Do not use this form for consenting research participants unless the Johns Hopkins Medicine Logo appears here.

Date: March 22, 2022
Principal Investigator: William Werbel, MD
Application No.: IRB00248540

WAIVER OF DOCUMENTATION OF CONSENT – ONLINE

Protocol Title: COVID-19 Antibody Testing of Recipients of Solid Organ Transplants and Patients with Chronic Diseases

KEY INFORMATION

This research study is looking at COVID-19 antibodies in transplant recipients, people with chronic diseases, and children that have received a COVID-19 vaccine. Antibodies are proteins that help fight off infections and can show the body's immune response to a COVID-19 vaccine.

PURPOSE

You are being asked to take part in a research study. The purpose of this study is to determine if you have COVID-19 antibodies after receiving a COVID-19 vaccine and increase our knowledge about the vaccine in specific patient populations

PROCEDURES

If you agree to be in this study, we will ask you to do the following things:

- Complete a survey about your medical history, knowledge and exposure to COVID-19.
- We will collect blood at seven time points: baseline testing, 2 weeks, month 1, month 3, and month 6, and month 12.
- Once we receive your sample and process it in our lab, we will contact you with your test results.
- Be available for future contact depending on the test results.
- Some participants may be asked to draw additional 30-50 cc of blood at baseline, 1 and 6 months after their second test for additional testing.

RISKS/DISCOMFORTS

Blood Collection via Seventh Sense TAP Device

The blood collection kit is simple. There may be discomfort, bleeding, or bruising during this process.

Interviews or questionnaires

You may get tired or bored when we are asking you questions or you are completing questionnaires. You do not have to answer any question you do not want to answer.

Identifiable private information

There is the risk that information about you may become known to people outside this study.

BENEFITS

There is no direct benefit to you from being in this study. If you take part in this study, you may help other patients in the future. Information obtained from this study will help us create a program that we can offer to all our patients in the future.

VOLUNTARY PARTICIPATION

You do not have to agree to be in this study. If you do not want to join the study, it will not affect your care at Johns Hopkins.

You can agree to be in this study now and change your mind later. If you wish to stop, please tell us right away. Leaving this study will not stop you from getting regular medical care.

IDENTIFIABLE INFORMATION IN FUTURE RESEARCH

We may use the information or biospecimens collected through this study for future research including research with external collaborators. Generally, when sharing information or biospecimens for future research we will take precautions to remove any information that could identify you (like your name or medical record number) before sharing.

HIPAA DISCLOSURE

We will collect information about you in this study. People at Johns Hopkins who are involved in the study or who need to make sure the study is being done correctly will see the information.

People at Johns Hopkins may need to send your information to people outside of Johns Hopkins (for example, government groups like the Food and Drug Administration) who are involved in the study or who need to make sure it is being done correctly.

These people will use your information for the purpose of the study.

Your Authorization for the collection, use, and sharing of your information does not expire. We will continue to collect information about you until the end of the study unless you tell us that you have changed your mind. If you change your mind and do not want your information to be used for the study, you must contact the Principal Investigator at 443-874-3522. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

We try to make sure that everyone who needs to see your information uses it only for the study and keeps it confidential - but we cannot guarantee this.

CONTACT INFORMATION:

If you have any questions about this study, please feel free to contact the Principal Investigator Dr. William Werbel at covidtransplant@jhmi.edu.

The IRB can help you if you have questions about your rights as a research participant or if you have other questions, concerns or complaints about this research study. You may contact the IRB at 410-502-2092 or jhmeirb@jhmi.edu.