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Fred Hutchinson Cancer Research Center

University of Washington

Seattle Cancer Care Alliance

Consent to take part in a research study:

Pharmacokinetics of a SARS-CoV-2 Monoclonal Antibody in Hematopoietic Stem Cell Transplant Recipients (COVIDMAB)

Protocol Number:	**10691**
Principal Investigator: (Study Doctor)	**Alpana Waghmare, MD, Assistant Professor, University of Washington; Fred Hutchinson Cancer Research Center**
Sub-Investigators:	**Jim Boonyaratanakornkit, MD, PhD, Associate, University of Washington; Fred Hutchinson Cancer Research Center** **Michael Boeckh, MD, PhD, Professor University of Washington; Fred Hutchinson Cancer Research Center**
Telephone:	**(206) 987-2000** **covidmab@fredhutch.org**
Address:	**Fred Hutchinson Cancer Research Center** **1100 Fairview Ave N, Mail Stop E4-100** **Seattle, WA 98109**

Emergency 24-hour Number *Ask for the Infectious Disease fellow On-Call.* **206-987-2000**

If you are serving as a legally authorized representative, the terms "participant", "you", and "your" refer to the person for whom you are providing consent.

Thank you for your interest in our research study. This is an informed consent form. It describes a type of research study called a clinical trial. Some of the information in this consent form is required by law. Please read this consent form or ask someone to read it to you. If you decide to join the study, we will ask you to sign and date or make your mark on this form. We will offer you a copy to keep. We will ask you questions to see if we have explained everything clearly. You can also ask us questions about the study.

You may refuse to participate or you may withdraw from the study at any time and for any reason without penalty or anyone blaming you.

Research is not the same as treatment or medical care. The purpose of a research study is to answer scientific questions.

Key Information

- The study will only include people who want to take part in it. Your participation is voluntary. It is your choice.
- The purpose of this study is to learn more about coronavirus disease 2019 (COVID-19) and how long the research study drug, VIR-7831, stays in the blood and nose in the setting of transplant. We want to learn the best way to give VIR-7831 and how much can be given safely.
- You will receive the study drug, VIR-7831, once during the study through an IV (intravenous) infusion.
- Your participation in this study will generally last for about 9 months. Procedures will include blood draws, samples collected from your nose, frequent questionnaires and monitoring your health. You will come to the clinic or hospital once for enrollment and once for the infusion. Other blood draws and nasal swabs will be collected while you are in the hospital or clinic during your transplant care or self-collected. At other times we will contact you by phone. We may email or call you at week 4, 8, 12, 16, 20, 24, and 36 to remind you to send in your nasal and blood specimens and complete the questionnaire.
- We do not know if getting the study drug will benefit you in any way. In this early phase of the research, it is not yet known if VIR-7831 will prevent or treat COVID-19 in transplant patients.

Joining the Study

It is completely up to you whether to join the study. You can decide not to participate and there will be no penalty or loss of benefits. If you do not wish to participate there will be no impact on the quality of care you receive. We ask that you read this form and all other information you are provided about the study. Ask the study staff any questions you may have about the study. You may talk to your family, friends and/or your family doctor to help make your decision. You can take as much time as you like to decide.

If you decide to take part in the study, sign, and date the pages at the end of this form. This is called "giving your consent." Even after you have signed and dated the consent form you can change your mind at any time and decide not to take part in the study. You should know that you do not have to give a reason.

Why have I been asked to take part in this research study, and who is in charge of it?

The Infectious Disease Sciences Program at Fred Hutchinson Cancer Research Center is doing this study to learn more about coronavirus disease 2019 (COVID-19) and how long the research study drug, VIR-7831, stays in the blood and nose of transplant recipients. VirBio is a company that discovers and makes medicines and is providing the study drug. GlaxoSmithKline (GSK) is a company that is collaborating with VirBio to research and develop solutions for coronaviruses, including COVID-19.

The researcher in charge of this study is Dr. Alpana Waghmare. Her phone number is (206) 667-7329.

You are being asked to take part in this study because you are a hematopoietic stem cell transplant candidate.

How many people will take part in this study?

The study will include about 50 participants.

□ Why is this research study being done?

This research study is being done to learn more about coronavirus disease 2019 (COVID-19) and how long the study drug, VIR-7831, stays in the blood and nose of transplant recipients. VIR-7831 is an investigational (experimental) drug that is an antibody. Antibodies are proteins our bodies make which help us fight infections. The antibody (VIR-7831) has been modified to last longer in humans and may or may not improve the body's ability to fight off coronavirus (also known as SARS-CoV-2) infection, the virus that causes COVID-19. COVID-19 is a disease that can affect your lungs and airways and other major organs in your body. It's caused by a type of virus called a coronavirus. Common symptoms include fever, fatigue, or dry cough. Participants with severe COVID-19 may have shortness of breath, damage in their lung tissues, increased inflammation, and increased abnormal clotting in theblood vessels.

We also would like to answer the following questions:

- Is VIR-7831 safe in the setting of transplant?
- Can it potentially be used to protect against COVID-19 in the setting of transplant?

VIR-7831 is not yet approved by the U.S. Food and Drug Administration (FDA) for use in people.

□ How does the study work?

The study will be about 36 weeks long (9 months) from the time you receive the study drug, with some participants providing a blood sample 4 months after their last visit depending on their antibody test results. All participants will receive the study drug. This study will look at how the body responds to VIR-7831 and if there are any side effects.

□ What do I have to do if I am in this study?

Before Entering the Study

If you choose to take part in this study, you need to sign and date this consent form. You will be offered a copy of the signed and dated consent form.

If you decide to join the study, we will screen you to see if you are eligible. The study staff will tell you where to go for your clinic visits and will provide you with directions as needed.

The screening visit will require at least 2 - 4 hours of your time and includes tests to see if you qualify to be in the study. Screening involves a health history. We will ask you about medications you are taking. We will collect personal information about you including your name, date of birth, address, contact and emergency contact information, race, ethnicity, and gender.

We will ask you about any previous SARS-CoV-2 test results. As part of the lab testing, some of your personal information will be collected including your name, address, and telephone number. This information is collected because nasal swabs collected as part of the study may also be tested by PCR for SARS-CoV-2 and by U.S. law, positive test results have to be reported to relevant state or local public health agencies. By consenting to be in this study you are consenting to the release of your name, contact information, and SARS-CoV-2 test results to public health officials. The nasal swab PCR for SARS-COV-2 is a research test and should not be considered a replacement for a clinical test.

We will review the screening results with you. The screening results may show you are not eligible to join the study, even if you want to. If you qualify, you will be able to receive the study drug while you are in the hospital for your transplant.

Screening	
Screening visit **Approx. 2-4 hours**	You will be asked to give informed consent, then have the following assessments: • Questions about your health, medical history, & medications • Collection of demographics (background) information • Questions about any previous SARS-CoV-2 tests
A decision about whether you can take part will be made when all your screening results are available**.**	

Before participating, you need to consider if being in a research study will affect any insurance you currently have or may purchase in the future. Seek advice if necessary, from your insurance company.

You will be asked to provide the study staff with contact information of a family member, caregiver, or friend in case the study staff aren't able to contact you during the study. You will also be asked to provide the contact information for your primary doctor to the study staff, if you have one. You will be asked to confirm this information during the time you are in the study.

With written permission and if you agree, the study doctor may tell your primary doctor(s) that you are taking part in this study, which may include sharing this informed consent form. Tell the study doctor if you are currently in another research study.

During the Study

On Day 0, the study drug will be given to you by an intravenous (in a vein) infusion over about 30 minutes.You will only get one infusion of the study drug. There are a total of at least 12 blood draws and nasal swabs over the 6-month duration of the study. While you are in the hospital or clinic for the transplant, blood draws will be collected by clinical staff. At week 12 and after post-transplant, blood draws will be self-collected using a device called TASSO and mailed to our lab.

During the study, your blood will be collected frequently, and you will be asked to give up to 10 mL (1/2 tablespoon) of blood at the visits conducted while you are hospitalized or in the clinic for your transplant. The volume of blood self-collected in the TASSO-SST and TASSO+ device is less than 0.3 and 0.6 mL, respectively. Each time blood is collected, we will use either two TASSO-SST devices or one TASSO+ device. The total volume of blood collected over 24 weeks (6 months) for this study will be about 94 mL (5 tablespoons). Details concerning how much blood to be collected at each visit are provided at the end of this form.

You will complete an online questionnaire regarding symptoms weekly up to week 36 during the study through a secure online portal called REDCap. A study clinician may call you about any symptoms during the study. You will need to answer questions about how you are feeling and symptoms you may be experiencing on an electronic device like your mobile phone or a computer that has web access weekly throughout the study.

While using the electronic device, data about you including email address, first and last name, phone number, address and internet usage data may be collected and transmitted to the researchers and to people outside of the research study. Transmission of information via the internet is not completely secure, so there is a small risk of unintentional release of your information and safeguards are in place to protect your personal information.

The tables below show the schedule of clinic visits during this study.

<table>
<tr><th colspan="2">Dosing</th></tr>
<tr><td>Dosing Day 0</td><td>This visit may occur on the same day of screening visit.

Day 0
Confirmation of your eligibility to participate in the study
Questions about your health and medications to evaluate your condition
You will answer questions on an electronic device about how you are feeling and symptoms you may be experiencing
Vital signs will be checked (blood pressure, heart rate,breathing rate, oxygen saturation, temperature) prior to dose administration, and at the end of the IV infusion of study drug
Blood samples will be drawn for:
Laboratory tests
PK samples (tests to see how the body affects the study drug) before the study dose, at the end of IV infusion
Tests to assess your body’s immune response to the study drug
Nasal swab samples will be collected for:
Measuring the amount of antibodies in your nose
Measuring the amount of coronavirus and may look at any other possible infections you could have
Dose of VIR-7831 given by intravenous (IV) infusion for approximately 30 minutes
Approximate total blood volume: 10 mL (1/2 tablespoon) at this visit</td></tr>
<tr><th colspan="2">Follow-up Period</th></tr>
<tr><td>Visits

Day 1 and Weeks 1, 2, 3, 4, 8, 12, 16, 20, 24</td><td>Visits after Day 1 may be done at your home, in clinic, or in the hospital
Questions about your health and medications
Nasal swab samples will be collected for:
Measuring the amount of antibodies in your nose
Measuring the amount of coronavirus and may look at any other possible infections you could have
Blood will be collected by venipuncture or from a central venous catheter weekly up to week 4, monthly up to week 12, and once a week 24. From week 12 to 24, a TASSO device can be used. Blood samples will be used for:
Laboratory tests
PK samples (tests to see how the body affects the study drug) before the study dose, at the end of IV infusion
Tests to assess your body’s immune response to the study drug</td></tr>
<tr><td colspan="2">Additional nasal swabs will also be collected as needed based on respiratory symptoms within 48 hours of symptom onset, up to week 36. If positive for SARS-CoV-2, weekly nasal swabs will be collected until negative or until week 36. Additional blood and nasal specimens maybe collected if the study doctor determines this is needed for your safety.</td></tr>
</table>

If you do develop COVID-19 while on study, you can still receive FDA-authorized or approved medications for treatment, including VIR-7831 if available or other monoclonal antibodies, as determined by your health care providers involved in your clinical care. A second dose of VIR-7831 is not provided as part of the study.

What are my responsibilities?

If you are enrolled in this study, you will have the following responsibilities:

- Follow the study staff's directions regarding the study
- Complete all study visits.
- Tell the study clinician about any side effects or problems that occur during the study
- Tell the study clinician about any illnesses or injuries you have or have had in the past
- Tell the study staff about any medications you are taking and about any changes in your health.
- Talk to the study staff before you decide to get any other vaccines, such as a COVID-19 or flu vaccine. Please ensure that study staff is aware of any other vaccinations you may receive throughout the course of the study.
- Tell the study clinician if you plan to have any surgery or any other medical treatment or procedure
- Talk to the study staff if you feel the study is taking too much of your time. We will try to make changes to help you.
- Talk to the study staff if you don't like how you are being treated. We will try to fix the problem.
- Stay in touch with the study staff. Tell them if your address, phone number, or email address changes, if you are moving away, or if you want to leave the study.

It is important for your safety that you are completely honest with your study clinician throughout the duration of the study.

You should not:

- Donate blood.
- Donate body parts, body fluids, or body tissues without talking to the study staff first.
- Get pregnant (if you are a woman of childbearing potential) without talking to the study staff first
- Share needles or injection equipment.
- Join another research study without talking to the study staff first.
- Leave the study without telling the study staff first.

Are there benefits to taking part in this study?

- There may or may not be direct benefit for you in taking part in this study.
- You will have regular health check-ups.
- This study helps to learn more about COVID-19 and the effects of VIR-7831. Your participation will help to understand your condition/disease better and make new drugs for other people suffering from the same condition/disease as you.
- When the study is completed, the data will be analyzed. You will have an opportunity to learn of the study results. You may ask your study doctor for the results and to have them explained to you.

What are the side effects, risks, and inconveniences of the study?

Like all drugs, VIR-7831 can cause side effects, although not everybody experiences them. Some people may experience serious side effects and some of these side effects may require treatment. In a previous study of 430 patients (non-transplant) who received VIR-7831 for treatment of COVID-19, no safety signals related to VIR-7831 were observed.

Allergic Reactions and Infusion-Related Reactions

As with any drug, an allergic reaction can occur. Allergic reactions can by mild or serious and can rarely result in death. Common symptoms of an allergic reaction are:

- Rash
- Itching
- Skin problems
- Swelling of the face and throat
- Trouble breathing

In the treatment trial, infusion-related reactions were observed in 1% of patients treated with VIR-7831 and 1% of patients treated with placebo. These reported events started within 24 hours and were generally mild to moderate. If you think you are having an allergic reaction, call the study clinician right away. If you are having trouble breathing, call your local emergency phone number immediately.

VIR-7831 is given by intravenous infusion (administered into a vein). Intravenous infusions may be associated with pain, redness, swelling or bruising at site of the infusion. Rarely, infusion of antibodies against a specific disease can result in reactions which can include worsening of disease, or severe shortness of breath. The study clinician will monitor you closely for any potential reaction while VIR-7831 is administered in order to detect and treat any infusion reaction.

What about pregnancy and breastfeeding?
It is not known whether or how VIR-7831 may affect an unborn baby. You cannot join this study if you are pregnant or planning to become pregnant. You cannot join this study if you are breastfeeding. Tell the study clinician if you are pregnant. If you get pregnant during the study, you may remain in the studyfor follow-up. We will follow-up until the delivery of the baby and for up to one year after birth.

Unknown risks:
Since the study drug is investigational, there may be risks that are unknown. Some side effects/risks are unforeseeable and could be permanent or even result in death. Additionally, there may be unknown risks to a pregnancy, embryo, or fetus if you become pregnant.

We do not know if the study drug will increase, decrease, or not change your risk of disease progression with COVID-19. We do not know if receiving VIR-7831 will affect how you respond to a future approved COVID-19 vaccine or therapeutic product.

There may be risks that are unknown that may (although unlikely) impact transplant outcomes such as engraftment, infections, graft-versus-host-disease, or relapse.

If you have multiple myeloma, the antibody could potentially interfere with some of the diagnostic blood tests used by your oncologist to monitor your disease.

Risk of loss of privacy:
You will either receive a hard-copy or be emailed a PDF copy of this signed and dated consent form. There may be risks of loss of privacy and confidentiality if the copy of this consent form is viewed and/or stored on a personal electronic device(PED), especially if that PED is shared with other users or is lost, hacked, or subject to a search warrant or subpoena. Also, the PDF copy of the consent may not be able to be permanently removed from a PED.

Risks of drawing blood:
Drawing blood can cause bleeding, bruising, pain, soreness, redness, swelling, itching, and/or muscle damage at the site where blood samples are taken. Rarely an infection at the site where blood samples are taken may occur or a blood clot may form. There is also the risk of fainting, dizziness, and anemia (low numbers of red blood cells). Please let us know if you have ever fainted during a blood draw.

Risks of nasal swabs:
Nasal swab sampling can result in discomfort or pressure during the procedure. You mayhave a sore nose or have a mild nosebleed during the procedure or for a short time afterwards.

□ What other choices do I have besides this study?

You may choose not to join this study. Other services you receive at this institution will not be affected. If you choose not to join this study, you could join another study if one is available and you are eligible. You should talk with your primary doctor about all of your options for other treatments or clinical trials, before you decide to take part in this study. The study clinician can advise you and answer any questions about potential risks and benefits. Currently, there are no antibody products approved for protection against COVID-19 in the early post-transplant period.

□ Do I have to stay in the study?

No. You can leave the study at any time without penalty or loss of benefits. Tell the study clinician if you no longer want to take part. Your choice will not change the quality of care you receive outside of this study.

The study clinician will tell you as soon as possible if there is any new information that might change your decision to stay in the study.

□ Can I be asked to leave the study?

Yes. You may be asked to leave the study for any reason, including if:

- You do not follow the study instructions.
- The study clinician thinks it is best for you to stop, for example if you have specific health problems.
- The entire study is stopped for everyone. If this happens, the study clinician will explain the reason to you as soon as possible.

□ What happens if I decide to leave the study?

Tell us if you decide to leave the study.

If you decide to leave the study, you and the study doctor will discuss the best way to do this. The study staff may ask to contact you or your secondary contact to ask about your health and to follow up on any safety concerns unless you do not wish for them to contact you. Knowing about your health is very important. It will help to learn more about the potential long-term effects of VIR-7831.

If you do not agree, then you will not be contacted anymore. But any information that can be found in the public domain may be used for the study.

□ What will you do with my blood and swab samples?

You will be asked to give:

- Blood
- A nasal swab (a swab taken from inside your nose)

These samples will be used to:

- Measure the amount of coronavirus and other possible infections
- Measure the study drug inside your body
- Perform additional tests to understand how VIR-7831 works in the body

Your blood and swab samples will be given a code and stored securely. This means that no one but the site study staff will be able to link you to your samples. Anyone who works with your samples will hold the coded information and results securely and in confidence.

Your biological samples will initially be sent for analysis, storage and evaluation to the laboratories associated with this study and may end up being sent to other third-party laboratories around the world. The samples will be kept in a secure environment, under the laboratory responsibility.

The Fred Hutchinson Cancer Research Center may store your blood and swab samples for up to 15 years after the end of the study, after which time your samples will be destroyed. You may request destruction of your samples at any time by telling the study doctor. If you choose to stop participating in the study after giving a sample, no new tests will be conducted on the sample. The Fred Hutchinson Cancer Research Center will keep and use any results generated before you withdrew from the study. Additional blood samples may be requested if the laboratory requires these to perform testing, for example, ifthere are issues processing your sample.

Different types of testing often use the same kind of biologic sample. For example, serum from blood can be used to test for antibodies, viruses, circulating factors and many other things. On some occasions, a sample that was originally collected for one type of test may be used in a different type of test, a process called "repurposing". This could happen if the lab has issues processing your samples, or there is not enough sample collected. In these situations, these repurposed samples will be used only for tests that are described in this study.

We may also conduct genetic testing on your tissue. Your tissue contains DNA. DNA makes up the genes that serve as the "instruction book" for the cells in our bodies. By studying genes, researchers can learn more about diseases such as cancer. There are many different types of genetic tests.

In addition to the planned uses described above, we might remove all identifiers and codes from your information or tissue samples. We could then use or share them with other researchers for future research. If you do not want your anonymous information or tissue samples used for other projects, you should not participate in this study.

If we do share your information or tissue with others, we would not be able to stop the future research, even if you asked later. There will be no way to link the information or tissue samples back to you. We will not contact you or otherwise inform you before we share your information or tissue for future research.

Protecting Your Privacy / Who has access to my research records?

We will do our best to protect your private information.

Your study records and samples will be kept in a secure location. We will label most of your samples and records with a code number, not your name or other personal information. Except when required by law, we will not share your name or personal information with the lab that does the tests on your samples, or with anyone else who does not need to know your name. The code list is kept secure and confidential by the study clinic. All of your personal information that is transferred by the study doctor or the study clinic will use this code number and will not include your name. However, it is possible to identify you, if necessary.

- Clinic and study staff will have access to your study records. Your records may also be reviewed by groups whowatch over this study to see that we are protecting your rights, keeping you safe, and following the study plan. These groups include:
    - Researchers involved with this study.
    - Vir Biotechnology, Inc., GSK, and their affiliates.
    - Institutional Review Boards (IRB), including the Fred Hutchinson Cancer Research Center IRB. An IRB is a group that reviews the study to protect the rights and welfare of research participants.
    - Fred Hutchinson Cancer Research Center, University of Washington, and Seattle Cancer Care Alliance.
    - Office for Human Research Protections, Food and Drug Administration, and other regulatory agencies as required.

All reviewers will take steps to keep your records private. At this clinic, we have to report your personal information:

- If you have a test result or disease that we must report to the health department.
- If we suspect that you may be harming yourself or others or planning to do so.

If your confidential information is released, you will be told.

We will do our best to keep personal information confidential. But we cannot guarantee total confidentiality. Personal information may be given out if required by law. For example, workplace safety rules may require health workers to contact you about lab tests. Or a court may order study information to be disclosed. Such cases are rare.

Your de-identified data may be used for this study or other scientific purposes, including research in connection with the study drug to further knowledge about COVID-19.

We will not use personal information in any reports about this study, such as journal articles or presentations at scientific meetings.

We may share information from the study with other researchers. We will not share your name or personal information that can identify you.

When the study is done, we may share the information from the study with others so they can see it and use it. We will not share any information that will let someone identify you.

If you join this study, information about your participation may be made part of your permanent medical record. This information would include a copy of this consent form. If an insurance company or employer or anyone else were authorized to see your medical record, they would see a copy of this consent form.

How is my genetic information protected?

A federal law called the Genetic Information Nondiscrimination Act (GINA) helps protect genetic information about people who join research studies.

GINA restricts access to genetic information so that it cannot be used for health insurance coverage decisions. GINA prevents health insurance companies or group health plans from:

- Asking for genetic information obtained in research studies, or
- Using genetic information when making decisions regarding your eligibility or premiums

GINA does not help or protect against genetic discrimination by companies that sell life, disability or long-term care insurance.

Where can I find a study description and results?

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.

Who owns the study results?

The Fred Hutchinson Cancer Research Center will own the study results. This research may lead to patentable discoveries and inventions, the sale of products or services in the future, or to other profits. There are no plans to share any money with you.

What happens if I am injured?

For a life-threatening problem, call 911 right away or seek help immediately. Contact your study clinician when the medical emergency is over or as soon as you can.

If you think you have been injured or have experienced a medical problem as a result of participating in this study, tell the study clinician or study staff as soon as possible. The lead study doctor's name and phone number are listed on the first page of this consent form. Treatment will be available to you for any injury that directly results from your participation in this research study.

Vir and/or GSK will pay any reasonable and necessary costs for diagnosis and treatment of injuries caused by a defect in the design or manufacture of the study drug.

You or your insurer will be billed for treatment of problems or complications that result from your condition or from standard clinical care.

If you are injured, you will not be offered payment for losses, damages, or lost wages.

You will not lose any legal right to seek payment for treatment if you sign and date this form.

If you need further information about research-related injuries, please ask the study doctor or a study staff member.

This research study is covered by a US government program that may provide compensation for a serious injury or death. We will give you a handout with more information about this program.

Will I receive any payment?

You will receive $25 compensation for the completion of Visit #1. You will also receive $25 after swab and blood specimens are received at weeks 8, 12, 16, 20, and 24. This amount is to cover the costs of your time, travel, and inconvenience. If you are asked to come to the clinic for a repeat test or any unscheduled visit, you will receive $25 for that visit.

The compensation you receive for being in this study may be considered taxable income. The study staff may collect your name, address, and social security number for tax purposes. This information may be shared with

the accounting department at Fred Hutchinson Cancer Research Center and the US Internal Revenue Service (IRS). We will not share the name of this study or nature of the research with these groups.

What are the costs to me?

There will be no costs or charges to you for taking part in this study. As part of the study, you will receive the study drug and all the study tests and procedures at no cost to you. You and your insurance company will continue to pay for your regular health care.

Will I be asked to join future studies?

By participating in this study, you may become eligible for one or more studies that the COVID-19 Clinical Research Center (CCRC) may conduct. If so, we will contact you and give you additional information about these studies. You do not have to join these studies, and you can tell study staff if you do not want to be contacted.

➢ Who should I call if I have questions or research study problems?

For Questions About	Please Contact
This study and what it involves	Dr. Alpana Waghmare [206-667-7329] Dr. Michael Boeckh [(206) 667-6706] Dr. Jim Boonyaratanakornkit [(206) 667-2379] **Email:** covidmab@fredhutch.org
Your rights as a participant in a research study	Director of Institutional Review Office of the Fred Hutchinson Cancer Research Center: (206) 667-5900 or by email: irodirector@fredhutch.org
Your rights as a participant in a research study and/or concerns or complaints regarding this research study	By Mail: Fred Hutchinson Cancer Research Center 1100 Fairview Ave N, Mail Stop J2-100 Seattle, WA 98109 Or call **toll free**: 206-667-5900 Or by **email**: iro@fredhutch.org and covidmab@fredhutch.org Please reference the following number when contacting the Study Subject Adviser: 10691
What is done to your personal information, or if you require additional information	**Email:** covidmab@fredhutch.org
A research related symptom or injury	Marta Levkova [206-667-6807] Dr. Jim Boonyaratanakornkit [(206) 667-2379]
What if I need emergency care?	Emergency (24 hour) pager: [**206-987-2000]**

FHCRC IRB Approval
02/24/2022
Document Released Date

VOLUNTEER'S STATEMENT

I have carefully read this consent form. This study has been explained to me. I have a choice whether to take part or not to take part in this study. I have been told of the risks and benefits of taking part in this study. I have had the chance to ask questions about it, and all questions were answered to my satisfaction. For future questions I may have, I know I can contact one of the investigators or individuals identified above. I will not begiving up any of my rights by signing and dating this consent form. I now agree to take part in this research study. I give permission to the people and organizations connected with this research study to review and copymy research records, both during and after the study.

I acknowledge that I will be offered a signed and dated copy of this consent form.

By signing and dating this form, I agree:

- To take part in the study.
- That my personal information and biological samples may be used and transferred as described in the form.
- I have been given names of study staff who I can call if I have any questions about the study.
- I know that the study doctor can ask me to stop taking part in the study at any time and he/she will tell me the reason why.
- That my medical records may be sent offsite and a remote review of my records can take place.
- It has been explained to me that I have not waived my legal rights by signing and dating this document. I will receive a copy of this signed and dated document to take with me.

STUDY PARTICIPANT CONSENT TO INFORM PRIMARY DOCTOR OF STUDY PARTICIPATION

☐ **YES** I agree that my primary doctor may be informed about my study participation.

☐ **NO** I do not agree for my primary doctor to be informed about my study participation.

_____(Participant initials)

STUDY PARTICIPANT CONSENT TO TAKE PART IN THE STUDY

By signing and dating below, I agree to take part in the study.	
Study Participant	
Signature:	Date:
Printed Name:	

FHCRC IRB Approval
02/24/2022
Document Released Date

Legally Authorized Representative: Please sign below if you:

- have read this form (or had it read to you);
- had the opportunity to ask questions;
- had the opportunity to discuss the research with the person obtaining consent; and
- agree to consent on behalf of the participant for him or her to participate in this study.

Legally authorized representative:

Printed Name	Signature	Date

Relation to the participant

If you were a witness for a participant who was not able to read this written consent form, sign below to indicate (1) you were present at the consent discussion in person, (2) you witnessed the verbal presentation of the written consent form, and (3) the participant had the opportunity to ask questions and agreed to take part in the study.

Impartial Witness:

Printed Name	Signature	Date

MEDICAL STAFF PERSON'S STATEMENT

I have discussed the above research study, including the study purpose, procedures, risks and benefits, and possible alternatives, with the person signing and dating above. All the elements of informed consent were reviewed and discussed with the participant. Special concerns that the participant expressed were noted and appropriately addressed. I encouraged questions and have answered all questions to the best of my ability. The participant is aware that he/she has a choice in taking part in this study. A signed and dated copy of the consent form will be offered to the participant.

<table>
<tr><td colspan="2">By signing and dating below, I show that:
I have explained the study to the potential study participant and what will happen to his/her blood and swab samples collected during the study.
I have given the potential study participant the chance to ask questions and I have answered them to his/her satisfaction.
I have given the potential study participant enough time to think and decide whether or not he/she wants to take part in the study.
I explained that he/she may talk with others before making a decision.
A copy of this signed and dated Informed Consent Form will be provided to the study participant.</td></tr>
<tr><td>Signature:</td><td>Date:</td></tr>
<tr><td colspan="2">Printed Name:</td></tr>
</table>

Protocol: 10691
Current consent version date: 01/21/2022
Previous consent version date: 12/14/2021
Copies to: Participant medical file, research file