ASSENT AND CONSENT FOR 12-17 YEAR-OLD PARTICIPANTS

STUDY TITLE: An Exploratory Longitudinal Study on the Immune Response to COVID-19 Vaccines

Protocol Number: ACU-COVID-01

Sponsor: **Abilene Christian University**

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Co-Investigator: George B. Thornton, Ph.D.
Co-Investigator: Michael L. Corrado, M.D.
Co-Investigator: Jennifer R. Huddleston, Ph.D.

Research Site: **Dept of Biology, Abilene Christian University**
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Abilene, TX 79699
Phone: 325.674.4883

1. Researchers' Statement:

You have the option to take part in a research study. The goals of this form are to give you information about what would happen in the study if you choose to take part and to help you decide if you want to be in the study.

Feel free to take notes, write questions or highlight any part of this form.

Potential Participants: This form also serves as an assent form. That means that if you choose to take part in this research study, you would sign this form to confirm your choice. Your parent or guardian would also need to give their permission and sign this form for you to join the study.

Parents/Guardians: You have the option of having your child or teen join a research study. This is a parental permission form. It provides a summary of the information the research team will discuss with you. If you decide that your child can take part in this study, you would sign this form to confirm your decision. If you sign this form, you will receive a signed copy for your records.

The word **"you"** in this form refers to your child/teen.

2. What you should know about this study:

- This form explains what would happen if you join this research study.
- Please read it carefully. Take as much time as you need.

- Please ask the research team questions about anything that is not clear.
- You can ask questions about the study any time.
- If you say 'Yes' now, you can still change your mind later.
- You get to decide if you will take part in this study.
- You can quit the study at any time.
- You would not be penalized if you decide not to take part in the study or to quit the study later.

3. What is the goal of this study?

The goal of any research study is to answer questions. We want to answer one question, which is how long do vaccines for COVID-19 protect people? To help us know this, we want to take small samples of your blood over the next few months and test it for antibodies. Antibodies are large Y-shaped proteins that can stick to the surface of viruses and instruct the other cells of your body to attack the viruses. These antibodies can help protect you from getting sick with COVID-19. We want to know the levels of these antibodies in your body at different points in time.

4. Why do I have the option of joining the study?

You have the option to take part in this research study because you are about to be vaccinated or you have been vaccinated against COVID-19. If you have had naturally acquired COVID-19 and recovered, you may choose to join the study as well.

5. How many people will take part in the study?

We think that about 500 people will take part in this research study at ACU.

6. If I agree to join this study, what would I need to do?

If you join the study, you would have some blood drawn (taken). We would like you to come to ACU for blood draws. We would take no more than 2 teaspoons of blood at a time, maybe less depending on your weight. A professional phlebotomist will draw your blood. Each visit will take about 10 minutes. Your donated blood and its antibodies will then be studied in the lab. This will help the scientists and doctors determine how well and how long vaccines work.

7. How long would I be in the study?

Your participation in this study will require multiple visits that each visit will take approximately 10 minutes to complete. You are asked to complete the 1st draw within two weeks before you receive 1st shot of the COVID vaccine. Participants are asked to complete following blood draws two weeks and up to six weeks after a major event (such as vaccine shot, natural infection, anti-

viral therapy, and antibody infusion). After major events, you may come in for blood draws every three months for up to two years.

8. What are the potential harms or risks if I join this study?

The risks of drawing blood from your arm includes discomfort at the site of the needle stick, your arm might bruise or swell around the site of the needle stick, although this is rare, you might get an infection, and you might feel faint, like you are going to pass out, from the blood draw. There are also risks that your personal information could be shared with other people.

9. What are the potential benefits if I join this study?

Potential Benefits for You:

We do not expect this study to benefit you.

Potential Benefits for Others:

The knowledge to be gained from this research may be beneficial for other people or science.

10. What other options do I have?

You get to decide if you will take part in this activity.

11. How would you keep my information confidential?

If you take part, we will make every effort to keep your information confidential.

We will store all of your research records in locked cabinets and secure computer files at ACU. We will not put your name on any research data. Instead, we will label your information with a code number. The master list that links a person's name to their study number is stored in a locked cabinet or on a secure computer file. Your name initials, address (only with city and state information), phone number, email address, and age will be recorded in case report forms.

If results of this research are published, we would not use information that identifies you.

We would only use your information for research. These are some reasons that we may need to share the information you give us with others:

- If it's required by law.
- If we think you or someone else could be harmed.

- Sponsors, government agencies or research staff sometimes look at forms like this and other study records. They do this to make sure the research is done safely and legally. Anyone who reviews study records would keep your information confidential.

12. Would I get to see/know my antibody levels during the study?

Yes, upon your request, your antibody levels will be provided to you after related experiments are successfully conducted and analyzed. However, results from this study should not be used to make any medical decisions.

13. Would it cost me money to be in the study?

If you take part in this study, there would be no cost to you.

14. Would I be paid if I join this study?

You will not be paid to take part in this study.

15. Who do I contact if I have problems, questions or want more information?

If you have any questions, concerns or complaints about the research, or develop a research-related problem, contact Dr. Xu at:
Dept of Biology
ACU Box 27868
Abilene Christian University
Abilene, TX 79699
Tel: 325-674-4883
Email: qxu@acu.edu

If you have questions about your rights as a research subject, you should contact the Institutional Review Board at:
Office of Research and Sponsored Programs
320 Hardin Administration Building
ACU Box 29103
Abilene, Texas 79699-9103
Phone: 325-674-2885
Fax: 325-674-6785
Email: orsp@acu.edu

16. If I join the study, can I stop?

Yes. Taking part in research is always a choice. If you decide to be in the study, you can change your mind at any time.

17. What would my signature on this form mean?

Your signature on this form would mean:

- The research study was explained to you.
- You had a chance to ask all the questions you have at this time. All your questions have been answered in a way that is clear.
- You understand that the persons listed on this form will answer any other questions you may have about the study or your rights as a research study participant.
- You have rights as a research participant. We will tell you about new information or changes to the study that may affect your health or your willingness to stay in the study.
- By signing this consent form, you do not give up any of your legal rights. The researcher(s) or sponsor(s) are not relieved of any liability they may have.
    - You agree to take part in the research study.
    - If the person reading this form is a parent/guardian, you agree to have your child take part in this research study.

Please Note: If the person taking part in this research study is a foster child or a ward of the state, then please tell the researcher or their staff.

_____

Printed Name of Research Participant

_____

Signature of Research Participant (required if 12 years or older)

_____ _____

Date *Time*

_____

Printed Name of Parent or Legal Guardian

_____

Signature of Parent or Legal Guardian

_____ _____

Date *Time*

18. Researcher's Signature

I have fully explained the research study described by this form. I have answered the participant and/or parent/guardians questions and will answer any future questions to the best of my ability. I will tell the family and/or the person taking part in this research of any changes in the procedures or in the possible harms/possible benefits of the study that may affect their health or their willingness to stay in the study. It is my opinion that the participant understands the risks, benefits, alternatives and procedures involved with this research study.

_____

Printed Name of Researcher Obtaining Parental Permission or Consent

_____

Signature of Researcher Obtaining Parental Permission or Consent

_____ _____

Date *Time*