

**University of Wisconsin-Madison
Consent to Participate in Research
and
Authorization to Use Protected Health Information for Research**

Study Title for Participants: EVADE: SARS-COV2 Vaccine Effectiveness

Formal Study Title: Evaluating SARS-CoV2 Vaccine effectiveness Among health care personnel During Early phase vaccination

Lead Researcher: Nasia Safdar, MD, PhD

Where Lead Researcher works: Department of Medicine, University of Wisconsin-Madison School of Medicine and Public Health

Invitation

We invite you to take part in a research study to evaluate the effectiveness of the SARS-COV2 vaccine in during early phase implementation. We are inviting you because you are a healthcare worker who has been tested for COVID-19. This includes all paid and unpaid persons in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials.

The purpose of this consent and authorization form is to give you the information you need to decide whether to be in the study. It also explains how health information will be used for this study and requests your authorization (permission) to use your health information. Ask questions about anything in this form that is not clear. If you want to talk to your family and friends before making your decision, you can. When we have answered all your questions, you can decide if you want to be in the study. This process is called “informed consent.”

Why are researchers doing this study?

The purpose of this research study is to evaluate the effectiveness of the SARS-COV2 vaccine in during early phase implementation. We are doing this research to learn how these vaccines work in a real life setting before the widespread distribution to the general public.

This study is being done at the University of Wisconsin-Madison (UW-Madison). A total of about 1000 people will participate in this study.

Funding for this study is provided by Centers for Disease Control and Prevention

What will happen in this study?

If you decide to participate in this research study, the researchers will ask you to respond to eligibility questions, complete a baseline enrollment form around the time of COVID testing, and may ask you to provide data release permission for vaccine records, testing records, and medical records if more information is needed.

You may elect to complete the survey via electronic survey or telephone interview.

You may skip any question on the questionnaire and/or in the interview that you do not wish to answer.

Protected health information (PHI) used in this study

Protected health information, also called PHI, is information about your physical or mental health that includes your name or other information that can identify you, like your date of birth or medical record number. To do this study, we will use the following kinds of PHI:

- Results of tests or procedures done as part of the study
- Things you tell the researchers about your health
- Information currently in your medical records as well as information added to your medical records during the course of this study. This information could include medical records on clinical signs and symptoms of illness, laboratory tests for SARS-CoV-2 (test type, date, result), vaccination history, and underlying medical conditions. We will get this information from your health care providers such as UW Health and Employee Health and we may ask for you to sign a medical release of information, if additional information is necessary.

How long will I be in this study?

You will be part of the study for about 4 weeks. You will be asked to complete a survey during your time in the study. We anticipate this survey may take up to 1 hour of your time.

Do I have to be in the study? What if I say “yes” now and change my mind later?

No, you do not have to be in this study. Taking part in research is voluntary. This means that you decide if you want to be in the study. If you decide now to take part, you can choose to leave the study at any time.

If you decide to be in the study, the researchers will tell you about new information or changes in the study that may affect your willingness to continue in the study.

Let the researchers know if you choose to leave the study.

If you decide not to take part in the study, or if you choose to leave the study, your choice will not affect any treatment relationship you have with healthcare providers at UW-Madison, UW Health, or any affiliated organizations, or any services you receive from them. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

Your authorization for researchers to use your protected health information (PHI) does not have an end date. However:

- You can choose to take back your authorization for researchers to use your health information. You can do this at any time before or during your participation in the research.
- If you take back your authorization, information that was already collected may still be used and shared with others, but the researchers will no longer be able to collect NEW information about you.
- If you take back your authorization, you will not be able to take part in the research study.
- To take back your authorization, you will need to tell the researchers by writing to the Lead Researcher, Nasia Safdar at University of Wisconsin-Madison, Division of Infectious Disease, 5th Floor UW Medical Foundation Centennial Building, 1685 Highland Ave, Madison, WI, 53705.

What are my other choices if I do not take part in this study?

You do not have to be in this research study to be protected in your work caring for patients. If you decide not take part in the study, you will still have access to all other infection protection equipment and procedures (for example, personal protective equipment) as designated by your employer.

Participation in this research study, or refusal to do so, will not affect your employment.

Will being in this study help me in any way?

- Being in this study will not help you directly. Your participation in the study may benefit other people in the future by helping us learn more about how these vaccines work in a real life setting before the widespread distribution to the general public.

What are the risks?

There is a risk that your information could become known to someone not involved in this study.

Will being in this study cost me anything?

There will be no cost to you for any of the study activities or procedures.

Will I be paid or receive anything for being in this study?

As a thank you for your efforts in participating in this study you will receive a \$15 stipend at the completion of study participation.

How will researchers keep my research information confidential?

We have strict rules to protect your personal information and protected health information (PHI). We will limit who has access to your name and other information that can identify you; all research data will be handled with the highest confidentiality and discretion by trained researchers who are approved to work on this study. We will also store this information securely. All samples you provide will have your name and all personal information removed. Only authorized study team members will be able to trace your samples and data back to you, and they will perform all work following UW's privacy policy. No study results that could identify you will be shared with others outside of the study.

However, we cannot promise complete confidentiality. Federal or state laws may permit or require us to show information to university or government officials responsible for monitoring this study. We may also have to tell appropriate authorities, such as child protective services or health care providers, if we learn during the study that you or others are at risk of harm (for example, due to child or elder abuse, or suicidal thoughts). Authorizing the research team to use your PHI means that we can release it to the people or groups listed below for the purposes described in this form. Once your health information is released outside UW-Madison or UW Health it may not be protected by privacy laws and might be shared with others. Also, with appropriate institutional permissions and confidentiality protections, we might use information and biospecimens that we collect during this study for other research or share with other researchers without additional consent or authorization from you or your legally authorized representative.

Who at UW-Madison can use my information?

- Members of the research team
- Offices and committees responsible for the oversight of research

Who outside the UW-Madison may receive my information?

- U.S. Office for Human Research Protections
- The study sponsor the Centers of Disease Control and Protection,

Will information from this study go in my medical record?

- None of the information we collect for this study will go in your medical record. The researchers are not required to release health information to you if it is not part of your medical record.

What if I have questions?

If you have questions about this research or you feel you have been harmed by participating in this study, please contact the Lead Researcher, Nasia Safdar at (608) 213-4075. If you have any questions about your rights as a research subject or have complaints about the research study or study team, contact UW Health Patient Relations at 608-263-8009. The Patient Relations Representatives work with research subjects to address concerns about research participation and assist in resolving problems.

Agreement to participate in the research study

You do not have to continue with this research.

If you [check the box the line below], [or continue with telephone interview], it means that:

- You have read this consent and authorization form.
- You have had a chance to ask questions about the research study, and the researchers have answered your questions.
- You want to be in this study.
- You give authorization for your protected health information to be used and shared as described in this form.