University of California, San Diego
Consent to Act as a Research Subject

Neutralizing Antibody Project for COVID-19 (ZAP COVID-19)

Dr. Jacobs and her collaborators are conducting a research study to find out more about antibodies to SARS-CoV-2, the virus that causes COVID-19, and risk of contracting the virus. You have been asked to participate in this study because you are a student or employee at UCSD. There will be approximately 20,000 participants at UCSD.

Why is this study being done?
The purpose of this study is to determine whether levels of neutralizing antibodies, a measure of a person's immune response, to SARS-CoV-2 can be used to determine a person's risk of contracting the virus. We are also interesting in understanding how levels of neutralizing antibodies change over time following vaccination.

Study Procedures:

The study consists of a study visit at an existing on-campus test or vaccination site to collect the samples listed below. If you agree to be in this study, the following will happen to you:

Prior to the study visit:
- Complete an online survey of demographic, health characteristics, and attitudes and behaviors towards catching COVID-19.

At the time of the visit, the following procedures will be done:
- Collection of any COVID-19 symptoms.
- An anterior nares swab. This involves putting a swab (which is similar to a small, flexible q-tip) about ½ inch into each nostril to collect a sample from the inside of your nose.
- A fingerstick blood sample. Fingerstick blood samples are collected using a small, sterile needle to make a small prick in your finger tip, and then collecting a few drops of blood on a paper test card.

In addition to the procedures above, we will collect information on dates of COVID-19 vaccination, testing, and results, if applicable, from your medical record maintained at UCSD. Follow-up surveys of current attitudes and behaviors towards catching COVID-19 will be sent to you 30 and 90 days following your initial study visit.

All of the samples you will provide will be used for research purposes (none of them will be used for clinical purposes).

The pre-study health questionnaire and study visit are each expected to take less than 10 minutes to complete. Study visits can be scheduled online at on-campus testing and vaccination sites at a time that is convenient for you. Participation in this research project will not impact your ability to receive separately scheduled COVID testing or COVID vaccination, or any other treatment you have scheduled.

This study will last for up to two years. You may be re-contacted up to every 30 days for follow-up visits where the same procedures may be performed. You may decline participation in any of these visits.

Risks associated with participation:
Participation in this study may involve some added risks or discomforts. These include the following:

1. Soreness at the site of the blood draw.
2. Mild discomfort from anterior nares swab collection.
3. Loss of confidentiality

Because this is a research study, there may be some unknown risks that are currently unforeseeable. You will be informed of any significant new findings.

Alternatives to study participation
The alternative to participation in this study is not to participate.

Benefits to participation
There is not expected to be any direct benefit to you from these procedures. However, if desired, results of the antibody testing will be reported back to you in MyChart for your information only. Antibody levels will be reported as research results in your medical chart approximately 30 days following your study visit, and should not be interpreted as clinical test results. Through your participation, the investigators may learn more about changes in immune response to SARS-CoV-2 over time following vaccination or prior infection, and whether these changes increase risk for contracting the virus. Findings may help inform the value of measuring antibody levels to assess risk and the need for vaccination or booster shots.

Can you choose to not participate or withdraw from the study without penalty or loss of benefits?
Participation in research is entirely voluntary. You may refuse to participate or withdraw at any time without penalty or loss of benefits to which you are entitled. If you decide that you no longer wish to continue in this study, you will be requested to notify the principal investigator, Dr. Marni Jacobs, at mbjacobs@health.ucsd.edu. Your decision will not result in any penalty or loss of benefits to which you are entitled and you will still be able to receive care from and maintain education and employment at UCSD.

You will be told if any important new information is found during the course of this study that may affect your wanting to continue.

Can you be withdrawn from the study without your consent?
You may be withdrawn from the study for the following reasons:

1. Your clinical provider believes that it is in your best medical interest.
2. You may also be withdrawn from the study if you do not follow the instructions given to you by the study personnel.

Will you be compensated for participating in this study?
No compensation will be given for participation.

Are there any costs associated with participating in this study?
There will be no cost to you for participating in this study.

What if you are injured as a direct result of being in this study?
If you are injured as a direct result of participation in this research, the University of California will provide any medical care you need to treat those injuries. The University will not provide any other form of compensation to you if you are injured. You may call the Human Research Protections Program Office at 858-246-HRPP (858-246-4777) for more information about this, to inquire about your rights as a research subject or to report research-related problems.

What about your confidentiality?
Research records will be kept confidential to the extent allowed by law. All protected health information will be kept in locked and/or password protected files. Research records may be reviewed by the UCSD Institutional Review Board.

Personal identifiers might be removed from the information or biospecimens collected as part of the research. After such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

Biospecimens (such as blood and swabs) collected from you for this study and/or information obtained from your biospecimens may be used in this research or other research, and shared with other organizations. You will not share in any commercial value or profit derived from the use of your biospecimens and/or information obtained from them.

Who can you call if you have questions?
If you have any questions about this study or research-related problems, you may reach Dr. Marni Jacobs at 858-249-0972.

You may call the Human Research Protections Program Office at 858-246-HRPP (858-246-4777) to inquire about your rights as a research subject or to report research-related problems.

Your Signature and Consent
You have received a copy of this consent document and a copy of the “Experimental Subject's Bill of Rights” to keep.

You agree to participate.

_____ _____

Subject's signature Date