WAIVER OF DOCUMENTATION OF CONSENT SCRIPT

Protocol Title: COVID-19 Antibody Testing of Patients with ESRD (Hemodialysis Patient)

KEY INFORMATION

The COPE study is a research study to test for the presence of COVID-19 antibodies in patients with End Stage Renal Disease (ESRD) and people they live with to help us improve our knowledge and understanding of the disease as well as to determine the impact of the disease on psychological and social behaviors.

Participation involves completing a survey about your medical history, any potential COVID-19 related symptoms and behaviors, testing history, and other questions that will help us better understand the disease and how it has impacted you. You will also receive two at-home antibody test kits through the mail: one for you and one for a member of your household who is not on hemodialysis. You will collect 0.1 ml of your blood and return the kit via mail to the Johns Hopkins Hospital. Your samples will be tested for possible COVID-19 exposure. Testing kits will be sent four times: initial testing, month 2, month 4, and month 6.

The main risks are from the temporary discomfort from the collection of blood samples, feeling uncomfortable about answering questions, and that information may become known to people outside of the study. You will not benefit directly from being in the study and there is no payment for participation.

PURPOSE

You are being asked to take part in a research study. The purpose of this study is to determine if you have antibodies to COVID-19 and to increase the knowledge about virus transmission within dialysis centers.

PROCEDURES

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

- Complete a survey to ask you questions about your medical history, exposure to COVID-19, your awareness, knowledge and concerns about the disease, social distancing practices, and other questions that will help us better understand the disease and how it has impacted your psychological and social behaviors. The survey will take about 15-20 minutes to complete and will happen every time you receive a testing kit. The survey can be completed by your preferred method: by telephone or online.
- Receive a COVID-19 antibody testing kit in the mail. The testing kits will be sent four times: initially, at 2, 4, and 6 months. Directions are provided in the kit on how to collect a small amount of blood. You will return the testing kit and your samples to the labs at Johns Hopkins in the pre-paid envelope.

If you will be obtaining a SARS-CoV-2 vaccine for your standard clinical care, you will receive two at-home blood collection kits that will be used to test your blood for antibodies before your first vaccine dose and before your second dose. You will also receive additional kits for blood collection at 1 month, 3 months, 6 months, and 12 months after your second dose.

Once we receive your sample and process it in our lab, we will contact you to inform you of your test results by your preferred contact method: by phone, email or by letter.

Be available for future contact depending on your test results.

RISKS/DISCOMFORTS

You may get tired or bored when we are asking you questions or are completing the survey. You do not have to answer any question you do not want to answer. You may stop the survey at any time.

You may experience some pain or discomfort, bleeding, or bruising when obtaining a sample of your blood. There is a small risk of infection.

You may experience anxiety, frustration, and feelings of uncertainty while awaiting your test results. There may be undue stress associated with finding out about a previous exposure to COVID-19through antibody testing even if you did not experience any symptoms.

There is the risk that information about you may become known to people outside this study. However, this risk is minimal as all information collected about you and data gathered from the survey will be kept strictly confidential. All data we collect will be stored in a secure, password-protected database accessible only to members of the study team.

BENEFITS

There is no direct benefit to you from being in this study. By taking part in this study, you are contributing to a better understanding of the disease which may help healthcare providers and other patients in the future.

VOLUNTARY PARTICIPATION

Your participation in the study is completely voluntary. 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 or at your healthcare provider.

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 need to make sure the study 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 by using the contact information provided in this document. 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, Mara McAdams DeMarco, PhD at 410-502-1950 or the Research Program Manager, Maria Lourdes B. Steckel at 443-287-0613. You may also contact us via email at covidesrd@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 410-955-3008 or jhmeirb@jhmi.edu.