INFORMED CONSENT FORM
TO PARTICIPATE IN A RESEARCH STUDY

Sponsor / Study Title:	**Regents of the University of Minnesota / "An International Observational Study of Outpatients with SARS-CoV-2 Infection"**
Protocol Number:	**INSIGHT 011**
Principal Investigator: (Study Doctor)	**«PiFullName»**
Telephone:	**«IcfPhoneNumber»**
Address:	**«PiLocations»**

KEY INFORMATION

- You can join this study if you have already tested COVID-19 positive within the last 3 days or if you are being tested on the day of joining the study.
- If you are positive for COVID-19, we will call you at 7, 14, and 28 days after you enroll to see how you are doing.
- If you are negative, you won't be followed after the enrolment visit, but you will be told your result.
- There are no risks or direct benefits to you from being in this study. You will help us learn more about how COVID-19 affects people like you. You may have the chance to join other studies about COVID-19.
- This study does not include any treatments apart from your usual care. You and your doctor will decide how to treat your COVID-19.
- You do not have to be in this study. You can stop being in the study at any time. This will not change your medical care or other benefits.

This is a research study to find out what might predict whether people who test positive for COVID-19 get sick enough to be admitted to the hospital. You are being asked to participate because you have either very recently tested positive for COVID-19, or are being tested for the virus that causes COVID-19. It is your choice whether to be in this study or not. If you haven't yet had your test for COVID-19, you will still get that test in the usual way, whether or not you agree to be in this study.

This study does not provide any treatment for COVID-19. You do not have to be in this study if you do not want to be. If you agree to be in the study, you can stop at any time. Your decision about whether to be in this study or to stop the study will not result in any penalty and will not affect your usual medical care or any benefits to which you are otherwise entitled. There is no cost to you for being in this study, and you will not be paid for being in the study.

We are doing this study in many countries around the world. We hope to enroll 10,000 people with COVID-19 in this study.

What do you have to do in the study?
If you agree to be in this study, we will ask you about what other medical conditions you have, what symptoms you are having, whether you smoke, and what medicines you are taking. We will ask you to give us contact information for one or two people who will know how to reach you if we cannot reach you to follow your medical progress.

[The next sentence should only be included for sites consenting participants for blood collection and storage. See separate specimen consent.]
We will ask if you are willing to have some blood taken and 1-2 extra swabs of your nose and/or throat done; this will be described in a separate consent form. For people having a nose or throat swab for COVID-19 at the same time as enrolling into this study, you will go home to wait for your test results.

We will call you to let you know the results of your test for COVID-19. If your test is negative, you do not have to do anything else for the study. We will keep the information you have already given us.

If you already have a COVID-19 positive test when you join the study, or if you test positive for COVID-19 at enrolment in the study, we will follow you for a total of 28 days. We will contact you three more times by phone, e-mail, text, or some other way that you have agreed to at about 7,14 and 28 days after you joined the study. At each contact, we will ask about how you are feeling, your prescribed medications and treatments, and whether you have been admitted to the hospital or returned to your normal activities. If you are hospitalized, study staff will ask you for your permission to obtain medical records from the hospital. If we are not able to reach you, we will try to contact the other people you named to find out how you are doing. After the third contact at 28 days, you are finished with this study.

If you join this study, we will also seek your permission to contact you again at a later date. If you gave your permission to be contacted again you could be invited to join either an extension to this study or a new study to collect long-term data on how people who joined this study are doing. You can still take part in this study even if you don't want to be contacted about a future study.

What are the risks and benefits of being in this study?
There are no physical risks to you to be in this research study. There may be a risk of loss of confidentiality, and there may be risks which are currently unknown. You will not get any direct benefit from being in this study, but it may help others in the future if we can get a better understanding of how COVID-19 affects different people. You may have the opportunity to participate in other studies about COVID-19.

How is your privacy protected?
We will take every reasonable step to keep your information private and to prevent misuse of it. You will not be identified by name, or in any other way, in anything published about this study. You will be identified only by a code. We will not release information from your records without your written permission.

These people may see your medical and research information:

- Advarra IRB, the independent committee established to help protect the rights of research subjects;
- The study staff and monitors and people they designate as helping with the study;
- The Food and Drug Administration (FDA) and other health and regulatory agencies.

All of these people are committed to protect your privacy, but absolute confidentiality cannot be guaranteed.

As the study staff at the study site, we are required to make sure that people not involved with this study cannot see your research and medical information while collecting personal information about you. We will keep your information in a safe place and will handle your personal information very carefully.

Your study data are sent electronically to the University of Minnesota (UMN) in the US through a secure application. By signing and dating this consent, you agree to having your data sent to UMN. No information that could directly identify you is sent to UMN. In this information, you are identified only by a code number, your year of birth, and a 3-letter code that you or the study staff choose. This is called “pseudonymized data”. Access to the data at UMN is limited through security measures, and no data breach or unauthorized access has ever occurred in this system. After the study is over, the data will be stored securely for the period required by law.

UMN may share your data with other people who study COVID-19. UMN will remove the code number, year of birth, and 3-letter code from your data before sharing. This is called “anonymizing the data” and makes it impossible for anyone to link the data back to you. We will not ask you for additional consent for this sharing. UMN will only share data for research projects that are approved by INSIGHT.

This study has a Certificate of Confidentiality from the US Federal government. This means that UMN cannot share any data it has about you with national, state, or local civil, criminal, administrative, legislative, or other authorities unless you specifically allow us to share it. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (see below); if you have consented to the disclosure, including for your medical treatment; or if it is

used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the agency which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of, for instance, child abuse or neglect, harm to self or others, and communicable diseases.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

Alternatives to participation
This research study is for research purposes only. The only alternative is to not participate in this study.

New findings
Any new important information that is discovered during the study and which may influence your willingness to continue participation in the study will be provided to you.

Compensation for participation

«Compensation»

[sites should describe compensation or state that none will be provided]

Costs
There will be no charge to you for your participation in this study.

What if you are hurt as part of this research?
We will provide treatment right away if you are hurt because of the research. The costs may be charged to you or your insurance company. We will give you information about where you can get additional treatment. You do not give up any of your legal rights by signing and dating this form.

Compensation for injury
If you become ill or are injured while you are in the study, get the medical care that you need right away. You should inform the healthcare professional treating you that you

are participating in this study. If you tell the study staff that you think you have been injured then they will help you get the care you need.

If you are injured as a result of the procedures done for the purpose of this study, the sponsor will pay for those medical expenses necessary to treat your injury that are not covered by your medical insurance or any other third-party coverage. By signing and dating this document, you will not lose any of your legal rights or release anyone involved in the research from responsibility for mistakes.

To pay medical expenses, the sponsor will need to know some information about you like your name, date of birth, and Medicare Beneficiary Identifier (MBI). This is because the sponsor has to check to see if you receive Medicare and if you do, report the payment it makes to Medicare.

Voluntary participation / withdrawal
Your decision to participate in this study is voluntary. You may choose to not participate or you may withdraw from the study for any reason without penalty or loss of benefits to which you are otherwise entitled and without any effect on your future medical care. However, please note that the FDA requires that any information collected up to the point of your withdrawal cannot be removed from the study.

The study doctor or the sponsor can stop your participation at any time without your consent for the following reasons:

- If it appears to be medically harmful to you;
- If you fail to follow directions for participating in the study;
- If it is discovered that you do not meet the study requirements;
- If the study is canceled; or
- For administrative reasons.

WHOM TO CONTACT ABOUT THIS STUDY
During the study, if you have questions, concerns or complaints about the study, please contact the study doctor at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, contact**:**

- By mail:
  Study Subject Adviser
  Advarra IRB
  6940 Columbia Gateway Drive, Suite 110
  Columbia, MD 21046
- or call **toll free**: 877-992-4724

- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00043524.

SIGNATURE PAGE FOR CONSENT TO PARTICIPATE IN THE INSIGHT 011 STUDY (ICOS)

I have read the consent or have had it explained to me. I am satisfied that I understand the information. By signing and dating this consent, I am stating that I want to join this study. I understand that I do not waive any of my legal rights as a study subject by signing and dating this consent. I understand that I will receive a copy of the signed and dated consent.

_____	_____	_____
Subject's name	Subject's signature	Date

_____

Name of study staff member conducting consent process (typed or printed)

_____ _____

Study staff member's signature Date

NOTE: This consent form, with the original signatures, MUST be retained on file by the Investigator of Record. A copy of the signed and dated consent must be given to the subject. A copy should be placed in the subject's medical record, if applicable.