Date: April 26, 2022
Principal Investigator: William Werbel, MD
Application No.: IRB00248540

WAIVER OF ASSENT/DOCUMENTATION OF PARENTAL PERMISSION – ONLINE

Protocol Title: COVID-19 Vaccine Antibody Response in Recipients of Solid Organ Transplants and Patients with Chronic Disease Study

KEY INFORMATION

This research study is being done to examine the immune response in transplant recipients or patients with chronic diseases who have received a COVID-19 vaccine. Antibodies and white blood cells (T and B cells) are important components of the immune system that help fight off infections and can show the body's immune response to a COVID-19 vaccine.

PURPOSE

You are being asked to allow your child to take part in a research study. The purpose of this study is to characterize your child's immune response (antibody or cellular) after receiving a COVID-19 vaccine and increase our knowledge about the vaccine in specific patient populations

PROCEDURES

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

Surveys:

- Complete an enrollment survey about your child's medical history, knowledge, and exposure to COVID-19.
- Complete follow-up surveys at scheduled time points to assess how your child has been doing after vaccination.
- Be available for contact during the study period and future.

Antibody Testing:

- Visit your local LabCorp facility or regular clinic with provided study requisition forms to collect and process blood from your child for antibody testing at scheduled time points.
    - Time points: before receiving any vaccine (baseline), between their first and second vaccine, and 1, 3, 6, 12 month(s) after their second vaccine.
    - If you and your child's transplant team plan on getting your child any additional COVID-19 vaccines, there may be an additional scheduled lab before your child's additional vaccine. In addition, the 1, 3, 6, 12 month(s) lab dates will then be based on your child's last vaccine date.

- Once your child's blood has been processed by LabCorp and their antibody result is available, our study group will contact you with the results directly.

Cellular Testing:

- You may also be asked to allow your child to participate in additional T and B cell studies. If your child participates, we will ask to collect blood samples using phlebotomy services or additional testing sites from your child. These samples will be stored and processed at institutional facilities by our basic science team.

If your child weighs less than about 52 pounds (24 kg), the blood for antibody testing and the blood of cellular testing will have to be collected on separate days.

RISKS/DISCOMFORTS

Blood Collection: Blood collection is simple and fast. However, there may be discomfort, bleeding, or bruising for your child during this process.

Interviews or questionnaires: You may get tired or bored when we are asking you questions or when you are completing questionnaires about your child. You do not have to answer any question about your child that you do not want to answer.

Identifiable private information: There is the risk that information about your child may become known to people outside this study.

In order to protect confidentiality of your child's personal health information (PHI):

- The information we collect will be kept in a secure, web-based application designed to support data capture for research studies.
- Your child will be assigned a unique subject ID.
- No public records or publications will contain PHI.

BENEFITS

There is no direct benefit to your child from being in this study. If your child takes part in this study, your child 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 for your child to be in this study. If you do not want your child to join the study, it will not affect your child's care at Johns Hopkins or other study institutions.

You can agree for your child to be in this study now and change your mind later. If you and your child wish to stop, please tell us right away. Leaving this study will not stop your child 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. When sharing information or biospecimens for future research, we will take precautions to remove any information that could identify your child (like your child's name or medical record number) before sharing.

HIPAA DISCLOSURE

We will collect information about your child 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 child's 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 child's information for the purpose of the study.

Your Authorization for the collection, use, and sharing of your child's information does not expire. We will continue to collect information about your child 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 child's information to be used for the study, you must contact the Principal Investigator at (443)-252-2811. 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 child's 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 contact our study email at <covidpedstransplant@exchange.johnshopkins.edu> or call (443)-252-2811.

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.