

**SERIMMUNE
CONSENT TO BE IN RESEARCH STUDY**

TITLE: Human antibody repertoire profiling for serosurveillance of SARS CoV-2 and other emerging pathogens

PROTOCOL NO.: IRB Protocol #20204131

SPONSOR: Serimmune, Inc

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STUDY-RELATED

PHONE NUMBER(S): (805) 690-5225 ext. 225 (24 Hours)

This is a medical research study, and you do not have to take part. The study administrator will explain this study to you. If you have any questions, you may ask the administrator.

You are being recruited for this study to determine your baseline SARS-CoV-2 antibody status and monitor your blood over time for evidence of SARS-CoV-2 infection/reinfection ²¹using an investigational device.

In this study, the researchers are also collecting blood samples to learn more about how your antibody profile changes over time and after exposure to seasonal or novel emerging pathogens.

About 2,000 people will give blood samples over a five year period for this research.

What will happen if I take part in this study?

If you agree to be in this study, you will be provided with a home blood collection kit to collect. Approximately 100 µl of blood will be drawn from your upper arm. An instructional video will be provided to ensure that the blood is collected accurately. The device is relatively painless. Blood collection will take 5-10 minutes. You will send the blood to the Serimmune lab for processing in a prepaid envelope. The blood should be shipped within 24 hours of collection.

You will be asked to collect blood every 6 months for a period of five years, or 2-3 weeks after onset of illness. Kits will be sent to you on a regular basis, or may be requested if you become ill. If at any time you wish to terminate the study, you may opt out.

You will be given a questionnaire to collect demographic information and medical history. Information gathered will include age, sex, the state and country where you live and your country of origin, medical history including a checklist of previous infections, history of autoimmunity and cancer, and a checklist of drugs that you are currently taking including immunosuppressants, IVIg, or therapeutic Monoclonal Antibodies.

Are there risks?

The blood collection device is relatively painless, but your arm may be sore for a day or two after collection. There is a small risk of bruising.²¹ There may be unforeseeable risks.

Are there benefits?

There is no benefit to you. The blood will be used only for research. You will be provided with a report indicating whether or not you have antibodies to SARS-CoV-2. These antibodies do not mean that you are immune to SARS-CoV-2, but they do indicate whether you have been infected with the virus or received a vaccine.

Please note that these results are from a research assay that is not clinically validated and the assay is not meant to serve as a clinical assay.

Can I say “No”?

Yes, you do not have to donate a blood sample for this study and you may opt out at any time throughout the study.

Are there any alternatives?

This research is not intended to diagnose any disease, your alternative is not to participate.

Will my medical information be kept confidential?

We will do our best to protect the information we collect from you. Information that identifies you will be kept secure and restricted. However, your personal information may be given out if required by law²⁴ and may be reviewed by the sponsor, the U.S Food and Drug Administration (FDA) and the IRB. If information from this research is published or presented at scientific meetings, your name and other identifiers will not be used. Information that identifies you will be destroyed when this research is complete.

How will my specimens and information be used?

Researchers will use your specimens and information to conduct this study. Once the study is done using your specimens and information, we may share them with other researchers so they can use them for other studies in the future. We will not share your name or any other personal information that would let the researchers know who you are. We will not ask you for additional permission to share this de-identified information.

Are there any financial considerations I should know about?

Kathy Kamath, PhD and John Shon, MD are employees and have stock options and/or intellectual property rights with the sponsor. Please feel free to ask any further questions you might have about this matter.

Are there any costs or payments?

There are no costs or payments to you that are associated with this research.

Voluntary Participation and Withdrawal

Your participation in this study is voluntary. If you decide to participate, but later change your mind, you can leave the study at any time. There will be no penalty or loss of benefits to which you are otherwise entitled.

What if I get injured?

Tell the study Principal Investigator if you feel that you have been injured because of being in this research. You can tell the PI in person or call him/her at (805) 690-5225 ext. 225 (24 Hours).

Treatment and Compensation for Injury Statement (standard)

Treatment and Compensation for Injury: If you are injured as a result of being in this study, Serimmune will provide necessary medical treatment. The costs of the treatment may be billed to you or your insurer just like any other medical costs, or covered by Serimmune, depending on a number of factors.

Who can answer my questions about the study?

You can talk to the study administrator about any questions, concerns, or complaints you have about this study. Contact the administrator at (805) 690-5225 ext. 225 (24 Hours).

This research is being overseen by WCG IRB. An IRB is a group of people who perform independent review of research studies. You may talk to them at 855-818-2289 or researchquestions@wcgirb.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

Serimmune Inc. management does not urge, influence, or encourage anyone who works for the company to take part in a research study. Your participation in this study is completely voluntary. You may withdraw from the study at any time and for any reason. Your decision to not participate in the study, or a decision on your part to withdraw from the study, will have no effect whatsoever on your employment status at Serimmune Inc. You may refuse to participate or you may withdraw from the study at any time without penalty or prejudice.

CONSENT

You have been given copies of this consent form and the Experimental Subject's Bill of Rights to keep.

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

Participant's Signature for Consent

Person Obtaining Consent

Experimental Subject's Bill of Rights

California law, under Health & Safety Code '24172, requires that any person asked to take part as a subject in research involving a medical experiment, or any person asked to consent to such participation on behalf of another, is entitled to receive the following list of rights written in a language in which the person is fluent. This list includes the right to:

1. To be told about the nature and purpose of the study.
2. To be told about the procedures to be followed in the research study, and whether any of the drugs, devices, or procedures is different from what would be used in standard practice.
3. To receive a description of any side effects, discomforts, or risks that you can reasonably expect to occur during the study.
4. To be told of any benefits that you may reasonably expect from the participation in the study, if applicable.
5. To receive a description of any alternative procedures, drugs, or devices that might be helpful, and their risks and benefits compared to the proposed procedures, drugs or devices.
6. To be told of what sort of medical treatment, if any, will be available if any complications should arise.
7. To be given a chance to ask any questions concerning the research study both before agreeing to participate and at any time during the course of the study.
8. To refuse to participate in the research study. Participation is voluntary. You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your right to receive the care you would receive if you were not in the experiment.
9. To receive a copy of the signed and dated written consent form and a copy of this form.
10. To be given the opportunity to freely decide whether or not to consent to the research study without any force, coercion, or undue influence.

If you have any concerns or questions regarding the research study you should contact the research team listed at the top of the consent form, by emailing covid19study@serimmune.com or calling (805) 690-5225 ext. 225 (24 Hours).

If you are unable to reach a member of the research team and have general questions, or you have concerns or complaints about the research study, research team, or questions about your rights as a research subject, please contact WCG IRB by emailing researchquestions@wcgirb.com or calling (855) 818-2289.