INFORMED CONSENT FORM

Sponsor / Study Title:	**University of Minnesota/INSIGHT / "A Multicenter, Adaptive, Randomized, Blinded Controlled Trial of the Safety and Efficacy of Investigational Therapeutics for Hospitalized Patients with Acute Respiratory Distress Syndrome Associated with COVID-19"**
Protocol Number:	**INSIGHT 015/ACTIV 3b/TESICO**
Principal Investigator: (Study Doctor)	**«PiFullName»**
Telephone:	**«IcfPhoneNumber»**
Address:	**«PiLocations»**

This form is for use in a research study that may involve participants who may or may not have the capacity to consent to take part in the study. When the participant cannot legally consent to take part, pronouns "you" and "your" should be read as referring to the participant rather than the person (legally authorized representative) who is signing and dating this form for the participant. In cases where the participant's representative gives consent, the participant should be informed about the study to the extent possible given his/her understanding. During the course of the study, if the participant regains the capacity to consent, informed consent will be obtained from the participant and the participant offered the ability to leave the study if desired.

Key information:

We are asking you to join a research study about COVID-19. It is your choice whether or not you want to join. This form gives you information about the study that will help you make your choice. You can discuss this information with your doctor or family or anyone else you would like before you make your choice. Your choice will not affect the care you are getting for COVID-19.

What is the research question we are trying to answer?

We are studying two investigational treatments for COVID-19. We are asking you to join the study because you are in the hospital with COVID-19 and have significant trouble with your breathing.

First, we are studying an experimental study drug, aviptadil (also called VIP), supplied by NeuroRx. We are trying to find out if giving this study drug can help sick people in the hospital with COVID-19 have fewer bad effects from the disease, and if it may possibly help them get better and go home faster. We are also trying to see if it is safe. Aviptadil has not been approved by the U.S. Food and Drug Administration (FDA) for the treatment of COVID-19. Its use is experimental in this study.

This study drug is a man-made version of a naturally occurring hormone in the body. It may decrease COVID-19 virus levels, inflammation, and blood clotting, and help protect the lung against injury. We think this study drug may possibly help participants with COVID-19, and we think it will be safe, but we are not sure and so we are doing this study.

Second, we are studying a drug called remdesivir (also called Veklury) supplied by Gilead. Remdesivir is approved in the United States for the treatment for COVID-19 in people who are in the hospital. We are trying to find out if remdesivir helps participants with your level of COVID-19 illness get better and go home faster. Remdesivir may decrease COVID-19 virus levels and lung injury. Currently we do not know if remdesivir will help people with your level of COVID-19 illness which is why we are doing this study. Its use is experimental in this study.

What do you have to do if you decide to be in the study?

The study staff at your hospital will check to see if there is any reason you should not be in the study. They will check your medical history. They will look at tests commonly done for your condition. They will also check to see if you are able to get both of the study drugs we are studying or just one of the study drugs. For example, if you are pregnant you will not be able to receive the aviptadil or matching placebo (inactive solution containing no active study drug) but you will be able to receive the remdesivir or matching placebo.

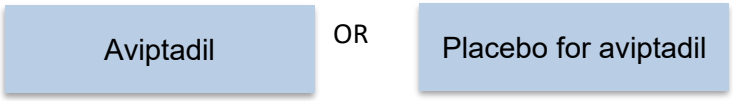
If you agree to be in the study, and you are able to get both study treatments, we will assign you to one of four study groups. This will be done by random chance -- like flipping a coin. You will have an equal chance of getting either the active study drug or placebo for both study drugs.

You will be assigned to one of the following 4 groups:

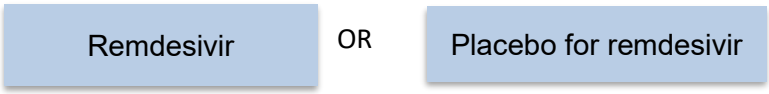
Aviptadil + Remdesivir	OR	Aviptadil + Placebo for remdesivir	OR	Remdesivir + Placebo for aviptadil	OR	Placebo for remdesivir + Placebo for aviptadil

Your study doctor will NOT decide and will not know which of these four options you will get. The study staff will also not know which option you will get. However, your study doctor can find out which group you are in if there is an emergency.

If you agree to be in the study, and you are ONLY able to get Aviptadil we will assign you to one of two study groups. This will be done by random chance -- like flipping a coin.



If you agree to be in the study, and you are ONLY able to get remdesivir we will assign you to one of two study groups. This will be done by random chance -- like flipping a coin.



Aviptadil: You will receive the Aviptadil study drug (either the active study drug or the matching placebo) for three consecutive days starting on the day you join the study (study Day 0). You will get it by an intravenous (IV) drip through a tube in your vein. This is called an infusion. The infusion will take about 12 hours on each day that it is given.

Aviptadil is the only thing you may be given that is experimental. It is NOT approved for use in people with COVID-19 by the United States Food and Drug Administration (FDA) or any other regulatory body in the world. It is approved in some countries outside the US for another condition but is given in a different way. Its use in the United States is strictly limited to research.

Remdesivir: You will receive the remdesivir study drug (either the active study drug or matching placebo) once per day for up to 10 days. You will also get this by an IV drip through a tube in your vein, which will generally take 1-2 hours. Remdesivir is approved in the United States for the treatment of COVID-19 in people who are in the hospital. It's not known whether it works in people with more severe COVID-19.

Other study treatments: As part of the study you may also get a drug called a steroid for up to 10 days while you are in the hospital, as care for your COVID-19, unless your study doctor thinks the steroid would not be safe for you to take. Steroids have been shown in prior studies to help people survive COVID-19. Steroids are available for other diseases in the United States, so your study doctor will be using it "off-label," which means that while there is no formal FDA approval for this use, your study doctors think it is reasonable. It is likely that you would receive steroid medicine even if you were not in the study.

Any other medications or treatments you will be given will be what you would usually receive in this hospital for your condition. There may be some additional procedures or testing done for study purposes. We will describe these below.

You will be in the study for 180 days. We will check on your health every day while you are in the hospital, and regularly after you leave the hospital.

We will swab your nose to see how much of the virus that causes COVID-19 is present. We will take blood samples from you to better understand the body's response to the infection. Some of the blood may be used in future studies.

To be in the remdesivir/placebo part of the study, you will need to agree to not have sex that could make you or a partner pregnant for seven days after you finish the remdesivir or placebo infusion. This may involve not having sex at all (abstinence), or you may use effective contraception (hormonal contraception or barrier methods with spermicide) to avoid pregnancy. Methods like rhythm, sympto-thermal or withdrawal are not effective for the purpose of the study. You can ask the study team about this if you have questions or concerns.

If you are pregnant, you cannot be in the aviptadil/placebo part of the study. You can still be in the remdesivir/placebo part of the study.

If you become pregnant during the study, please let your study team know as soon as possible. We will ask to follow you until your pregnancy is over, to see if there were any problems that may have been caused by any of the study treatments.

We will need to do the following things with you, and gather detailed information at these times:

Study Timepoint	**What will happen & what we will check**
Up to 1 day before you get study drug	• Informed consent (this document) • Check to see how you are feeling • Your medical history • Whether you are taking certain medicines • A swab of your nose for virus detection • Blood tests to check your health (9 mL, about ½ tablespoon) • Blood for future research (18 mL, about 1 tablespoon) • Collection of urine or blood for a pregnancy test • Contact information like telephone numbers and addresses for you and at least two close relatives or friends

Day 0, Day 1, Day 2	• Infusion of study drug (the study drug or else placebo) if able to get this study drug • Infusion of remdesivir study drug (active study drug or placebo) if able to get this study drug (you may get this study treatment for up to 10 days) • Blood tests to check your health (9 mL, about ½ tablespoon), unless your treatment team didn't already perform the tests**)**
Day 3, Day 5	• How you are feeling • Blood for future research (18 mL, about a tablespoon) - at Day 5 this will only be done if you are still in the ICU • If you're not in the hospital, we will not draw your blood and the visit may take place by phone
Day 2, Day 4, Day 5, Day 7, Day 14, Day 42, Day 60, Day 75	• How you are feeling (Days 2, 4, 7, 14, 60) • Update on return to home (Days 14, 42, 60, 75) • On Days 0–7, 14, also whether you have taken certain medicines These "visits" may take place by phone.
Day 28, Day 90, and Day 180	• How you are feeling • On Day 28, also whether you have taken certain medicines • On day 90 and 180 only: we will ask you additional questions about your health These "visits" will take place by phone.

We may need to get some information from your medical record.

- By signing and dating this consent, you agree to let us get information for this study from your medical record.
- By signing and dating this consent, you are giving us permission to contact other hospitals or medical facilities if you are admitted there during the time you are in the study. We will contact them to be sure we know how you are doing.
- We will ask you to give us information about other people we can contact if we are not able to reach you after you leave the hospital, so we can find out how you are doing.

We will send the information we collect to the University of Minnesota (UMN) in the US where it will be stored and analyzed. In this information, only a code number, your year of birth, and a 3-letter code that the study staff chooses identifies you.

The study staff here at this site are responsible for keeping your identifying information safe from anyone who should not see it.

We will send the blood samples to a laboratory in the US for storage. We will keep them for as long as we have the funding and space to do so, which we expect to be many years. There is more information below about how we will use these samples.

Why would you want to be in the study?

If you get study drug, it is possible it may help you get better, or that you may get home faster, but we do not know that.

It is important to remember that some people in this study will get inactive placebo and will not get study drug.

By being in this study, you will help doctors learn more about how to treat COVID-19 in people in the hospital. Because so many people are getting hospitalized with COVID-19, this could help others. There may be a large health impact if a treatment proves to be safe and is shown to be effective.

Why would you NOT want to be in the study?

Since only some people in this study will get study drug, you may not receive it. Even if you do get study drug, it may not be useful, or it may have harmful side effects, so being in the study would not be of any direct help to you.

What are the risks or side effects of the study treatments?

All treatments have risks and may cause side effects. These may happen to you from the study treatment. There may be other risks that are unknown at this time.

You may have an allergic reaction, including hives, trouble breathing, or other allergic responses. Allergic reactions like these are likely to be rare, but may be severe or life-threatening.

You will be monitored very closely while you are being given the infusion of the study drug (aviptadil or placebo) and for at least 2 hours after the infusion is finished. We will give you prompt medical care if needed to treat any side effects from the infusion.

There are discomforts and risks associated with blood draws and getting a swab of your nose. You will have these things done while you are in the hospital even if you are not in the study. You may have some pain, bleeding, or bruising when a needle is put into your vein to draw blood or to give the study infusion. Getting your nose swabbed can be uncomfortable and you might gag. These discomforts and risks are no different from what you would experience if they were performed as part of your regular hospital care for COVID-19.

If you receive placebo (the inactive substance, containing no study drug) as part of this study, your symptoms of COVID-19 may not improve or may get worse.

What are the risks or side effects of Aviptadil?

One effect of aviptadil is that it relaxes smooth muscle such as in your lungs, blood vessels, and intestines. Relaxing this type of muscle opens up your airways so it is easier to breathe and get oxygen into your body.

The most common side effect of aviptadil infusion is decreased blood pressure. In early studies of very ill participants with lung injury, about 1 in 5 people (20%) had lower blood pressure during the infusion of aviptadil. The decrease was usually small and went away within 10 minutes of stopping the infusion.

Facial flushing is common with aviptadil and is not dangerous. It is caused by relaxation of the blood vessels in the skin and goes away when the infusion is stopped.

Increases in heart rate are common and usually not dangerous. The increase in heart rate is mostly due to blood vessel relaxation.

Some people getting aviptadil have had mild to moderate diarrhea. The diarrhea goes away when the infusion is stopped.

What are the risks or side effects of Remdesivir?

The most common side effects of remdesivir included abnormal liver function test results, abnormal blood clotting test results, constipation, diarrhea, nausea, vomiting, decreased appetite, and headache. The abnormal liver function tests lasted longer than a few days in some people but went back to normal within a few weeks or less.

Remdesivir might affect the way that other medications are processed by your body. They might stay in your body longer, or shorter, at higher or lower levels. At the time this document was written, one person in another study had an increase in the level of a medication in their blood that was considered by study doctors to be at least possibly related to having taken remdesivir. There did not appear to be any harm from this temporary change. You can ask the study team more about this if you are concerned.

Some people may have some side effects after the infusion of remdesivir. Other people may have no side effects.

What are the risks and benefits of taking steroids?

Steroids may cause your sodium (salt) and glucose (sugar) levels to rise in your blood. You may feel anxious while taking steroids. You may be given steroids to treat your COVID-19 even if you do not join this study.

What if you are pregnant or breastfeeding?

If you are pregnant or breastfeeding, you can still join this study, although you cannot participate in the aviptadil portion of the study. However, we do not have any information about how either aviptadil or remdesivir may affect your baby. The risks to a pregnant woman or an unborn baby might be serious. Please take this into account as you make your decision about whether to join this study.

Additional information:

Here is some additional information about the study that may help you make your choice about whether you want to be in the study.

The NIH, an agency of the US Federal government, is paying for this study.

We are required to comply with all rules and regulations for human research as well as the laws of each country where the study is taking place.

This study is taking place in several countries. We expect to enroll about 800 people around the world.

You do not have to join this research study if you do not want to. If you choose to join the study, you can stop at any time. If you choose not to join or to stop, the medical care you are getting now will not change. However, please note that the FDA requires that any information collected up to the point of your withdrawal cannot be removed from the study.

If you are an employee or relative of an employee of this research center, you are under no obligation to participate in this study. You/your family member may withdraw from the study at any time and for any reason, and neither you/your family member's decision to participate in the study, nor any decision on your/their part to withdraw, will have any effect on your/your family member's performance appraisal or employment at this clinical research center. You/your family member may refuse to participate or you/your family member may withdraw from the study at any time without penalty or anyone blaming you.

If you are a student, your participation will not place you in good favor with the study doctor or other faculty for example, receiving better grades, recommendations, employment). Also, not participating in this study will not adversely affect your relationship with the study doctor or other faculty.

If we get any new information that might change whether you want to join or stay in the study, we will tell you right away.

If you do not want to be in this study, you will still get the usual care to treat COVID-19, which may include remdesivir if your regular doctors feel it is appropriate and available. However, you cannot get Aviptadil because it is experimental. Because the response to COVID-19 is evolving so quickly, your study doctor or regular healthcare provider can explain your options to you.

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.

If you leave the study for any reason, the study doctor may ask you to have some end-of-study tests for your safety.

What are the costs to you?

We will give you the study treatment at no cost. We will pay for all clinic visits, lab work, and other tests that are part of this study.

You, your insurance company, or some other third-party payer must pay for all other medicines and hospital costs.

Will you be paid to be in the study?

«Compensation»

We will compensate you for your time and inconvenience participating in the study.

What if you are hurt as part of this study?

If you are hurt because of being in this study, the study site will treat your injury right away. You or your insurance will have to pay for this treatment. The study cannot pay you or pay for any care for study-related injuries or for your illness.

A Declaration under the Public Readiness and Emergency Preparedness (PREP) Act was issued by the Secretary of the United States Department of Health and Human Services on March 10, 2020. This Declaration limits the legal rights of a subject participating in clinical studies utilizing COVID-19 countermeasures. Because this study is covered by the Prep Act Declaration, covered persons, such as the manufacturers, study sponsor, researchers, healthcare providers and others have liability immunity (that is, they cannot be sued by you or your family under the laws of the United States).

If you believe that you may have been harmed as a result of this research study, certain claims for serious injury or death caused by the countermeasure may be eligible for compensation through the Countermeasures Injury Compensation Program. This is a program set up by the United States Government.

Information about this program can be found at https://www.hrsa.gov/cicp/about/index.html or by calling 1-855-266-2427. If you are eligible for this program, you must file a claim within one year of the administration or use of the covered countermeasure.

What happens to the blood samples?

We will send the blood samples to a central laboratory in the United States. You and your study doctor will **not** get the results of any tests done on these samples. We will not sell your samples and they will not be used for research aimed at making money (commercial research). The laboratory where the samples are stored will not have any information that could identify you.

The blood samples will measure how many COVID-19 antibodies are in your blood. This will tell us how your immune system responded to your COVID-19.

Any blood samples that are left over after these tests will be stored at the central laboratory for as long as we are able to keep them. We hope to use these in the future to answer other questions about COVID-19, the virus that causes it, and how people respond to treatment. You and your study doctor will **not** get any results from these tests. Some of the blood will also be given to the company that made the study drugs to help them learn more about its effects. Your biospecimens collected during this study may be used for commercial profit (even if identifiers are removed) and you will not share in this profit.

Researchers can look closely at large amounts of your genetic information by sequencing, or "reading", every letter in your DNA (your genome). Reading a person's entire genetic code is called whole genome sequencing. The research might include whole genome sequencing (for example, sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

You can withdraw your consent for us to keep these specimens at any time. Let your study team know if you do not want the study to keep your specimens anymore, and every effort will be made to destroy all of your specimens that are still at the central laboratory.

At the end of this form, you will have the chance to consent to optional additional blood draws for future research, including genomic research (on your DNA or genes). You can continue to participate in the main portion of this study even if you do not agree to this additional sample collection.

How do we protect your privacy?

We will take every reasonable step to keep your health information private and to keep anyone from misusing it.

Your information (data) and samples will not be identified by name, or in any other way, in anything published about this study.

We will do everything we can to keep your personal information private, but we cannot guarantee that nobody will get it. We may have to release your personal information if required by law.

These people may see your medical and research information:

- Advarra IRB, the ethics committee (institutional review board [IRB]);
- The sponsor, the group paying for the research (US NIH), other study research staff and study monitors
- US and other participating countries' health regulatory agencies, including the US FDA.

They are committed to protecting your privacy.

As the research 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. We will keep your research files in a safe place and will handle your personal information very carefully.

Your study data are sent electronically to the UMN in the US through a secure system. 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. 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.

Your study data will be shared with the US National Institutes of Health (which is paying for this study), and with regulators that oversee the study, including the US FDA, as required by law. Your study data will also be shared with the drug company that provides the study drug to help them develop the study drug.

UMN may share your data and specimens with other people who study COVID-19. UMN will remove any information that could possibly be used to identify you before sharing. This is called "anonymizing the data." We will not ask you for additional consent for this sharing. UMN will only share data and specimens for research projects that are approved by the group that is conducting this study.

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, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. 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.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

A description of this clinical trial is also on the EU Clinical Trials Register (http://www.clinicaltrialsregister.eu/).

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you experience any medical problems, suffer a research-related injury, or 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
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00049911.

SIGNATURE PAGE FOR CONSENT TO PARTICIPATE IN THE TESICO STUDY

I have read the consent or have had it explained to me. I believe 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 participant by signing and dating this consent. I understand that I will receive a copy of the signed and dated consent.

If you agree to be in this study, please sign below.

_____ Date: _____
Signature of participant

_____
Printed name of participant

_____ Date: _____
Signature of study doctor/designee

_____
Printed name of study doctor/designee

FOR ADULTS NOT CAPABLE of GIVING CONSENT

_____ Date: _____
Signature of Legally Authorized Representative (LAR)

_____
Printed name of Legally Authorized Representative

_____
Relationship of Legally Authorized Representative to Participant

(Indicate why the Legally Authorized Representative is authorized to act as a surrogate health care decision-maker under state or applicable local law)

Witness to Consent Interview

On the date given next to my signature, I witnessed the consent interview for the research study named above in this document. I attest that the information in this consent form was explained to the participant, and the participant indicated that his/her questions and concerns were adequately addressed.

_____ Date: _____
Signature of witness

_____
Printed name of witness

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 participant. A copy should be placed in the participant's medical record, if applicable.

If no-touch / electronic consent is used, the participant must be provided with a copy of the consent in a manner appropriate to the method used to obtain it. A record of the act of consent must also be appropriately retained in the participant's medical record.

Additional Consent for Genetic Testing on Stored Specimens

WHY IS GENETIC TESTING BEING DONE? The study team would like your permission to collect a small amount of your blood and store them for researchers who will do genetic testing (testing on your genes) and other related tests in the future. These tests will help us understand how the genetic makeup of people affects the COVID-19 virus and how it makes people sick.

Any future research done on the blood collected for this study will be related to the COVID-19 virus for which you are being studied in this trial.

WHAT WILL HAPPEN DURING GENETIC TESTING?

If you agree to take part in this study, three blood specimens will be collected along with other blood being drawn for the study, approximately 15 mL (about 1 tablespoon) in total. The blood will be taken with other laboratory test samples so you will not get an extra needle stick.

HOW WILL YOUR BLOOD BE USED? Your blood will be used to learn more about the health problems that may be caused by COVID-19. This may include tests to better understand why some people have more severe complications (get sicker) than others and why medicines to prevent or treat these infections might work better in some people than in others.

Researchers involved with this blood collection project do not know yet exactly which tests will be done.

You and your study doctor or nurse will not get any results from the tests done on your blood collected for this genomics study. These tests will only be used for research and may not apply to your medical care.

Your blood sample collected for this study will:

- Become the property of INSIGHT.
- Not be sold or used to make commercial products.
- Not be tested for any specific research study unless the plan for using your blood is approved - based on scientific and ethical considerations - by the INSIGHT Scientific Steering Committee, the U.S. National Institutes of Health (NIH), and a special committee (an Institutional Review Board or Ethics Committee) at the researcher's institution.

HOW WILL YOUR PRIVACY AND THE CONFIDENTIALITY OF YOUR INFORMATION BE PROTECTED?

Every reasonable step will be taken to protect your privacy and the confidentiality of your health information and to prevent misuse of this information, and to make sure your blood sample is handled with care at the storage facility. For example, your research records will be identified only by a code. Your blood sample and results of any genetic testing will be identified by a second code. Only a few statisticians (persons who analyze the study results) associated with the INSIGHT studies will have access to both codes in order to analyze the test results. These statisticians will not have access to any information that can identify you.

Researchers will write reports, including information they learn from future tests on your blood. These reports will be shared with participating research sites. These findings will also be submitted for publication in scientific or medical journals. When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity.

However your records may be seen by:

- Institutional Review Boards (IRBs) or Ethic Committees (ECs) who review the study to make sure it is ethically acceptable
- Agencies of the U.S. government that fund or oversee this research, for example, the U.S. National Institutes of Health (NIH) or the U.S. Office for Human Research Protections (OHRP)
- Research staff and study monitors, and their designees.

Staff at the study site will handle your personal information very carefully. They are required to make sure that people not involved with this study do not have access to your research and medical records.

In addition to these efforts to keep your information confidential, the INSIGHT Genomics study is covered by a *Certificate of Confidentiality* from the U.S. Department of Health and Human Services, which is fully explained earlier in this form. This certificate means that researchers cannot be forced to give information collected as part of this study to people who are not involved with the study, for example, the court system. However, this certificate has limited protection rights. You should know that it does not stop the doctor in charge of this study from taking appropriate steps to prevent serious harm to yourself or others. Federal and state laws also help protect research participants and others who have genetic testing done.

HOW LONG WILL YOUR BLOOD BE KEPT?

Your blood specimen will be stored as long as funding is available for storage and testing.

Risks: There are few risks involved with your participation in this study. Having your blood drawn may result in a little pain and slight bruising where the needle goes into your skin. You may also feel lightheaded, bleed, develop a small blood clot where the needle goes into your skin, or faint. Very rarely, your skin may get infected. Another small but unlikely risk is the possibility of others finding out about your participation in this study.

Benefits: You will not receive any direct benefit from your samples. Information obtained from the tests may provide useful information, to help other patients, about the causes, risks, and prevention of the COVID-19 virus.

WHAT IF YOU DON'T WANT YOUR BLOOD FOR GENETIC TESTING STORED ANY LONGER?

If you sign and date the consent that your blood can be stored for research to be done at a later date you can change your mind at any time. If you change your mind, you must contact the study doctor using the contact information on the first page of this form to let them know that you do not want your blood specimen collected for this study used for future research. A sample letter will be given to you as a guide to help you express your request in writing.

When the study doctor receives your request, the research staff will contact you to come to the clinic to verify your decision by signing and dating this original informed consent form. A second copy of this consent will be given to you as proof that we received your request. If we do not hear from you within 30 days after getting your letter to withdraw from this study, we will send your request to the storage facility.

If you decide to withdraw consent for this study, your blood sample, including any parts separated from the sample, will not be used. Every effort will be made to destroy your blood sample and any parts separated from it. If some testing has already been done on your blood sample, the results from this testing will remain as part of this research. The research staff at the study site will notify you of the date your blood specimen and any of its parts were destroyed.

Costs or compensation of study: There will be no costs to you or compensation.

Consent: Please ***mark the box*** *for* yes or no and ***sign your name*** and date, indicating you have freely given your answers and consent:

- My blood samples may be stored for future genetic research in COVID-19 or other serious illness: **Yes** ☐ **No** ☐

_____ _____

Signature of participant Date

_____

Printed name of participant

_____ _____
Signature of Person Obtaining Consent Date

FOR ADULTS NOT CAPABLE of GIVING CONSENT

_____ Date: _____
Signature of Legally Authorized Representative (LAR)

_____
Printed name of Legally Authorized Representative

_____
Relationship of Legally Authorized Representative to Participant

(Indicate why the Legally Authorized Representative is authorized to act as a surrogate health care decision-maker under state or applicable local law)

WITNESS SIGNATURE (if applicable)

_____ Date: _____
Signature of witness

_____
Printed name of witness