally).
• Please 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 COVID-19 below designated by the CDC which include:

- Fever (temperature of 99⁰ 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.
• Let the researcher know if you have traveled anywhere outside of the state in which you live within 14 days of your scheduled visit.
• Wear a cloth face covering or mask over your nose and mouth when you are at any Trinity Health Of New England location, or participating in any Trinity Health Of New England 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.

You also may be asked to comply with additional safety measures such as temperature checks or other testing before entering a clinical setting, 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.

Trinity Health Of New England 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!