**[INSERT SITE NAME-XXXX]**
**Information about participating in a Research Study during COVID-19.**

**Version Date:** XXXXXX
**IRB Study #** XX-XXXX
**Title of Study**: XXXXXXXXX
**Principal Investigator**: XXXXXXXXX

**Study Contact Telephone Number:** XXXXXX
**Study Contact Email:** XXXXXX

The “you” referenced in this information sheet either refers to the participant, “your child”, or the individual you are providing consent on behalf of as a legal authorized representative, as applicable.

The following information should be read as an addition to the original Consent process. Unless specifically stated otherwise in the following paragraphs, all information contained in that original Consent Form is still true and remains in effect. Your participation continues to be voluntary. You may choose not to participate or may withdraw your consent to participate at any time, and for any reason, without jeopardizing your future care at this institution or your relationship with your study doctor.

**New or additional information**

COVID-19 is a novel (previously unidentified) coronavirus and has been declared a pandemic due to its global spread. The virus causing coronavirus disease 2019 (COVID-19), is not the same as the [coronaviruses that commonly circulate among humans](https://www.cdc.gov/coronavirus/types.html) and usually cause mild illness, like the common cold. Many countries, states, and local governments have implemented restrictions (e.g., physical distancing requirements, closure of public places) to attempt to limit the spread of the virus. If your community does not permit travel or otherwise limits interaction, please tell the study team. UNC’s [or insert applicable sites-XXXX] permission for certain studies to continue is not intended to interfere with a person’s ability to follow their community’s requirements.

Physical distancing is the primary strategy used to prevent the spread of the virus that causes [COVID-19](https://www.rochesterregional.org/coronavirus-covid19). Physical distancing calls for people to increase the space between one another and to avoid gatherings and crowds. The Centers for Disease Control and Prevention (CDC) [or insert applicable public health entity for non-U.S. sites-XXXX] says people should maintain a distance of at least six feet from others when possible.

If you choose to continue your participation in research at UNC [or insert applicable institution staff, (e.g. Malawi, UNC Rex)-XXX] Project, UNC [or insert applicable institution staff, (e.g. Malawi, UNC Rex)-XXX] Project research personnel will do their best to follow the below recommendations described in this information sheet that were developed based on guidance from the CDC [or insert applicable public health entity for non U.S. sites-XXXX] and in partnership with study teams, departments, UNC’s Infectious Disease specialist and [insert applicable institution staff, (e.g. Malawi, UNC Rex)-XXX]. Despite everyone’s efforts, there is still the risk that you may already have or may become infected with COVID-19 and may then infect others.

**COVID-19 Symptoms**

People with COVID-19 have had a wide range of reported symptoms – ranging from mild symptoms to severe illness which may lead to death. Symptoms may appear 2-14 days after exposure to the virus. People with these symptoms may have COVID-19:

* Cough
* Shortness of breath or difficulty breathing
* Fever
* Chills especially repeated shaking chills
* Muscle pain
* Sore throat
* New loss of taste or smell
* Vomiting and diarrhea

This list is from the CDC [or insert applicable public health entity for non-U.S. sites-XXXX] but may not include all possible symptoms. People experience the virus in many different ways. Please contact your medical provider if you are experiencing symptoms that are concerning to you.

Pandemics can be stressful for everyone. Fear and anxiety about a disease can be overwhelming and cause strong emotions in both adults and children. Please talk with the study team if you are experiencing COVID symptoms, fear or anxiety.

Please seek emergency medical care immediately if experiencing the following symptoms:

* Trouble breathing
* Persistent pain or pressure in the chest
* New confusion
* Inability to wake or stay awake
* Bluish lips or face

\*This list is not all possible symptoms. Please call your medical provider for any other symptoms that are severe or concerning to you. Call 911 or call ahead to your local emergency facility: Notify the operator that you are seeking care for someone who has or may have COVID-19. [INSERT local language if outside the United States and 911 is not applicable-XXX]

**Children and Multisystem Inflammatory Syndrome (MIS-C)**

Multisystem Inflammatory Syndrome (MIS-C), is a condition in children where different body parts can become inflamed, including the heart, lungs, kidneys, brain, skin, eyes, or gastrointestinal organs. We do not yet know what causes MIS-C, however we know that many children with MIS-C had the virus that causes COVID-19, or had been around someone with COVID-19. MIS-C can be serious, even deadly, but most children who have been diagnosed with this condition have gotten better with medical care.

Contact your child’s doctor, nurse, or clinic right away if your child is showing symptoms of MIS-C:

* Fever
* Abdominal pain
* Vomiting
* Diarrhea
* Neck pain
* Rash
* Bloodshot eyes
* Feeling extra tired

Be aware that not all children will have all the same symptoms. Seek emergency care right away if your child is showing any of these emergency warning signs of MIS-C or other concerning signs:

* Trouble breathing
* Pain or pressure in the chest that does not go away
* New confusion
* Inability to wake or stay awake
* Bluish lips or face
* Severe abdominal pain

**What steps are the study team and UNC [or insert applicable sites-XXXX]** **taking to prevent the spread of COVID?**

To help prevent the spread of COVID study teams across UNC **[or insert applicable sites-XXXX]** are taking the following steps:

Conducting an individual risk assessment with subjects to determine if the individual is part of a high-risk group as defined by the CDC and discussing with you if the specific research activities that may break physical distancing recommendations is in your best interest. The wellness screen will include questions about whether the you have or had COVID-19, possible exposure to the virus, possible symptoms, and about risk factors.

If the subject would like to participate but is in a high-risk group as defined by the CDC including those over the age of 65, live in a nursing home or long-term care facility, or who have underlying medical conditions, particularly if not well controlled, they should discuss if study activities can be safely delayed with the study team or if participation should continue.

1. Prior to a face-to-face visit, research personnel must confirm your appointment and perform telephone wellness screenings no more than 24 hours prior to the scheduled visit.
	1. You and anyone required to attend the visit with you must be rescreened by front desk staff or research personnel upon arrival before the study visit begins (i.e., to confirm there are no symptoms, no fever, etc.). You and anyone required to attend the visit must be masked upon arrival at the clinic/research site. Anyone who fails rescreening will be immediately isolated in a private room. Clinical study personnel will be contacted and recommendations from **Infection Prevention** **[or insert applicable group/staff]** regarding referral for testing should be followed. You may be responsible for cost of testing, and treatment of COVID-19 unless this is specifically part of the study you are participating in or otherwise covered. The study specific consent form will cover this if applicable.
2. During face-to-face visits, research personnel and you should maintain a physical distance of 6 feet whenever possible, wear a facemask and eye protection, and perform hand hygiene before and after face-to-face interaction with all participants.
3. Interactions should take place in an outdoor setting, if possible.
4. Research personnel have developed and implemented a regular schedule for frequently cleaning and wiping touched surfaces and objects (e.g., door and cabinet handles, faucets, light switches, keyboards, and other frequently touched objects) with an approved disinfectant or disinfectant wipes. Research personnel will also follow routine surface decontamination of common equipment like instrumentation and computers. Disinfecting any surfaces that may be thought to be contaminated and use an approved disinfectant such as a 1:10 dilution of bleach or 60% to 90% alcohol solution.
5. Research that involves participants of 10 or fewer individuals in a group, such as a focus group, is allowed. Seating should be arranged to allow 6 feet between group members, and all focus group participants must wear masks.
6. If research involves travel or overnight stays, accommodation and meals should allow for adequate physical distancing (6 feet or more) wherever feasible. Vehicle occupancy should be limited to no more than two people in a standard car, with open windows while travelling, if possible. Vehicle occupants should wear masks.
7. Some locations may have additional safety procedures. If your visit is at such a location, the study team will describe what to expect when they call to confirm your study visit.

If you feel as though the above precautions are not being followed please either talk with the study staff, submit an anonymous request through Ethics Point by calling 1-866-294-8688, or reach out to the UNC OHRE IRB at 919-966-3113 [INSERT appropriate local phone number for reporting of concerns or not following appropriate precautions-XXXX].

You should receive a copy of this form when possible. Please discuss with your study team, ask all questions you may have, and confirm whether you would like to continue your participation. The study team may also withdraw you from the study or request to delay study activities if they have concerns about safety.