RESEARCH SUBJECT INFORMATION AND CONSENT FORM

Subject Name: _____

Title of Protocol: Evaluation of Post-Vaccinated Neutralizing Antibodies following the Pfizer COVID Vaccine

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This consent form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that you do not clearly understand.

1. Purpose of the Study:

You are being asked to voluntary participate in a research study. You are being asked to take part because you have taken the Pfizer COVID vaccine. This research is being done to determine the rise in antibody production following vaccine administration. Antibodies are proteins that recognize the virus and help your body get rid of it. Prior findings so far suggest that people's bodies make

antibodies to the virus after the first vaccine dose and even more following the second dose. Using this test, we will also look at any racial/ethnic and/or gender differences in response to the vaccine. This research study may help to lead to better understanding of the response to the vaccine and protection against the SARS-CoV-2 (COVID-19) virus. Because many people who are infected with COVID-19 do not have any symptoms, we will also check saliva samples for the presence of active viral infection at the time of each blood draw. Approximately 300 participants who are greater than 18 years of age will take part in the study at Woman's Hospital in Baton Rouge, Louisiana. Your part in this study will take about 75 minutes (Five 15 minute visits over 1 year).

Procedures

If you take part in this study, you will give us the following information about yourself:

- date of birth
- child birth status
- dates of vaccine injection(s)
- race/ethnicity
- gender
- height
- weight
- cigarette smoking history
- blood pressure (normal or high)
- medicines that you are currently taking
- immunocompromising diseases (type 2 diabetes, lupus, rheumatoid arthritis, cancer chemotherapy)
- history of vaccine reactions
- COVID medical history including prior COVID antibody testing, recent exposure to COVID, positive test for COVID

You will be asked to give 5 blood samples over 1 year after your first vaccine shot. You will be asked to come to the laboratory at Woman's to give a blood sample approximately 14 days after your first vaccine dose. A second vaccine dose will be administered 21 days later. There will be another blood draw approximately 7 days after your second vaccine dose (28 days from the first dose). Another blood sample will be ordered 6 months after the first shot, another 9 months after the first shot, and at 12 months after the first shot. We will help schedule all of your blood draws.

During each testing period, a blood sample will be taken from your arm. There will be 5ml of blood drawn at each of the 5 collections (about 1 teaspoon of blood per draw). A total of 2 tablespoons of blood will be drawn during your taking part in this study. This study will take about 15 minutes for each blood draw. **We will also ask you to collect a saliva sample at the time of each blood draw.** We will follow-up your vaccination health and outcome by looking over the medical forms we have asked you to fill out.

You will have your blood drawn in the main Pathology lab on the second floor of the Support Services Building. Your saliva sample will be returned to the lab where you got your blood drawn. You will be provided with an appointment card after consented that will instruct you on when to return to the lab to provide a blood and saliva specimen.

Your blood and saliva samples will be analyzed at Woman's Hospital Pathology Laboratory. Your blood and saliva samples will also be sent to Pennington Biomedical Research Center for further analysis. Your samples will be "de-identifed" (will not have your name rather a study identification number). After the analysis is done your remaining samples will be stored at Pennington Biomedical Research Center until study completion.

If you have had antibody levels drawn or saliva samples submitted prior to enrollment of this study and the samples were within the window of collection described above, (whether drawn as part of clinical testing, lab quality control or in in preparation for this study), we ask if we may use the left over blood samples to be included as part of this study.

Please add your initials below if we may use your left over blood and saliva samples collected prior to your enrolling in this study for inclusion in this study:

_____ Initials

Should you develop COVID related symptoms, please let us know by calling 225-231-5275. We will ask you to provide an additional saliva sample within 3 days of symptom development in a collection kit we will give you so that we can test you for the COVID-19 virus. Please call the research department (225-231-5275) to let us know you need to pick up a kit.

2. Risks/Side Effects

The risks and discomforts in taking blood for this study are no different from those in taking blood for regular blood tests. A needle stick in your arm may cause local pain, bruising, and swelling, as well as lightheadedness, dizziness, and rarely, fainting and/or a local infection. To minimize risk, a pressure dressing will be applied to the blood draw site. You will be told to watch for signs of infection to the area.

There may be risks or side effects that are not known at this time.

If you do not understand any of the above risks you may talk about them with Dr. Ogden or Dr. Elkind-Hirsch at (225) 231-5275. Although the risks of developing the above side effects are small, they do exist. Your primary care physician is still responsible for your medical care.

3. Benefits

You may not get any direct benefit from this study. The information from the post-vaccination antibody tests may be of future use to you. They may help predict your response to the vaccination. Society could gain from learning if this test can better predict which participants respond to the vaccine and how long the vaccine produces an immune response. If you should develop COVID related symptoms during this study, we will provide testing for you at no charge using the saliva collection kit.

4. Alternative Treatment

You do not have to be in this study to get vaccinated. Your participation is voluntary and if you decide not to enter this study, you will still get the vaccine.

5. Costs

There will be no charge for the blood tests. Your results will be offered to you as well as your private doctor(s) [if you give separate written consent for information to be sent to your doctor(s)] **at the completion of the evaluation of your antibody status.** Your health insurance company or you will pay for all other costs associated with your medical care.

6. Confidentiality

The results of this study may be published. Your name and identity will be kept private although absolute confidentiality cannot be guaranteed. The files will be kept in a locked filing cabinet, and all computer-stored information will be password protected. The Woman's Hospital Foundation Institutional Review Board, Woman's Hospital Research and Development Committee, Woman's Hospital Research Center, and government agencies, as required, may also check your medical and study records. The data will be kept for 5 years.

7. Contacts for Extended Medical Care

If an injury happens while you are taking part in this study, medical care will be given to you. No funds have been set aside to pay your costs in the event of an injury as a result of this study. The cost of this medical care will be the responsibility of you and/or your insurance company. You are not giving up any of your legal rights by signing this form.

If you are hurt while taking part in this study, you should contact Dr. Beverly Ogden at the Woman's Hospital Research Center at (225) 231-5275 and your primary care physician. For more information about this research or patients' rights in research, you may also contact Ericka Seidemann, Human Protections Administrator at (225) 231-5296.

8. Termination of Participation

At any time, you may ask that your test results not be used for research. Your decision to not take part will not have a penalty. You can leave the study at any time without

changing your further care. You can also call Dr. Elkind-Hirsch at (225) 231-5278 if you no longer wish to take part in the study. The researchers may need to stop your taking part in the study for any of the following reasons:

- not following study instructions
- new information about the vaccine is discovered that may affect your wish to continue taking part
- the study doctor feels it is in your best interest

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Signature page follows.]

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Acknowledgement Of Receipt Of Information And Consent To Participate

I HAVE HAD AMPLE OPPORTUNITY TO ASK ANY QUESTIONS CONCERNING THE STUDY AND MY PARTICIPATION IS VOLUNTARY AS REFLECTED BY THE SIGNED STATEMENT BELOW.

I have read the preceding description and have heard the verbal explanation of these procedures from my doctor. I freely give my consent to participate in this research. I have the right to ask questions and may refuse to continue in the study any time.

During the course of the research study, I will be informed of any new significant findings that may relate to my willingness to continue to participate.

At any time I am free to discuss with my doctor or his/her designee or the WHF Human Protections Administrator my rights as a participant and any side effects that might occur.

I AM MAKING A DECISION WHETHER OR NOT TO PARTICIPATE IN THIS STUDY. MY SIGNATURE INDICATES THAT I HAVE DECIDED TO PARTICIPATE, HAVE READ (OR BEEN READ) THE INFORMATION PROVIDED HEREIN, AND THAT I HAVE RECEIVED A COPY OF THIS INFORMED CONSENT FORM.

_____

Participant Name Date

_____

Participant Signature Date

_____

Signature of Person Administering Consent Date