Informed Consent Form

SARS-CoV-2 Vaccination Strategies in Previously Hospitalized and Recovered COVID-19 Patients

03 August 2021

NCT04969250

Appendix A Sample Informed Consent form

Short Title: Vaccination for Recovered Inpatients with COVID-19 (VATICO)

Sponsored by: The University of Minnesota (UMN)

Funded by: The National Institute of Allergy and Infectious Diseases (NIAID), US National Institutes of Health (NIH)

Full Title of the Study: SARS-CoV-2 Vaccination Strategies in Previously Hospitalized and Recovered COVID-19 Patients

CONSENT FOR PARTICIPATING IN AN NIH-FUNDED RESEARCH STUDY

SITE INVESTIGATOR:_____ PHONE: _____

ALL SITE INSTRUCTION THAT IS INCLUDED IN A TEXT BOX SHOULD BE REMOVED FROM THE SITE'S INFORMED CONSENT FOR PARTICIPANTS

US Office for Human Research Protections (OHRP) Requirements to be read by the sites:

PLEASE NOTE THAT THIS SAMPLE LANGUAGE DOES NOT PREEMPT OR REPLACE LOCAL IRB/EC REVIEW AND APPROVAL. INVESTIGATORS ARE REQUIRED TO PROVIDE THE LOCAL IRB/EC WITH A COPY OF THIS SAMPLE LANGUAGE ALONG WITH THE LANGUAGE INTENDED FOR LOCAL USE. LOCAL IRBs/ECs ARE REQUIRED TO WEIGH THE UNIQUE RISKS, CONSTRAINTS, AND POPULATION CONSIDERATIONS AS A CONDITION OF ANY APPROVAL. ANY DELETION OR SUBSTANTIVE CHANGE OF INFORMATION CONCERNING RISKS OR ALTERNATIVE TREATMENT MUST BE JUSTIFIED BY THE INVESTIGATOR, APPROVED BY THE LOCAL IRB/EC, AND NOTED IN THE IRB/EC MINUTES. JUSTIFICATION AND IRB/EC APPROVAL OF SUCH CHANGES MUST BE FORWARDED TO THE INTERNATIONAL COORDINATING CENTER OR COLLABORATING NETWORK. SPONSOR-APPROVED CHANGES IN THE PROTOCOL MUST BE APPROVED BY THE LOCAL IRB/EC BEFORE USE UNLESS INTENDED FOR THE ELIMINATION OF APPARENT IMMEDIATE HAZARD. NEW INFORMATION SHALL BE SHARED WITH EXISTING SUBJECTS AT NEXT ENCOUNTER, WITH ALL NEW SUBJECTS PRIOR TO INVOLVEMENT, OR AS THE LOCAL IRB/EC MAY OTHERWISE ADDITIONALLY REQUIRE.

Key information:

You are being asked to take part in this research study because you were treated with investigational therapy or placebo in the ACTIV-3/TICO research study and have not yet had a COVID-19 vaccination. We are trying to find out the best time to give COVID-19

vaccine to people who have already had COVID-19. We are also trying to find out the best number of shots to give after you recover from COVID-19. It is your choice whether or not you want to join. This form gives you information about the study that will help you make your choice. You can discuss this information with your doctor or family or anyone else you would like before you make your choice. Your choice will not affect the care you are getting.

WHY IS THIS STUDY BEING DONE?

New vaccines are being developed for the virus that causes COVID-19. Some of the vaccines have received Emergency Use Authorization from the US Food and Drug Administration (FDA). This means the FDA has given permission for them to be used even though they have not completed the full FDA approval process. Studies of these vaccines are still going on, and there are some scientific and medical questions that have not yet been answered. For example:

- we do not know how well a person's immune system responds to a COVID-19 vaccine if they have had SARS-CoV-2 infection, and
- we do not know how a person's immune system responds to vaccination after being treated for COVID-19.

This study is for people who had COVID-19 and received the study treatment or placebo as part of the ACTIV-3/TICO study. This study is looking at how the immune system responds to one type of COVID-19 vaccine called an mRNA vaccine. The vaccines made by Moderna and Pfizer, for example, are mRNA vaccines. You might respond more or less strongly to the vaccine because you've had COVID-19. There may be no change.

We will be trying different vaccine schedules to find out if a person's response to the vaccine changes due to when the vaccine is given or the number of doses given. We think that the immunity you get from having COVID-19 might be like getting one dose of

vaccine. If that is so, then getting just one more shot would be like getting a "booster" shot. You might have the same response as someone who never had COVID-19 and gets 2 doses of vaccine.

At least one study has shown that it might be better to wait longer between vaccine doses than the usual 3 to 6 weeks. If your COVID-19 infection is like a first vaccine dose, we want to see if your immune response to the shot is stronger if you wait longer to get vaccinated. We do not know if this is what will happen.

WHAT DO I HAVE TO DO IF I AM IN THIS STUDY?

The study staff following you in TICO will check to see if there is any reason you should not be in the study. They will check your medical history, including whether you have already been vaccinated. If you got vaccinated since you joined the TICO study, you cannot be in this study.

Everyone in this study will be scheduled to get an available mRNA vaccine to help prevent another SARS-CoV-2 (COVID-19) infection. We are studying whether you should get the vaccine right away or about 12 weeks from now. We are also studying whether you should get one or two doses of the vaccine. If you join the study, you will be assigned by random chance – like rolling dice – to one of 4 groups:

1. You will be scheduled to get ONLY one dose, given as soon as you can and no later than 14 days from now.
2. You will be scheduled to get a dose right away AND to get a 2nd dose about 4 weeks from your first dose.
3. You will be scheduled to get ONLY one dose. This will be given to you about 12 weeks from now.
4. You will be scheduled to get a first dose in about 12 weeks from now AND a 2nd dose about 4 weeks after that.

You will have an equal chance of being in each of the above 4 groups.

You will get the vaccine as a shot in your upper arm. You will have to stay at the site where you get the vaccine for at least 15 minutes after you get the vaccine. This is to make sure you are not having any side effects right away from the vaccine that need medical care . You may need to stay longer if you have any side effects that need attention.

In addition to getting the vaccine you will have 4 in-person study visits. These will happen just after you are randomized in the study, and 12, 24 and 48 weeks after that. The study staff will also contact you every 4 weeks for the first 24 weeks to see how you are feeling. A member of the study staff will give you your exact schedule.

At the in-person visits, you will have some blood taken from a vein in your arm, using a needle. We will use the blood to test how your immune system responded to your previous COVID-19 infection and treatment. We will test your immune system's response to the study vaccine. We will also store some of this blood for future studies to learn more about COVID-19, the virus that causes it, and the vaccine.

We will also use your information and samples from ACTIV-3/TICO for this study

At the 4-week contacts, we will ask you about your health and any medications you are taking or have taken since the last time we contacted you. After your vaccination, we will also ask about any symptoms or side effects you may be having.

We will not use identifiers like your name or birthdate on your samples or on any private information that we collect about you. This means that no one looking at the labels on your samples or at other information will be able to know that the samples or information came from you. We will keep a locked-up secure list of the code numbers used on your study samples and forms, so that we can notify you if there are any issues or concerns.

The tests and blood storage described above are required by this study. If you do not agree to the storage or testing that has been described above, you should not join this study.

HOW MANY PEOPLE WILL BE IN THIS STUDY?

About 640 people from the ACTIV-3/TICO study will be in this vaccine study.

HOW LONG WILL I BE IN THIS STUDY?

You will be in this study for 48 weeks.

WHAT ARE THE RISKS OF THE STUDY?

As with any vaccine, the vaccine used in this study may have side effects. Some of these are listed below.

We do not know if getting a COVID-19 vaccine is more or less effective in people who have already had COVID-19. We do not know if it is more or less effective in people who were treated with study medicines like those in TICO. You should keep following the most current public heath advice where you live, on things like physical distancing and wearing a mask to keep yourself and others safe until your doctor or health authorities advise that you no longer need to do this.

Risks of mRNA vaccines

These side effects are common after a vaccine against any disease. They have been seen with the mRNA vaccines made by Moderna and Pfizer:

- Reactions where you get the shot: pain, swelling (hardness), and redness in the arm where you got the shot, tenderness and swelling of the lymph nodes in the same arm.
- General side effects: tiredness, headache, muscle aches, joint pain, chills, nausea and vomiting, and fever.

These side effects usually happen 12-24 hours after the vaccination. They usually go away on their own in a few days.

Any vaccine can cause an allergic reaction. This chance is very small. However, **severe allergic reactions can cause death if not treated.** A severe allergic reaction would usually occur within a few minutes after getting the vaccine. This is why we ask you to stay at the place where you get your vaccine for at least 15 minutes after your shot.

You should not get an mRNA COVID-19 vaccine if you:

- had a severe allergic reaction after a previous dose of this type of vaccine
- had a severe allergic reaction to any ingredient of the vaccine

You might have other serious or unexpected side effects. The place where you get your vaccine will be ready to treat you for side effects if needed.

Risks of having blood taken

You might have some slight pain, bleeding, bruising, and/or swelling where the needle goes into your body. In rare cases you might faint. There is a small risk you could get an infection.

[The following risks may differ substantially from one locality to another, and may change over time as policies shift with the pandemic. Please modify or remove as appropriate for your local situation.]

Risk of not being considered “fully vaccinated”

If you are assigned to get only one dose of the vaccine, you might not be considered “fully vaccinated” by your public health authorities. This may cause problems for you if your work requires you to be vaccinated. You may not be able to travel to places that require all visitors to be “fully” vaccinated. You might have to wear a mask in places that you would not have to if you had gotten two doses of vaccine. These restrictions are likely to become less over time.

Risks to privacy

As part of this study, we will collect health information about you. We will keep this information secure, but there is a slight risk that someone who should not see this information will see it.

ARE THERE RISKS RELATED TO PREGNANCY AND BREASTFEEDING?

Pregnancy

We do not have any information about using mRNA vaccines in people who are pregnant or breastfeeding. However, the American College of Obstetrics and Gynecology (ACOG) recommends that pregnant and breastfeeding people should have the chance to be vaccinated. This is because ACOG considers pregnant women at higher risk of getting very sick or dying from COVID-19. Therefore, you can still be in the study if you are pregnant or breastfeeding.

The vaccine may have risks to you (or to the embryo or fetus), if you or your partner (if you are male) become pregnant, which we do not know about at this time.

If at any point during the study you think you may be pregnant, you should let the staff at your site know so they can do a pregnancy test. If you get pregnant during the study, you can stay in the study and still get the vaccine

ARE THERE BENEFITS TO TAKING PART IN THIS STUDY?

We cannot promise you will have any direct benefit from being in this study. Getting vaccinated might help you. However, since COVID-19 vaccines are available in the community, you can still get a vaccine even if you do not join this study.

WHAT OTHER CHOICES DO I HAVE BESIDES THIS STUDY?

Instead of being in this study you have the choice of:

- getting a COVID-19 vaccine from your healthcare provider
- getting an experimental COVID-19 vaccine, if you qualify for a study testing such a vaccine
- not getting vaccinated

Please talk to your doctor about these and other choices you have. Your doctor will explain the risks and benefits of these choices.

WHAT ARE THE COSTS TO ME?

There will be no cost to you for the research tests, procedures, evaluations, and vaccinations done as part of this trial.

[The next paragraph is for US sites only. Sites in other countries should delete the next paragraph and replace it with the language appropriate for your location.]

You, your insurance company, or some other third-party payer must pay for all other medicines and health care costs.

WHAT IF YOU ARE HURT AS PART OF THIS STUDY?

If you are hurt because of being in this study, *[insert the name of the hospital/clinic]* will treat your injury right away. You or your insurance will have to pay for this treatment.

The study cannot pay you or pay for any care for study-related injuries or for your illness.

[If the above is not true for your site, i.e., if trial insurance covers such cost, please replace the above with appropriate language.]

[The following section, up to "How do we protect your privacy?", is for US sites only.]

A Declaration under the Public Readiness and Emergency Preparedness (PREP) Act was issued by the Secretary of the United States Department of Health and Human Services on March 10, 2020. This Declaration limits the legal rights of a subject participating in clinical studies utilizing COVID-19 countermeasures. Because this study is covered by the Prep Act Declaration, covered persons, such as the manufacturers, study sponsor, researchers, healthcare providers and others have liability immunity (that is, they cannot be sued by you or your family under the laws of the United States).

If you believe that you may have been harmed as a result of this research study, certain claims for serious injury or death caused by the countermeasure may be eligible for compensation through the Countermeasures Injury Compensation Program. This is a program set up by the United States Government.

Information about this program can be found at https://www.hrsa.gov/cicp/about/index.html or by calling 1-855-266-2427. If you are eligible for this program, you must file a claim within one year of the administration or use of the covered countermeasure.

HOW DO WE PROTECT YOUR PRIVACY?

We will take every reasonable step to keep your health information private and to keep anyone from misusing it.

Your information (data) and samples will not be identified by name, or in any other way, in anything published about this study.

We will do everything we can to keep your personal information private, but we cannot guarantee that nobody will get it. We may have to release your personal information if required by law.

These people may see your medical and research information:

- the *[insert the name of the hospital/clinic]* ethics committee (institutional review board [IRB]);
- the sponsor, the group paying for the research (US NIH), other study research staff and study monitors
- US and other participating countries' health regulatory agencies

They are committed to protecting your privacy.

As the research staff at *[inset the name of the hospital/clinic]*, we must make sure that people not involved with this study cannot see your research and medical information. We will keep your research files in a safe place and will handle your personal information very carefully.

[Note for US sites: The following brief HIPAA authorization is provided. Your site-specific consent should be modified to reflect the HIPAA authorization language requirements at your site.]

To do this research, we will collect and use your personal data, as described above and in any HIPAA Authorization Form we have given you. It is your choice whether you allow us to collect and use your data. However, you will not be able to be in this study if we cannot collect and use your data. Please tell us whether you agree to have us collect and use your personal data by placing your initials in front of your selection.

____**Yes**, I agree to the collection and processing of my personal data.

____**No**, I do not agree to the collection and processing of my personal data.

[The following section ("What are my rights regarding my data?") is for countries subject to the GDPR or similar legislation requiring this information. It should only be included in consents for sites subject to such legislation.]

WHAT ARE MY RIGHTS REGARDING MY DATA?

The UMN is a public research university, and this study is paid for mostly by the US Federal government. The sponsor (UMN) must follow regulations and policies that are meant to protect your privacy. UMN must comply with the General Data Protection Regulation (GDPR), because it handles data from people in Europe.

There is no specific independent supervisory authority overseeing the use of data in the US. Any complaint you might have about the use of your data would be made to your national data protection authority.

Your rights under the GDPR regarding your data were described to you when you joined the TICO study. They also apply to this study. You can ask the study staff to go over these rights again if you would like.

WHAT ARE MY RIGHTS AS A RESEARCH PARTICIPANT?

Taking part in this study is completely voluntary. You may choose not to take part in this study or leave this study at any time. Your decision will not have any impact on your participation in other studies conducted by NIH and will not result in any penalty or loss of benefits to which you are otherwise entitled.

We will tell you about new information from this or other studies that may affect your health, welfare, or willingness to stay in this study. If you want the results of the study, let the study staff know. We will not give you your individual results from tests done as

part of this research. If we do a pregnancy test for you during the study, we will give you the test result.

WHAT DO I DO IF I HAVE QUESTIONS OR PROBLEMS?

If you ever have questions about this study, or about the storage or use of your data or samples, or if you are hurt by being in the study, contact:

- *[name of the investigator or other study staff]*
- *[telephone number of the above]*

If you have questions about your rights as a research participant, you can call:

- *[name or title of person on the ethics committee (IRB) or other organization appropriate for the site]*
- *[telephone number of the above]*

SIGNATURE PAGE FOR CONSENT TO PARTICIPATE IN THE VATICO STUDY

I have read this consent or have had it explained to me. I have had a chance to learn about the vaccine I will get. I believe that I understand the information. By signing and dating this consent, I am stating that I volunteer to join this study. I agree to have my data sent to and used by the sponsor as described in this consent. I understand that I do not give up any of my legal rights as a study participant by signing this consent. I understand that I will get a copy of this signed and dated consent.

If you agree to be in this study, please sign **and date** below.

_____ Date: _____
Signature of participant

_____
Printed name of participant

_____ Date: _____
Signature of investigator/designee

_____
Printed name of investigator/designee

FOR ADULTS NOT CAPABLE of GIVING CONSENT

_____ Date: _____
Signature of Legally Authorized Representative (LAR)

_____
Printed name of LAR

_____
Relationship of LAR to Participant
(Indicate why the LAR is authorized to act as a surrogate health care decision-maker under state or applicable local law)

Witness to Consent Interview (if applicable)
On the date given next to my signature, I witnessed the consent interview for the research study named above in this document. I attest that the information in this consent form was explained to the participant, and the participant indicated that his/her questions and concerns were adequately addressed.

_____ Date: _____
Signature of witness

_____
Printed name of witness

NOTE: This consent form, with the original signatures, MUST be retained on file by the Investigator of Record. A copy of the signed and dated consent must be given to the participant. A copy should be placed in the participant's medical record, if applicable.

If no-touch / electronic consent is used, the participant must be provided with a copy of the consent in a manner appropriate to the method used to obtain it. A record of the act of consent must also be appropriately retained in the participant's medical record.