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UNIVERSITY OF WASHINGTON
CONSENT FORM
RG1121418
Multicenter Evaluation of SARS-CoV-2 Vaccines in Patients with CLL/SLL

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Organization:	University of Washington Seattle, WA
Study Site Principal Investigator:	Dr. Chaitra Ujjani (206) 606-1955
24-hour emergency telephone number:	UWMC Paging Operator (206) 598-6190 Please ask the operator to page the hematology/oncology fellow on call.

IRO received 08/06/21

We are asking you to be in a research study. This form gives you information to help you decide whether or not to be in the study. Being in the study is voluntary. Please read this carefully. You may ask any questions about the study. Then you can decide whether or not you want to be in the study.

KEY INFORMATION ABOUT THIS STUDY

- **We would like you to donate extra blood samples for research.**
- This consent is being sought for research purposes. Your participation in this research is voluntary and is not part of your regular health care.
- You have been diagnosed and are undergoing care for a type of cancer that has begun in your blood-forming tissue, such as the bone marrow, or the cells of the immune system.
- The purpose of this study is to find out how your blood immune markers change before and after a vaccination. We will use samples and data to better understand how your body's immune system reacts to the COVID-19 vaccine.
- The main tasks and procedures the study will require you to provide blood samples.
- The risks of participating in this research study include normal risks associated with standard blood draws.

PURPOSE OF THE STUDY

You have been diagnosed and are undergoing care for a type of cancer that has begun in your blood-forming tissue, such as the bone marrow, or the cells of the immune system.

In people who have ongoing health conditions, getting vaccinated is especially important. Vaccines can protect you from serious diseases such as flu, pneumonia, shingles, and COVID-19, and their related complications. However, your health conditions and your medications may change the way vaccines work in your body.

This research study aims to obtain blood from patients with CLL/SLL and study the samples to find out about changes in blood immune markers before and after a vaccination. We also would like to collect clinical data about your immune system and how it responds to vaccines. We will use the samples and data to understand better how your body's immune system reacts to COVID-19 vaccination.

About 500 people will join this study from across the United States. Testing will be done at the University of Washington, in Seattle, Washington. The purpose of the testing is to determine how well your immune systems responds to the COVID-19 vaccine.

We hope this study will help doctors find ways to improve vaccines and reduce the risk of infection in patients with blood cancer. The results may also be useful for other types of blood cancers and provide information for future vaccine studies in these patients.

Your sample will be connected to some of your clinical data and your name in a secure database at your study site. Only a limited number of trained researchers will have access to this information.

Why is this research being done?

We are asking you to participate in this research because you have CLL/SLL. We do not fully understand how commonly used vaccines work in patients who have such conditions. We are unable to predict exactly how the immune system will respond to a vaccine when you receive treatment for your cancer. We want to use these blood samples to find better ways to answer questions about how certain types of cancer and new medications to treat these cancers change the effectiveness of vaccines.

You do not have to be in the study. You are free to say "yes" or "no", or to drop out after joining. If you say "no," you would have no penalty or loss of benefits. Whatever you decide, your regular medical care would not change.

STUDY PROCEDURES

We will collect up to 10 teaspoons (50 ml) of blood for this research on each occasion.

We will try to collect samples at a time when you are already having blood collected as part of your regular treatment or follow up (clinical testing), but you may also be scheduled for the blood draw when no other testing is required. This would require you to have an extra blood draw visit.

If you are joining the study before you receive the 2-dose COVID-19 vaccine series, you will have a blood test prior to receiving your first dose of the COVID-19 vaccine, to determine whether you have ever been infected with COVID-19 before. Samples will then be taken on the day you have the second vaccine, then approximately 1 month, 6 months and 12 months after the second vaccine.

If you are joining the study before you receive the 1-dose COVID-19 vaccine series, you will have a blood test prior to receiving your COVID-19 vaccine, to determine whether you have ever been infected with COVID-19 before. Samples will then be taken 1 to 3 months after the vaccine, then approximately 6 months and 12 months after.

If you are joining the study after you received your 2-dose COVID-19 vaccine series, samples will be taken any time up to 4 months after you received your second vaccine, and then approximately 6 and 12 months after you received your second vaccine.

If you are joining the study after you received the 1-dose COVID-19 vaccine, your samples will be taken between 1 and 4 months after the vaccine, and then approximately 6 and 12 months after.

If you are joining the study after you have received either a 1- or 2-dose COVID-19 vaccine series, and have elected to receive additional booster shots, your samples will be taken 1, 6, and 12 months after your final shot.

If you have already joined the study and are planning to receive a booster shot, you will have a sample taken prior to your scheduled booster shot in addition to the samples mentioned above.

Follow up
If you join this study, we will contact you via telephone every six months after receiving vaccinations for two years. We will ask about any infections you may have experienced since the vaccination or other changes to your health.

Medical records
Once we collect your samples, we will also collect information about you from the medical record. This information may include your name, medical record number, date of birth, date of blood collections, and information about your clinical visits, treatments, and responses to treatment. This information will be associated with the samples you donate, and it will be used in the research study. We will keep this information private.

If you have completed antibody testing, we will be collecting your antibody reports from your local laboratory.

RISKS, STRESS, OR DISCOMFORT

As part of your clinical care, you are already having blood samples collected. This study may require up to one extra blood draw outside of your clinical care. The risks of blood tests are described below:

Blood tests
The risks of blood draws depend on whether the blood is taken by needle directly from a vein or from a device, such as a Port or Hickman catheter, that stays in place for blood tests. If blood is taken from a Hickman catheter, there is usually no pain or bruising.

Likely side effects (≥ 20%) of blood tests are:
- Temporary discomfort if blood is taken straight from a vein.
- A small bruise or redness at the site from which the blood was taken.

Less likely side effects (3-20%) of blood tests are:
- Fainting, sweating or feeling sick in the stomach for a short time
- Bruising larger than a "quarter" coin.

Rare but serious side effects (< 3%) of blood tests are:
- Infection from the blood draw.
- Injury to blood vessels, nerves, or other structures near the blood draw site.

There is a slight risk that information about you or your disease, including blood test results, may be disclosed by accident. This is unlikely as safeguards are in place to keep information related to your blood samples private and confidential.

BENEFITS OF THE STUDY

Although the study will not benefit you directly, we hope the information we learn will help people with blood cancer in the future.

USE OF INFORMATION AND SPECIMENS

How will the samples and information be used?
Your samples will be stored in a freezer in a restricted access lab at your local hospital until they are shipped to the University of Washington and stored there. We may arrange for testing at an outside lab, such as a lab at another research institution. Your samples and clinical information will be coded so that the outside lab and researchers will not receive any personal information about you. However, we will need access to your protected health information in order to link your immune response data to data about you and your CLL. This will help determine whether there are specific things about patients, their CLL or the treatment they receive for CLL that make them more or less likely to respond to the COVID-19 vaccine.

The information and/or specimens that we obtain from you for this study might be used for future studies. We may remove anything that might identify you from the information and

specimens. If we do so, that information and specimens may then be used for future research studies or given to another investigator without getting additional permission from you. It is also possible that in the future we may want to use or share study information that might identify you. If we do, a review board will decide whether or not we need to get additional permission from you.

Protecting your Privacy as an Individual and the Confidentiality of Your Protected Health Information

If you consent to donate blood samples for the research described in this consent form, we must also get your permission to share clinical and related health information about you (also called "Protected Health Information" or "PHI") for use in this research. A separate form called the HIPAA Authorization form describes what we will do if you give your permission (also called an "authorization").

Some organizations may need to look at your medical records for quality assurance or data analysis. These include:

- Researchers involved in this study, including applicable staff at Seattle Cancer Care Alliance, Fred Hutch, and the University of Washington.
- Institutional Review Boards (IRB). An IRB is a group that reviews the study to protect your rights as a research participant.
- The Office of Human Research Protections (OHRP)
- The study sponsor, CLL Global Research Foundation
- The Department of Health and Human Services (DHHS)

We will do our best to keep your Protected Health Information confidential. But we cannot guarantee total confidentiality. Your PHI may be given out if required by law. We will not use your PHI in any reports about this study, such as journal articles or presentations at scientific meetings.

If you join this study, information about your participation would 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.

In the future, if you give permission to any person or group to look at your medical record (such as an insurance company or employer), they could receive information that you agreed to participate in this study. If you have already given permission to anyone (such as your life or health insurance company) to look at your medical record, they may receive this information if they ask for a copy of your medical record.

Returning Results to You

As part of the study, we will be testing for immune response to the vaccine. These results are for research purposes only, but some may be of clinical relevance to you. The testing will be performed on an FDA emergency use authorized assay in a high complexity CLIA certified lab. If you are interested in these results, your provider may share them with you at a later point in time after thorough analysis has been completed.

OTHER INFORMATION

You may refuse to participate and you are free to withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled. If you wish to withdraw, please contact the researcher listed on page 1 of this consent form.

Will you pay me to be in this study?

There is no payment for being in this study.

Your blood samples might help researchers develop new products. This research could involve for-profit companies. There is no plan to share with you any revenue generated from products developed using your tissue samples.

How much will this study cost me?

You or your insurance will be responsible for vaccination charges and blood tests that would normally occur at your clinic visits. You or your insurance company will not be charged for the research test performed on your blood samples.

RESEARCH-RELATED INJURY

If you think you have been harmed from being in this research, contact the study doctor listed on page 1.

What if you get sick or hurt after you join this study?

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

For all other medical problems or illnesses related to this research, immediately contact the primary care provider. They will treat you or refer you for treatment. You or your health insurance will have to pay for the treatment. There are no funds to pay you for a research-related injury, added medical costs, loss of a job, or other costs to you or your family. State or national law may give you the rights to seek payment for some of these expenses. You do not waive any right to seek payment by signing this consent form.

You or your insurer will be billed to treat problems or complications that result from your condition or standard clinical care.

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

Your rights

- You do not have to join this study. You are free to say "yes" or "no."
- If you get sick or hurt in this study, you do not lose any of your legal rights to seek payment by signing this form.
- If you join this study, you would not have to stay in it. You could stop at any time (even before you start). Your regular medical care would not change. You would have no penalty for stopping, but it would be better not to join the study if you think you would change your mind later.

For more information

If you have questions or concerns about this study, you may talk to a member of your study team at any time. Other people you can talk to are listed below.

If you have questions about:	**Call:**
This study (including complaints and requests for information)	206-606-1955 (Dr. Chaitra Ujjani) 206-606-7140 (Heather Rasmussen, Research Manager)
If you get sick or hurt in this study	206-667-5398 (Dr. Chaitra Ujjani)
Your rights as a research participant	206-667-5900 or email irodirector@fredhutch.org (Director of Institutional Review Office, Fred Hutchinson Cancer Research Center) 206-543-0098 (Human Subjects Division, University of Washington)
Your bills and health insurance coverage	206-606-1113 (SCCA Patient Financial Services)

SIGNATURES

Subject's statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, or if I have been harmed by participating in this study, I can contact one of the researchers listed on the first page of this consent form. If I have questions about my rights as a research subject, I can call my study doctor. I give permission to the researchers to use my medical records as described in this consent form. I will receive a copy of this consent form.

Printed name of subject	Signature of subject	Date

If you served as an interpreter or witness during the consent process, sign below to indicate you attest to the accuracy of the presentation to the participant and the apparent understanding of the research by the participant.

Witness or Interpreter / Printed Name	Signature	Date

Copies to: Researcher
Subject
Subject's Medical Record

Researcher's statement

I have discussed the research study, including procedures and risks, with the person signing above. A copy of the signed consent form will be given to the participant.

Printed name of study staff obtaining consent	Signature	Date