1. Overview of the Research Study:

We are asking you to be in a research study that is being supported by the VA Boston Healthcare System. Before you decide to take part, you should know why the study is being done and what it will involve. This form tells you what to expect if you agree to be in the study. Taking part in this study is completely voluntary; it is your decision whether or not to participate in the study.

We are doing the research to try and find an effective therapy for SARS-CoV-2 infection (also called “coronavirus infection” or “COVID-19”). All patients who choose to enroll in the study will receive the standard-of-care treatments used in our hospital, and your electronic medical records data will be followed for 6 months after your enrollment. Patients who choose to participate will be randomized to receive either the usual standard of care, or the usual standard of care plus a single injection of additional medication called SARILUMAB. SARILUMAB is an anti-inflammatory medication that might improve how your immune system responds to the infection. There is a possibility that this medication will make your body’s response to infection better, and also a possibility that this medication will make your body’s response worse. That is why we are doing the study. You will be enrolled in the study for up to six months, during which you will receive a single injection of the study medication, or will not receive the study medication, and then study investigators will monitor your electronic medical record. We will describe your involvement in more detail later in this form.

The purpose of this research is to gather information on the safety and effectiveness of SARILUMAB (IL-6 receptor blocker), as an additional therapy for patients with confirmed SARS-CoV-2 infection and moderate respiratory symptoms. This anti-inflammatory medication has been used to treat other illnesses but has not been proven to be effective for reducing the severity of disease caused by SARS-CoV-2.

You might choose to volunteer in the study because we do not currently know what the best treatment for SARS-CoV-2 is, and this study will help us find out if SARILUMAB improves outcomes for patients who have this infection. There is also the possibility that you may benefit from receiving the medication. You will find more information about benefits later in this form.

You may choose not to volunteer to be in the study if you are worried about the impact of the medication on your immune system or are already feeling better without using this medication. You will find more information about these risks later in this form.

If you do not participate in this study, you will still receive the standard treatments that we provide all patients with SARS-CoV-2 infection and moderate disease. You will find more information about alternate treatment/procedures later in this form.

Your doctor may also be an investigator in this research study. Being an investigator means your doctor is interested in both you and the study. You may want to get a second opinion about being in
the study. You can do so now or at any time during the study. Another doctor who is not an investigator can give you a second opinion about being in the study. You do not have to agree to be in this study even though it is offered by your doctor.

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

2. WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study to try to find treatments that might or might not improve outcomes for patients infected with SARS-CoV-2. SARS-CoV-2 is a new infection that causes respiratory illness in some patients. It was first identified at the end of 2019, so we do not know very much about which treatments are and are not effective for treating it.

This randomized controlled study will compare usual treatments (also called “standard of care”) with or without an additional anti-inflammatory medication called SARILUMAB for treating patients with moderate illness caused by SARS-CoV-2. SARILUMAB is FDA-approved for treating some diseases caused by inflammation, such as rheumatoid arthritis. We hope to learn if SARILUMAB improves outcomes for patients with SARS-CoV-2, or if the anti-inflammatory treatments are ineffective or harmful. This study sponsored by the VA is being conducted at VA Boston Healthcare System. We expect to enroll approximately 120 participants.

You are being asked to participate because you have a confirmed SARS-CoV-2 infection.

Patients with moderate SARS-CoV-2 may have some new difficulty breathing because of their infection or may have new or increasing oxygen requirements. Patients with moderate disease are eligible to be randomized (like a coin flip) to receive SARILUMAB or not.

Patients with mild disease have SARS-CoV-2 infection, but may not have breathing problems. If you currently have a mild form of the disease, you may volunteer now in case you progress to a moderate form of the disease and you become eligible to be randomized (like a coin flip) to receive SARILUMAB or not.

If you are enrolled in the study, regardless of whether you receive SARILUMAB, we will continue to follow you (via your medical record) until hospital discharge, and up to 6 months after discharge.

3. HOW LONG WILL I BE IN THE STUDY? WHAT WILL HAPPEN AND WHAT CAN I EXPECT IF I TAKE PART IN THIS STUDY?
You will be in this study for 6 months if you choose to enroll. During these 6 months, you may or may not receive a dose of SARILUMAB and we will follow you (via your medical record. There are no follow-up study visits required. Diagnostic testing may occur as part of your usual care for SARS-CoV-2 but will not be impacted by the study. No matter what you decide to do about joining the research study, you will receive standard treatments for patients with SARS-CoV-2 infection.

If you agree to participate, you will be randomly assigned (like a coin toss) to either receive usual care or usual care plus SARILUMAB, a medication that blocks the action of IL-6 in your body. IL-6 is a substance that impacts how your body responds to infections.

If you are assigned to the group that receives the study medication you will receive one dose that will be injected underneath your skin (a “subcutaneous injection”).

4. WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

Since the medication being offered as part of this study is injected underneath your skin (a “subcutaneous injection”) it may be uncomfortable or unpleasant to some people. You also may get some bruising or bleeding around the injection site.

As with any other medication, SARILUMAB may result in some side effects. There is a risk that the medication may lower the ability of your immune system to fight infections. It is possible that you might get a severe bacterial infection that can lead to the need for antibiotics, treatment in the intensive care unit, or, under rare circumstances, death. It is also possible that this medication might make your SARS-CoV-2 infection worse, which could result in worsening respiratory failure, admission to the intensive care unit, or death.

Drugs like SARILUMAB cause a small increase in risk of bowel perforation, meaning a hole in your intestine, which is a dangerous condition. This risk has been observed only in conditions in which the drug is given repeatedly over a long time period for a chronic disease.

In addition to the risks listed above, you may experience a previously unknown risk or side effect.

Because this is a new treatment strategy for SARS-CoV-2, we do not know all of its bad effects. You should contact (Westyn Branch-Elliman, MD) at (617-705-4348, VA Boston, or call the page operator at 1-857-203-3000 and request to have Dr. Branch-Elliman paged) if you have any bad effects. Off hours, you can call the West Roxbury VA page operator (857-203-3000) and request to speak to the physician on call for the medical service.
5. WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

Because SARS-Co-V-2 is a new infection, we do not know very much about the best ways to treat it. You are being referred to this study because it is possible that SARILUMAB, a medicine that reduces inflammation may improve outcomes in patients who have this infection. There is some data from other countries that suggests that these anti-inflammatory medicines may be helpful, but we do not have enough data to know if they do or do not help.

6. DO I HAVE TO TAKE PART IN THE STUDY?

Participation in this study is entirely voluntary. Regardless of whether or not you chose to participate, you will receive the standard-of-care treatment as offered by your doctors. There is no penalty or loss of benefits to which you are otherwise entitled if you choose not to take part in this study.

You may choose to withdraw from this study at any time. If you are receiving standard-of-care treatments or the study medication, the only difference would be that study investigators will not access your electronic medical record to find out some of the things that happened to you, like how long it took for your oxygen levels to improve.

If you do decide to withdraw from the study, any data that was collected before your withdrawal may be reviewed by study investigators. However, the only additional data investigators will be able to collect is from public records, such as survival data. Investigators will not be able to access other medical records data collected after your withdrawal, such as laboratory results or information about your oxygen levels.

7. WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS STUDY?

Other treatment to that described above may include available standard of care treatments and will be under the supervision of your doctor or caregiver.

8. HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

Information collected for the purpose of this research study will be kept confidential as required by law. The results of this study may be published for scientific purposes, but your records or identity will not be revealed unless required by law.

Information about you is protected in the following ways: We will store your information in ways we think are secure. Data will be maintained on secure, password protected VA servers or on secure, password protected servers. The number of individuals with access to the data will be minimized and...
individuals no longer involved in research activities will have access to the secure server immediately revoked. Identifiable data will not be stored on desktops, laptops or jump drives.

Identifiers might be removed from the identifiable private information that are collected. After that removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

Your research records will be kept indefinitely or until the law allows their destruction per the VA Record Control Schedule (www1.va.gov/VHAPUBLICATIONS/RCS10/pcs10-1.pdf). Records will be destroyed, when allowed, in the following manner:

- Paper records will be shredded
- Electronic records will be destroyed in a manner in which they cannot be retrieved.

Your data will be entered into a data repository and may be used for future studies approved by an IRB.

An unsigned copy of this consent form will be posted on clinicaltrials.gov or Regulations.gov after all study participants have completed the study.

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.

9. WHO ELSE MIGHT SEE MY DATA?

You consent to the access of your VA research and medical records that may identify you by persons approved for this purpose. Such access may be by the Institutional Review Board and Research & Development Committees of VABHS, the VA, Federal agencies, or national research oversight and accreditation organizations. You understand that because this research study involves things that are regulated by the FDA they may choose to access and inspect your records.

You may expect the same confidentiality from these persons that is given to you by the Investigator and his/her research staff.

10. WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

You will be told of any significant new findings that come to light during the course of this study and that may relate to your wanting to stay in the study.

12. WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?
A participant will not be required to pay for medical care and services received as a participant in an approved VA research study. Some participants are required to pay co-payments for medical care and services provided by the VA. These co-payment requirements will continue to apply to medical care and services (including, but not limited to, dental services, supplies, medicines, orthopedic and prosthetic appliances, and domiciliary or nursing home care) provided by the VA that are not part of this research study.

12. WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?
In the event that you are injured as a result of your being in this research study, you will receive medical care, including emergency treatment. This care or treatment is governed by federal law and VA policy. You would also have the right to file any legal action, as in any instance of alleged negligence.

13. WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?
I understand that if I have any medical questions about this research study, I can page Dr. Westyn Branch-Elliman, at 617-705-4348 during normal working hours.

I understand that if I have any general questions about this research study, I can page Dr. Westyn Branch-Elliman, at 617-705-4348 during normal working hours.

I understand that if I have any medical problems that might be related to this study that during the day I can page Dr. Westyn Branch-Elliman, MD at 617-705-4348 OR call the West Roxbury VA Hospital Page Operator (857-203-3000) and request to have Dr. Branch-Elliman paged. After hours I can call the Medical Center operator at (617) 323-7700 and ask for the resident, fellow, or attending on call for Medical Service.

I understand that, if at any point during or after this study I have any questions about my rights as a research participant or I want to discuss problems, complaints, concerns, and questions about the research, obtain information, or offer input, I may contact the Research Compliance Officer at (857) 364-4182.

14. AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY
I have read or have had read to me all of the above. Study staff have explained the study to me and answered all of my questions. I have been told of the discomforts and risks of the study. I have been told of other choices of treatment that I could have.

I understand that my participation in this study is voluntary, that I do not have to take part in this study and that, if I do take part, I may withdraw from the study at any time. I also
understand that, if I refuse to take part or if I decide to withdraw, I will not suffer any penalty, loss of rights, or loss of VA or other benefits that I have a right to receive.

I voluntarily consent to be in this study. I will receive a signed copy of this consent form.

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