INFORMED CONSENT FORM

Sponsor / Study Title:	**University of Minnesota/ INSIGHT / "A Multicenter, Adaptive, Randomized, Controlled Trial Platform To Evaluate Safety and Efficacy of Strategies and Treatments for Hospitalized Patients with Respiratory Infections"**
Protocol Number:	**INSIGHT 018A/STRIVE Ensitrelvir (S-217622)**
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.

If you are an employee of this study site, you are under no obligation to participate in this study. You may withdraw from the study at any time and for any reason, and neither your decision to participate in the study, nor any decision on your part to withdraw, will have any effect on your performance appraisal or employment at this clinical study site. You 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.

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 change the usual care you are getting for your COVID-19 infection.

Why are we doing this study?

We are studying an investigational drug for treatment of people in the hospital with COVID-19. This drug is investigational because it can only be used for research in hospitalized participants. This study drug is approved in Japan to treat COVID-19 only for outpatients (those not hospitalized). It is not approved by the U.S. Food and Drug Administration (FDA) or any other national government agency.

We are trying to find out if this investigational drug is effective when given in addition to the current standard treatment for COVID-19. We are also trying to make sure it is safe for people who are sick in the hospital to take.

We are asking you to join the study because you are in the hospital with COVID-19.

We are testing the following investigational study drug:

- Ensitrelvir (S-217622) is made by a company called Shionogi. It is a pill that you swallow. You will take it for 5 days.

We will tell you more about the study drug below. This study is part of a group of studies for people in the hospital with lung infections like COVID-19 or flu. You may be asked if you would like to join other studies later on if you qualify for any of them.

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 usually done for your condition. They will also check to see if you are able to take the investigational study drug, ensitrelvir.

If you agree to be in the study, you will get either the active ensitrelvir or an inactive placebo. The placebo will be a pill that looks just like the active ensitrelvir but has no drug in it. Whether you get active ensitrelvir or inactive placebo will be decided by random chance, like flipping a coin or rolling dice. You will have an equal chance of getting active ensitrelvir or the inactive placebo. This means your chances of getting active ensitrelvir instead of placebo are 1 out of 2, or 50%. Your study doctor and the study staff will NOT decide and will not know whether you get active ensitrelvir or placebo.

You will be asked to take the study drug for five days. You will take three pills the first day (Day 0) and one pill for each of the next four days (Days 1-4). If you are able to leave the hospital before the fifth day, you will continue to take the pills at home.

The study drug ensitrelvir is the only thing you will be given that is completely investigational.

Your study doctor and the study staff will tell you about your COVID-19 treatment options.

Your study doctor will also give you other drugs or treatments that you would usually receive in this hospital for your condition.

We do not know what effects ensitrelvir may have on a pregnancy or an unborn baby. There may be bad effects or no effects. If you are pregnant, you cannot be in this study. If your partner is pregnant, please let the study staff know immediately. If you are breastfeeding, you must be able to stop while taking ensitrelvir or placebo and for 30 days after you take your last pill.

Pregnant animals were given higher doses of ensitrelvir than we are using in this study. The offspring (babies) of these animals had problems that included higher rates of bone problems, delayed development, and death.

If you decide to join the study, you must avoid pregnancy during and for 30 days after you have taken the last pill of ensitrelvir or placebo. The most certain way is to not have sex at all (abstinence). If you choose to have sex, you should use effective non-hormonal birth control (for example, barrier methods with spermicide) to avoid pregnancy. Methods like rhythm (calendar) method, sympto-thermal method, or withdrawal are not considered effective for preventing pregnancy. You should ask the study staff about this if you have questions or concerns.

If you get pregnant during the study, please let your study staff 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 the study treatment.

If your partner gets pregnant, please let your study staff know as soon as possible. We may ask your partner to let us get basic information about their pregnancy.

You will be in this study for about 60 days. We will need to do the following things with you, and get detailed information at these times:

Up to 1 day before you get the study drug	**Day 0 (day you first get study drug) to Day 7**	**Days 8 to 60**
• Ask you to read, understand and sign the informed consent (this document) • Check to see how you are feeling • Take medical history and do a physical exam • Do blood tests to check your health. If you already have these test results in your medical record, we do not need to take more blood • Do a pregnancy test if applicable • Get your contact information	• Give you ensitrelvir or placebo (every day through Day 4) • Check to see how you are feeling and whether you have any new symptoms or medical problems • **Days 0 to 7 if you are still in the hospital:** Check on your medications • **Day 5 if you have already been discharged:** Check on your medications • **Days 0 and 5 only:** Do a swab of your nose for COVID-19 virus • **Day 0:** Get blood sample (about 27 mL, or 2 tablespoons) for studying the COVID-19 virus, your antibodies, and your body's other responses to the virus; and for storage for future related research • **Days 0, 1, and 5 only:** Blood tests to check your health. If you already have these tests results in your medical record, we do not need to take more blood • **Days 3 and 5 only:** Get blood sample (about 27 mL, or 2 tablespoons) for measuring levels of ensitrelvir; studying the COVID-19 virus, your antibodies, and your body's other responses to the virus; and storage for future related research	• **Days 8-14 and 28 if you are still in the hospital:** Check on your medications • **Days 14 and 28 only, if you have already been discharged:** Check on your medications • **Days 14, 28, 42, and 60:** Check to see how you are feeling and whether you have had any new symptoms or medical problems • **Day 14 only, if you agree to this:** Get a blood sample (about 27 mL, or 2 tablespoons) for measuring ensitrelvir levels; studying the COVID-19 virus, your antibodies, and your body's other responses to the virus; and storage for future related research. We will also do a swab of your nose for COVID-19 virus • **Day 14 only, if you agree to this:** Blood tests to check your health. If you already have these tests results in your medical record, we do not need to take more blood • **Day 60 only:** Complete a questionnaire about your health

We may need to get some information about your health from your medical record or other institutions and people. You will be asked to sign a separate HIPAA form authorizing the release of your medical records for this purpose.

- By signing this consent, you agree to let us contact other hospitals or places you get medical care while 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 United States (U.S.) where it will be stored and analyzed. In this information you will only be identified by a code number, your year of birth, and a 3-letter code that the study staff chooses.

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

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

A short summary of the overall study results after the study has completed will be available.

You might become able to join other studies as part of STRIVE. If you do, we will give you detailed information for each study. If you choose to join another study, you will need to sign a separate consent form for each study you decide to join.

Why would you want to be in the study?

If you get active ensitrelvir, it is possible it may help you get better, or that you may get home from the hospital faster, but we do not know that.

It is important to remember that half of the people in this study will get inactive placebo and will not get active ensitrelvir.

By being in this study, you will help doctors learn more about how to treat COVID-19 in people in the hospital. There may be a large health impact if a study treatment works and is safe.

Why would you NOT want to be in the study?

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

You do not have to be in this study to receive treatment for COVID-19. You will continue to receive the usual care for COVID-19 recommended by your hospital. Your other options may include other experimental treatments. Your study doctor or regular healthcare provider can explain your options and their risks and benefits to you.

What are the risks or side effects of being in the study?

All treatments have risks and may cause side effects. These may happen to you from the study treatment. We will watch over you closely while you receive the study treatment. Medical staff, equipment, and medication will be available to treat you right away if you have side effects that bother you.

Any drug can cause an allergic reaction. You may have an allergic reaction to the active ensitrelvir or its placebo. This could be hives, trouble breathing, or other allergic symptoms which can be serious or life-threatening. Ensitrelvir has been approved for use in Japan in people with COVID-19 who have not been admitted to the hospital. Through June 13, 2023, over 50,000 people have already been prescribed it. Three of those people who took ensitrelvir were reported to have had a rash with anaphylaxis (a serious allergic reaction) within two hours of taking it. All three people received medical care and recovered. To ensure your safety, we are closely monitoring for any rashes and/or anaphylaxis in the current study.

More than 1,500 participants have received ensitrelvir in studies in people with COVID-19 who are not sick enough to be in the hospital. Half of them received the same dose of ensitrelvir as we are using in this study (375 mg on the first day, then 125 mg daily for 4 days). No participants had serious side effects from ensitrelvir. About 29% of people taking this drug at the same dose as used in this study had a temporary decrease in high-density lipoprotein (HDL) or “good cholesterol” and increase in triglycerides (a type of fat found in your blood) that did not cause any symptoms and returned to normal soon after stopping ensitrelvir. The side effect seen most frequently was a headache (2.2%).

Less common side effects of ensitrelvir seen in the studies include:

- Loose stools
- Nausea
- Vomiting
- Skin rash
- Discomfort in the belly

Temporary changes in blood tests for bilirubin (a byproduct of metabolism produced by your liver) and triglycerides were seen in participants. The changes in blood tests were mild in participants receiving the dose as used in this study.

Ensitrelvir works in your body in a way that can change how other drugs work. This is called a drug interaction. Your study doctor and study staff will talk to you about any

other drugs you are taking. You might have to stop or change one or more of these drugs if you agree to be in this study. Drugs called corticosteroids may be part of usual care for people hospitalized with COVID-19 at this hospital. A corticosteroid called dexamethasone has a strong drug interaction with ensitrelvir. If dexamethasone is part of your care, you will be given a different corticosteroid that has the same effect on COVID-19.

Since the study drug is investigational, there may be other risks that are unknown.

There are discomforts and risks associated with having blood taken. You will have blood taken 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. We will do our best to take blood for the study at the same time as you are having other blood tests. That way you will not have to get another needle stick.

You may have discomfort or cough or sneeze from having a nasal swab done. These discomforts and risks are no different from what you would experience if they were done as part of your regular hospital care for COVID-19.

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 National Institutes of Health (NIH), an agency of the United States (US) Federal government, is paying for this study.

We must follow all rules and regulations for human research and the laws of each country where the study is taking place.

This study is taking place in several countries. STRIVE expects to enroll about 1,500 people around the world into this trial.

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, it will not change your medical care.

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 care you would usually get to treat your COVID-19.

It is possible that your participation in this study may be stopped early. This could happen if your study doctor, the study staff, or health regulators decide that it is not safe for you to stay in the study. It could also happen if groups overseeing the study decide that the research question that this study is trying to answer cannot be answered by continuing, or if the answer is reached sooner than expected. It may also be stopped

early if results of other studies are published that answer the research question or make this study unnecessary.

What are the costs to you?

We will give you the study drug (ensitrelvir or placebo) at no cost. We will pay for all study 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, including other standard of care treatments for COVID-19.

Will you be paid to be in the study?

«Compensation»

We will compensate you for your time and inconvenience participating in the study. *[Specific details to be completed by site.]*

What if you are hurt as part of this study?

If you are hurt because of being in this study, the study staff 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. 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.

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 participant 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 and swab samples for central testing?

We will send your blood and swab samples to a central laboratory in the United States. This laboratory will not have any information that could identify you. As part of this study, we will test your samples for the amount of COVID-19 virus and antibodies

against it. We will also look at other measurements that may be related to how your body reacts to COVID-19. These measurements are called "biomarkers." You and your study doctor will **not** get the results of any of these tests. Some of your blood will also be sent to the company that provides ensitrelvir to help them develop the study drug.

Any blood or swab 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 study treatment. You and your study doctor will **not** get any results from these tests. We will not sell your samples and they will not be used for research aimed at making money (commercial research). We will not test your DNA (genetic testing) on these samples.

You can withdraw your consent for us to keep these samples for future studies at any time. Let your study staff know if you do not want the study to keep your samples any longer, and we will make sure that your samples are never used again.

How do we protect your privacy?

We will do our best to keep your personal and health information private and to keep anyone from getting it. It is your choice whether you allow us to collect and use your data. However, you will not be able to be in this study if we cannot collect and use your data.

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

We cannot guarantee that nobody will get your personal or health information. We may have to release your personal information if required by law.

These people may see your medical and research information:

- The members and staff of the Advarra IRB who review the study;
- The staff of the sponsor and of the group paying for the research (U.S. NIH), other study research staff, and study monitors; and
- The staff of health regulatory agencies in participating countries, including the U.S. FDA.

They are committed to protecting your privacy and are required by law to do their best to protect your privacy.

As the research staff at the study site, we must make sure that only people involved with this study can see your research and medical information. We will handle your personal and health information very carefully, and we will keep your research files in a safe, secure place for as long as required by law. After that time, we will either permanently archive the records or destroy them securely.

Your study data will be sent electronically to the UMN in the U.S. through a secure system. By signing this consent, you agree to having your data sent to UMN. Your information will be identified only with a code number, your year of birth, and a 3-letter code that the study staff chooses. No information that could directly identify you will be 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 and then will be formatted so that it is not possible for the data to be connected back to you.

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

UMN may share your data and samples with other people who study COVID-19. They will remove the code number, year of birth, and 3-letter code, and any other data that could possibly 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 specific data and samples for research projects that are approved by the STRIVE study leadership. However, UMN is also required by U.S. law to provide a limited anonymized data set in a secure repository for use by any researcher.

This study has a Certificate of Confidentiality from the U.S. National Institutes of Health. This certificate is a tool that helps protect your personal (private) information (information collected about you for the study) and your samples. Researchers can use this to legally refuse to give your information or samples to others. For example, researchers can say "No" to a court that is trying to get information about you. The court system cannot force researchers to talk about you being in the study.

The courts can make researchers give personal (private) information about you to prevent serious harm to you or others. Researchers also have to give your information to people paying for this study or the U.S. FDA when asked. In this case, the information will be used to check or evaluate the study.

Researchers can release your personal (private) information when you say it is okay. You can tell others about you being in the study. For example, you can allow your boss, insurer, doctor, or others to get study information. Then researchers cannot use this tool to withhold the information. This tool does not prevent you from having access to your own study information. It is not clear if this would work outside of the US. The certificate does not change the requirement for us to report information that is required by law, such as reportable diseases to public health authorities, or abuse or neglect.

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.

Information on this study will also be posted in a similar format on a European Web site at www.clinicaltrialsregister.eu.

To do this research, we will collect and use your personal data, as described above and in any HIPAA Authorization Form we have given you.

Future use of specimens

At the end of this study, we would like to store and be able to use and share your specimens with researchers for other research related to COVID-19. You can still take part in the research study even if you say "no" to this optional request.

If you agree to future use of your specimens, we will not ask you for additional consent before using or sharing your specimens. You will not receive any results or financial benefit from the future research done on your specimens. Your samples will not have any information connected to them that could directly identify you.

If you leave the study, you can ask to have the samples destroyed. This may not be possible if your samples have already been shared.

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 such as:

- Whom to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research participant;
- Eligibility to participate in the study;
- The study doctor's or study site's decision to exclude you from participation;
- Results of tests and/or procedures;

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 participants. If you have any questions about your rights as a research participant, 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: Pro00065898.

Optional Elements:

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

Yes, I agree	**No, I disagree**	
_____	_____	I plan to attend an in-person visit for a blood draw and nasal swab on Day 14 of my participation in this study.
_____	_____	My specimens/samples collected may be used for other future research studies.

SIGNATURE PAGE FOR CONSENT TO PARTICIPATE IN THE RESEARCH STUDY

I have read the consent or have had it explained to me. My questions about the study have been answered. 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 give up any of my legal rights as a study participant by signing this consent. I understand that I will get a copy of this signed and dated consent.

If you agree to be in this study, please sign and date 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 (LAR)

_____
Relationship of Legally Authorized Representative (LAR) to Participant
(Indicate why the LAR 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 with the participant for the research study named above in this document. I attest that the information in this consent form was explained to the participant named above, and the participant indicated that their 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 study doctor 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.

Optional: Additional Consent for Genetic Testing on Stored Specimens

WHY IS GENETIC TESTING BEING DONE? The study staff would like your permission to collect a small amount of your blood and store it for researchers who will do genetic testing (testing on your genes/DNA) 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.

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).

Any future research done on the blood collected for this study will be related to COVID-19.

WHAT WILL HAPPEN DURING GENETIC TESTING?

If you agree to provide blood for genetic testing, a blood sample will be collected along with other blood being drawn for the study, approximately 9 mL (about 2 teaspoons) 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 this virus. This may include tests to better understand why some people have more severe complications (get sicker) than others and why drugs 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 genes will be studied.

You and your study doctor or study 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 will not apply to your medical care.

Your blood sample collected for this study will:

- Become the property of STRIVE.
- 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 STRIVE 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, 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 will be identified only by a second code. The results of any genetic testing will be identified by a third code. Only a few statisticians (persons who analyze the study results) associated with the study will have access to all 3 codes in order to analyze the test results. These statisticians will not have access to any information that can directly 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.

Study staff at this 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.

HOW LONG WILL YOUR BLOOD BE KEPT?

Your blood samples 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 taken 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 giving your blood for genetic testing. Information obtained from the tests may provide useful information about the causes, risks, and prevention of COVID-19. This may help other people in the future.

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

If you agree that your blood can be stored for genetic research to be done at a later date, you can change your mind at any time. If you change your mind, let the study staff at this site know that you do not want your blood specimen collected for this study used for future research.

If you decide to withdraw consent for this genetic 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 study staff at this 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. We will not compensate or pay you for being in this genetic study.

It is your choice to participate in this additional genetic testing. You can still be in the STRIVE ensitrelvir study even if you do not want to participate in this optional testing.

Consent: By signing and dating this consent, I am stating that my blood samples may be stored and used for future genetic research about COVID-19.

_____ _____
Signature (participant or surrogate) Date

_____
Participant or Surrogate Printed Name

_____ _____
Signature of Person Obtaining Consent Date

_____
Printed Name and Title of Person

FOR ADULTS NOT CAPABLE of GIVING CONSENT

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

_____
Printed name of Legally Authorized Representative (LAR)

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

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_____ Date: _____
Signature of witness

_____
Printed name of witness

NOTE: This consent form, with the original signatures, MUST be retained on file by the study doctor 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.