Consent to Participate in a Research Study
ADULT
A Phase 1, Comparator-Controlled, Dosage-Escalation Study to Evaluate the Safety and Immunogenicity of Two Doses DCVC H1 HA mRNA-LNP in Healthy Adults
DMID 21-0009
Version;4.0; 12Sep2024

CONCISE SUMMARY
This is a research study to understand what happens when a person receives one of three dose levels of an investigational messenger ribonucleic acid (mRNA) influenza vaccine and how the body responds to the dose received. Participation in this research is voluntary. To do this research, 10 participants will be enrolled into each group to receive two doses of either a low dose (10 microgram [mcg]) or medium dose (25 mcg) of the investigational vaccine. Up to 20 paricipants will be enrolled into the high dose (50 mcg) group. Dosing will start at the 10 mcg dose level and only increase to the next level if no concerning side effects are found. Once determined which dose level is most tolerable and safe, a group of 10 additional participants will receive two doses of that particular dose to be studied further. To compare, a separate group of 10 participants will receive one of the US Food and Drug Administration (FDA) approved seasonal flu vaccines (IIV4). All study vaccine will be administered in the muscle of the upper arm (intramuscular). We will draw blood (varying from ½ tablespoon to about 5-½ tablespoons per visit) from the arm to monitor the safety of the vaccine and to measure the levels of antibody against the flu virus in the body that are present both before and after receiving the vaccine. We will also obtain samples from the nose using a filter paper to test for levels of antibody against the flu virus. If a flu-like illness occurs, we will collect a nasal swab to test for the presence of the flu virus.

Participants must consent to storage and future research use of their blood and nasal samples if they would like to take part in this study. Genetic testing may be performed on blood samples collected during this study after the study is over. The results of these tests will not be shared.

For participants receiving the investigational vaccine, participation in this study will last approximately 13.5 months with a screening visit to determine eligibility, two vaccination visits and ten follow up research clinic visits. For participants receiving seasonal flu vaccine (IIV4) in the comparator group, participation in this study will last approximately 13.5 months with a screening visit to determine eligibility, one vaccination visit and eight follow up research clinic visits.

The risks involved in participating in this study are described in detail below. Some of the more common risks to receiving an influenza vaccine include symptoms of flu-like illness such as fever, tiredness, body aches, chills, headaches, nausea, and vomiting along with redness, swelling and bruising at the injection site. Risks associated with mRNA vaccines for COVID-19 made in a similar way to this investigational vaccine include myocarditis (inflammation of the heart muscle) and pericarditis

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(inflammation of the lining outside the heart). These events are rare and have occurred particularly in adolescents and young adult males after the second dose of COVID-19 mRNA vaccine. Risks associated with blood draws include discomfort, bruising and fainting. Nasal absorption samples or nasal swabs can cause mild discomfort and bleeding in the nose and watery eyes.

If you are interested in learning more about this study, please continue reading below.

This research study involves the testing of a first-in-human investigational two dose influenza virus (flu) vaccine or flu shot. "Investigational" means that the vaccine has not been approved for use outside of research studies, or licensed for sale in the United States by the Food and Drug Administration (FDA), the government agency that licenses new vaccines. You are being asked to take part in this study because you are between 18 and 49 years of age, you are in good overall health, able to comply with the study procedures, and able to provide consent for your participation.

Research studies are voluntary and include only individuals who choose to take part. Before you decide to participate, it is important for you to know why the research is being done, what it will involve and what the possible risks are. Therefore, it is important you read and understand the following explanation of the study. Ask us if there is anything that is not clear or if you would like more information. Please take your time to make your decision. You may wish to discuss the study with family, friends, and/or your own doctor. Feel free to ask any questions before you agree to take part in the study. Also, please tell the study doctor or study staff if you are taking part in another research study.

Patricia Winokur will conduct the study and it is funded by the National Institute of Allergy and Infectious Diseases (NIAID), which is part of the National Institutes of Health (NIH). The sponsor of this study, NIAID, will pay the University of Iowa to perform this research, and these funds may reimburse part of Dr. Patricia Winokur's salary.

WHO WILL BE MY DOCTOR ON THIS STUDY?
If you decide to participate, Dr. Winokur will be your doctor for the study and will be in contact with your regular health care provider throughout the time that you are in the study and afterwards, if needed.

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WHY IS THIS STUDY BEING DONE?

Vaccines help your body produce both antibodies and immune cells in the blood to help you develop protection from a disease. This study is being done to explore immune responses that result following administration of an investigational vaccine. This investigational vaccine is named DCVC H1 HA mRNA-LNP. The study will also be used to collect information (such as side effects) following administration of the vaccine and to plan for potential future studies.

The flu is caused by influenza viruses and is very contagious. In most people the flu causes a relatively mild or moderate illness with fever and cough, but sometimes the flu can be more severe, resulting in pneumonia and, in rare cases, death. In the United States, an annual seasonal flu shot is recommended for all persons over six months of age to help protect against the flu. The current seasonal flu shot protects against four different strains of flu but is only partly effective, and it must be given on a yearly basis, as protection decreases over the course of a flu season. There is a need to develop improved flu vaccines that are more effective, last longer, and can help protect against new flu strains that may circulate. To address this unmet need, we are evaluating the side effects and protection following administration of the investigational DCVC H1 HA mRNA-LNP vaccine. DCVC H1 HA mRNA-LNP vaccine is given by injection using a needle into your upper arm muscle. This study will test two doses of the vaccine at three different dose levels (amounts of vaccine). Some people in this study will get the traditional flu shot. You and the study team will know which vaccine you receive, and if you receive the DCVC H1 HA mRNA-LNP vaccine, you will know the dose you receive.

DCVC H1 HA mRNA-LNP vaccine is made in a similar manner to the current mRNA COVID-19 vaccines that the FDA has approved for use. The DCVC H1 HA mRNA-LNP vaccine does not contain the whole flu virus or the parts of the flu virus that can make you ill. Instead, the vaccine is made up of the flu virus' genetic code for a protein called hemagglutinin (HA) that is found on the outside of the flu virus, from one flu strain. The genetic material is surrounded by fatty particles called lipids to help keep the genetic material from degrading. They use a person's cells' protein-making machinery to produce the HA protein. This HA protein, made by your body, may help your body produce antibodies to fight against the flu. We will check how many antibodies and immune cells your body makes by taking blood samples and testing them.

We will compare the side effects that participants experience following receipt of the DCVC H1 HA mRNA-LNP vaccine in people receiving different dose levels of the vaccine. We will also compare the

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levels of antibody and immune cells in the blood between people receiving different dose levels of DCVC H1 HA mRNA-LNP and people receiving the traditional flu shot.

The three different dose levels of the DCVC H1 HA mRNA-LNP vaccine being tested include: a low dose of 10 micrograms (mcg), a medium dose of 25 mcg, and a higher dose of 50 mcg. Dosing will start at the lowest dose (10 mcg) and only increase to the next highest dose if it is determined that there are no concerning side effects. Also, within each dose group, safety data for the first 2 participants will be reviewed for 3 days following the first vaccination before the remaining participants will be vaccinated. Up to 10 participants will receive the low and medium dose level. Up to 20 participants will receive the high dose level. Ten separate participants will be enrolled to receive the standard seasonal flu shot (Fluzone Quadrivalent, manufactured by Sanofi Pasteur, Inc.). All study injections will be given into the muscle of the upper arm.

Blood samples will be collected to measure levels of antibodies and immune cells in the blood before and after the injections, and the safety and tolerability of the vaccine will be evaluated. We will also collect samples from the nose using a filter paper to measure the levels of antibodies in the nose. The results of these tests will not be shared with you.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Up to 100 people may be consented into this study, with approximately 50 people taking part in this study at the University of Iowa.

WHO SHOULD TAKE PART IN THIS STUDY?

To be in this study, you should be 18 to 49 years of age and in general good health. If you take part in this study, you must not have health conditions that weaken your body's ability to fight infections or be taking drugs that weaken the body's ability to fight infections, or have infection with human immunodeficiency virus (HIV), hepatitis B virus, or hepatitis C virus. If you take part in this study, you must refrain from receiving another investigational agent or participate in another clinical trial with an investigational agent within 60 days before study vaccination through the entire study period of about 12 months. You must not receive any other approved or authorized vaccines within 60 days before or after the study vaccination. You must refrain from receiving the flu vaccine within 90 days before and 60 days after the study vaccination. You must also refrain from blood donation within 30 days before and

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60 days after the study vaccination. Children, prisoners, and pregnant women will not be included this study.

There may be other reasons why you cannot participate in this study. The study doctor or study staff will discuss these with you.

WHAT IS INVOLVED IN THE STUDY?
If you agree to be in this study, you will have 13 scheduled in-person study visits if you receive the DCVC H1 HA mRNA-LNP vaccine and possibly more if an unscheduled visit is needed. Those enrolled to receive the seasonal flu shot (comparator group) will have 10 scheduled in-person study visits. Every visit will include a blood draw and five to seven visits will include a nasal absorption specimen collection. For those receiving the DCVC H1 HA mRNA-LNP vaccine, the total amount of blood drawn throughout the entire study period of 13.5 months is approximately 704 mL (48 tablespoons). Approximately 190 mL (13 tablespoons) of the blood drawn will be collected for storage and used for future, yet unknown, testing that is not part of this study. The amount of blood drawn at each visit will vary between 9 mL (½ tablespoon) to 79 mL (5-½ tablespoons). Each study visit is detailed below.

Clinic Visit 0 - Screening Visit
The first visit will be a screening visit to help determine if you are eligible to participate. At this visit, you will be asked to sign and date this consent form. No study activities will occur until you decide that you want to participate and sign/date the form. Eligible participants will also be asked to sign a separate consent form for a separate biorepository protocol ((IRB# *202101599)*, DMID Protocol No. 19-0025), for the storage and use of leftover and extra samples and associated data for the purpose of future research. This will not include identifiers such as your name, date of birth or medical history. In addition to the nasal samples, some of the blood being collected at each study visit below will not be used for studies as part of this study, but will be collected and stored in the biorepository for use in future research. More information regarding the repository protocol is below in the section regarding future use.

Once you sign/date this consent form, the following screening procedures will be done to see if you are eligible for the study.

- We will review eligibility criteria
- We will collect demographic data such as sex, age, ethnicity, and race

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- We will review and document your medical history and recent medications taken within the last 90 days
- We will collect a history of any medication allergies including a hypersensitivity to any components of the study products
- We will ask if you are participating in another clinical trial or plan to enroll in another clinical trial during the study period
- We will document your influenza vaccinations for the 2021-2022, 2022-2023, and 2023-2024 influenza seasons
- We will obtain vital signs: oral temperature, heart rate, blood pressure
- We will measure your height and weight
- You will have a physical exam
- We will collect approximately 9 mL (about 1/2 tablespoons) of blood from a vein in your arm for laboratory tests, including blood counts, blood chemistry tests, blood pregnancy tests and troponin (cardiac protein) level. This will also include tests to see if you are infected with hepatitis B virus, hepatitis C virus, or HIV, the virus that causes AIDS.
    - You will be notified of the results of the testing, and counseled as to the meaning of the results, whether they are positive or negative. We are required to report all positive hepatitis B, hepatitis C and HIV results to the Iowa Department of Public Health. The test results will be kept confidential to the extent permissible under the law. As part of this protocol, you will be tested for hepatitis B and C, which causes liver damage and liver failure. If the test indicates that you are infected with hepatitis B or C, you will receive additional counseling about the significance of your care and possible risks to other people.
    - If you do not want to be tested for hepatitis B and C, then you should not agree to participate in this study. The study doctor or study staff will provide pre-test counseling for the HIV/AIDS tests so you will have information about the risks and benefits of being tested.
    - You will be notified of the results of the testing, and counseled as to the meaning of the results, whether they are positive or negative. If the test indicates that you are infected with HIV, you will receive additional counseling about the significance of your care and possible risks to other people.
    - If you do not want to be tested for HIV, then you should not agree to participate in this study.

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  - In rare cases, an HIV test result may be 'indeterminate', which means that it is not possible to say if it is positive or negative. This can occur for several reasons and most people with indeterminate tests do not have HIV. Indeterminate tests are not notifiable conditions and this information is not reported to the local health department.
  - If the hepatitis B or C or HIV tests are positive or if other tests are outside an acceptable range, you will not be able to continue in the study. Abnormal results will be provided to you for follow-up with your provider.
- You will have a urine drug screen to test for amphetamines, cocaine, and opiates.
- If you are able to become pregnant you will have a blood pregnancy test at this visit and will be counseled to completely abstain from vaginal intercourse or use at least one primary form of contraception from 30 days prior to receipt of the study vaccine until 30 days after receipt of the study vaccine.
- If you have a partner who could possibly become pregnant, you will be counseled to abstain from vaginal intercourse or use contraception from the date of receipt of the study vaccine until 90 days after receipt of the last dose of study vaccine. (This does not apply to men in the group receiving the quadrivalent seasonal influenza vaccine, IIV4.)
- All men will be counseled to refrain from sperm donation from the date of receipt of the study vaccine until 90 days after receipt of the study vaccine. (This does not apply to men in the group receiving the quadrivalent seasonal influenza vaccine, IIV4.)
- You will have an electrocardiogram (ECG; heart tracing) performed to see if you are healthy enough to participate in the study.
  - An ECG is a test that records the electrical activity of the heart. Small self-adhesive patches called electrodes are placed on select locations of the skin on the arms, legs, and chest. The test usually takes less than a minute to perform once the patches are in place. The ECG machine creates a paper print out of the electrical activity of the heart for the doctor to review.

The screening visit may take up to 2 hours. If the evaluations obtained at the screening visit confirm that you are eligible, the vaccination visit will be scheduled within 2 weeks of the screening visit.

<u>Clinic Visit 1 – Dose 1 Vaccination</u>
This visit will take approximately 2 hours and will consist of:

- We will review and confirm eligibility

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- We will review your medical history and update if needed
- We will review your current medications and influenza vaccination history
- We will obtain vital signs: oral temperature, heart rate, blood pressure
- A physical exam will only be obtained if the study investigator thinks it is necessary
- Approximately 79 mL (5-½ tablespoons) of blood will be collected from your arm to test for blood counts, blood chemistry and immune testing to determine your body's baseline level of protection from the flu. Some of the blood will be used for future, yet unknown, testing. Some of the collected blood may be used to test your troponin level at the discretion of the study doctor.
- At this visit, women who could possibly become pregnant will have a urine pregnancy test. Those with a positive test will not be able to continue in this study. You will also be counseled to completely refrain from vaginal intercourse or use at least one primary form of contraception from 30 days prior to receipt of the study vaccine until 30 days after receipt of the study vaccine.
- If you have a partner who could possibly become pregnant, you will be counseled to abstain from vaginal intercourse or use contraception from the date of receipt of the study vaccine until 90 days after receipt of the study vaccine. (This does not apply to men in the group receiving the quadrivalent seasonal influenza vaccine, IIV4.)
- All men will be counseled to refrain from sperm donation from the date of receipt of the study vaccine until 90 days after receipt of the study vaccine. (This does not apply to men in the group receiving the quadrivalent seasonal influenza vaccine, IIV4.)
- We will obtain a nasal absorption sample by placing a small synthetic filter paper material into one side of your nasal passage.
- Depending on what dose level the study is evaluating at time of vaccination visit, you will receive either the low dose (10 mcg), medium dose (25 mcg), or high dose (50 mcg) of DCVC H1 HA mRNA-LNP vaccine or a standard seasonal influenza shot (IIV4) into the muscle of your upper arm. You will need to stay at the study clinic for at least 30 minutes after your injection to be watched for study injection reactions. Study staff will look at your arm and the site of the shot before you leave.
- A study staff member will give you a paper memory aid or send you an electronic memory aid, ruler and thermometer, and will show you how to use them for the study. You will be asked to write down your temperature and any symptoms that you experience every day, starting the evening of the study vaccination, and continuing for the next 13 days. You should also write down any drugs or medicines you take during this time, even over-the-counter medicines such as

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Tylenol®. You should contact the study staff if you have any severe reactions in the week after the study injection. These reactions are described later in this form.

Follow up visits will take approximately 30 minutes and will consist of:

Clinic Visit 2 (Day 3 +/- 1 days after Dose 1)

- Approximately 9- ½ mL (3/4 tablespoons) of blood will be taken from your arm for immune tests to determine the level of protection in your body from the flu and for future use. Some of the collected blood may be used to test your troponin level at the discretion of the study doctor.
- We will obtain vital signs: oral temperature, heart rate, blood pressure.
- We will obtain a nasal absorption sample.
- An ECG will be performed.
- We will review your influenza vaccination history, medications and the Memory Aid diary with you.
- A physical exam may be performed.
- Participants who could become pregnant or father a child will receive abstinence and contraception counseling.

Clinic Visit 3 (Day 8 +/- 2 days after Dose 1)

- Approximately 74- ½ mL (5 tablespoons) of blood will be taken from your arm for safety and immune tests to determine the level of protection in your body from the flu and for future use.
- We will obtain vital signs: oral temperature, heart rate, blood pressure.
- We will obtain a nasal absorption sample.
- A physical exam and/or ECG may be performed.
- We will review your influenza vaccination history, medications, and the Memory Aid diary with you.
- Participants who could become pregnant or father a child will receive abstinence and contraception counseling.

Clinic Visit 4 (Day 15 +/- 2 days after Dose 1)

- Approximately 60 mL (4 tablespoons) of blood will be taken from your arm for immune testing to determine the level of protection in your body from the flu and for future use.

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- We will obtain vital signs: oral temperature, heart rate, blood pressure.
- We will obtain a nasal absorption sample.
- A physical exam and/or ECG may be performed.
- We will review your influenza vaccination history, medications, and the Memory Aid diary with you.
- Participants who could become pregnant or father a child will receive abstinence and contraception counseling.

Clinic Visit 5- Dose 2 Vaccination (Day 29 +/- 3 days after Dose 1)

This visit will take approximately 1.5 hours and will consist of the following for those receiving DCVC H1 HA mRNA-LNP vaccine:

- Review and confirm eligibility for dose 2
- We will review your medical history and update if needed
- We will review your influenza vaccination history, medications
- We will obtain vital signs: oral temperature, heart rate, blood pressure
- A physical exam and/or ECG will only be obtained if the study investigator thinks it is necessary
- Approximately 79 mL (5-½ tablespoons) of blood will be collected from your arm to test for blood counts, blood chemistry, and immune testing to determine your body's baseline level of protection from the flu. Some of the blood will be used for future, yet unknown, testing. Some of the collected blood may be used to test your troponin level at the discretion of the study doctor.
- At this visit, women who could possibly become pregnant will have a urine pregnancy test. Those with a positive test will not be able to continue in this study. You will also be counseled to completely refrain from vaginal intercourse or use at least one primary form of contraception from 30 days prior to receipt of the study vaccine until 30 days after receipt of the last study vaccine.
- If you have a partner who could possibly become pregnant, you will be counseled to abstain from vaginal intercourse or use contraception from the date of receipt of the study vaccine until 90 days after receipt of the last study vaccine. (This does not apply to men in the group receiving the quadrivalent seasonal influenza vaccine, IIV4.)
- All men will be counseled to refrain from sperm donation from the date of receipt of the study vaccine until 90 days after receipt of the last study vaccine. (This does not apply to men in the group receiving the quadrivalent seasonal influenza vaccine, IIV4.)

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- We will obtain a nasal absorption sample.
- Depending on what dose level the study is evaluating at time of vaccination visit, you will receive either the low dose (10 mcg), medium dose (25 mcg), high dose (50 mcg). You will need to stay at the study clinic for at least 30 minutes after your injection to be watched for study injection reactions. Study staff will look at your arm and the site of the shot before you leave.
- A study staff member will give you a paper memory aid or send you an electronic memory aid, ruler and thermometer, and will show you how to use them for the study. You will be asked to write down your temperature and any symptoms that you experience every day, starting the evening of the study vaccination, and continuing for the next 13 days following study vaccination. You should also write down any drugs or medicines you take during this time, even over-the-counter medicines such as Tylenol®. You should contact the study staff if you have any severe reactions in the week after the study injection. These reactions are described later in this form.

This visit will take approximately 45 minutes and consist of the following for the IIV4 comparator group:

- We will review your medical history and update if needed
- We will review your influenza vaccination history, medications
- We will obtain vital signs: oral temperature, heart rate, blood pressure
- A physical exam and/or ECG will only be obtained if the study investigator thinks it is necessary
- Approximately 79 mL (5- ½ tablespoons) of blood will be collected from your arm to test for blood counts, blood chemistry, troponin level and immune testing to determine your body's baseline level of protection from the flu. Some of the blood will be used for future, yet unknown, testing.
- We will obtain a nasal absorption sample.

<u>Clinic Visit 6 (Day 3 +/- 1 days after Dose 2)</u>

- This visit will only occur for those receiving DCVC H1 HA mRNA-LNP vaccine.
- Approximately 9- ½ mL (3/4 tablespoons) of blood will be taken from your arm for immune tests to determine the level of protection in your body from the flu and for future use. Some of the collected blood may be used to test your troponin level at the discretion of the study doctor.
- We will obtain vital signs: oral temperature, heart rate, blood pressure

- We will obtain a nasal absorption sample.
- An ECG will be performed.
- We will review your influenza vaccination history, medications and the Memory Aid diary with you.
- A physical exam may be performed.
- Participants who could become pregnant or father a child will receive abstinence and contraception counseling.

Clinic Visit 7 (Day 8 +/- 2 days after Dose 2)

- This visit will only occur for those receiving DCVC H1 HA mRNA-LNP vaccine.
- Approximately 74- ½ mL (5 tablespoons) of blood will be taken from your arm for safety and immune tests to determine the level of protection in your body from the flu and for future use.
- We will obtain vital signs: oral temperature, heart rate, blood pressure
- We will obtain a nasal absorption sample.
- A physical exam and/or ECG may be performed.
- We will review your influenza vaccination history, medications, and the Memory Aid diary with you.
- Participants who could become pregnant or father a child will receive abstinence and contraception counseling.

Clinic Visit 8 (Day 15 +/- 2 days after Dose 2).

- This visit will only occur for those receiving DCVC H1 HA mRNA-LNP vaccine
- Approximately 60 mL (4 tablespoons) of blood will be taken from your arm for immune testing to determine the level of protection in your body from the flu and for future use.
- We will obtain vital signs: oral temperature, heart rate, blood pressure
- We will obtain a nasal absorption sample.
- A physical exam and/or ECG may be performed.
- We will review your influenza vaccination history, medications, and the Memory Aid diary with you.
- Participants who could become pregnant or father a child will receive abstinence and contraception counseling.

Clinic Visit 9 (Day 29 +/- 3 days after Dose 2)

- Approximately 69- ½ mL (4- ½ tablespoons) of blood will be taken from your arm for safety and immune testing to determine the level of protection in your body from the flu and for future use.
- We will obtain vital signs: oral temperature, heart rate, blood pressure
- We will obtain a nasal absorption sample.
- We will review your influenza vaccination history and medications with you, any new or worsening medical problems.
- A physical exam and/or ECG may be performed.
- Participants who could become pregnant or father a child will receive abstinence and contraception counseling.

Clinic Visit 10 (Day 92 +/- 7 days after Dose 2)

- Approximately 60 mL (4 tablespoons) of blood will be taken from your arm for immune testing to determine the level of protection in your body from the flu and for future use.
- Vital signs may be obtained.
- We will review your influenza vaccination history and medications with you, any new or worsening medical problems.
- A physical exam and/or ECG may be performed.

Clinic Visit 11 (Day 184 +/- 7 days after Dose 2)

- Approximately 60 mL (4 tablespoons) of blood will be taken from your arm for immune testing to determine the level of protection in your body from the flu and for future use.
- Vital signs may be obtained.
- We will review your influenza vaccination history and medications with you, any new or worsening medical problems.
- A physical exam and/or ECG may be performed.

Clinic Visit 12 (Day 366 +/- 7 days)

- Approximately 60 mL (4 tablespoons) of blood will be taken from your arm for immune testing to determine the level of protection in your body from the flu and for future use.
- Vital signs may be obtained.

- We will review your influenza vaccination history and medications with you, any new or worsening medical problems.
- A physical exam and/or ECG may be performed.

Unscheduled Visit

You may be asked to come back to the study clinic at other times if needed to review your health. This visit may be conducted by phone or telehealth if an in-person visit is not possible. Study personnel will determine what activities will be needed after reviewing any symptoms that you are having. This visit may consist of:

- Obtaining blood for safety and immune testing
- Collecting vital signs: oral temperature, heart rate and blood pressure
- A physical exam
- Collecting a nasal absorption sample, if needed
- Collecting a nasopharyngeal swab to test for influenza virus. A cotton-tipped swab will be gently passed through your nostril to the back of your nose.
- An ECG
- Reviewing medications and influenza vaccination history
- Review of new or worsening medical conditions

Influenza-like Illness Visits

During the study, participants will be requested to report if they have any influenza-like illness (ILI) starting from the day of screening through Day 394. Participants reporting influenza or ILI will be evaluated. ILI is defined as fever (temperature of 100.4°F [38.0°C] or greater) and a cough and/or sore throat in the absence of a known cause other than influenza. If you have an ILI a nasopharyngeal swab will be collected to test for the presence of the influenza virus.

Early Withdrawal Visit

If you stop taking part in this study for any reason, you may be asked to return to the study center for a final visit. You will be asked about any reactions, illnesses, or any new or worsening medical problems you may have had since your last clinic visit. You also may be asked about any medications you may have taken or if you received an influenza vaccine since your last study clinic visit. A brief physical examination may be done and blood samples may be taken along with vital signs, nasal absorption and

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an ECG may be performed. Persons able to become pregnant or father children may receive abstinence and contraception counseling.

Additional blood samples may be collected at planned or unscheduled visits to test for troponin level or to repeat abnormal clinical labs for safety at your study doctor's discretion.

BLOOD AND NASAL SAMPLE STORAGE FOR FUTURE USE
As part of this study, we are obtaining blood and nasal samples from you for this study and extra samples for a repository (a place that stores samples). At the time of screening, eligible participants will be required to sign a separate consent form for the separate biorepository protocol ((Pro00104290), DMID 19-0025), for the storage and use of both extra nasal and blood samples as well as leftover samples and associated data (information) in future research. This will not include protected health information, such as your name, date of birth or medical history. If you do not want your leftover samples to be used for future research, you should not agree to participate in this main study.

Secondary research is research that is not part of this flu study but will be performed in the future. You will not be told about the secondary research or any results. Types of research include new or different immunological laboratory tests to provide information for the development of new flu vaccines, or to better understand flu virus or other infections. New genetic testing, including DNA testing, may occur. The tests we might want to use to study your blood and nasal samples may not even exist at this time. The consent form for the repository protocol will explain the types of genetic testing, how the data will be stored in databases, how this information will be shared with other researchers, and whether information will be shared with you.

Leftover samples will be labeled only with a code (a unique tracking number) to protect your confidentiality. The codes may stay on the samples and be stored indefinitely or used for future research. Personnel at the storage facility and research testing lab will not know your identity. However, the researchers who enrolled you will keep a "key" in a secured area that could connect the codes or tracking numbers to identify you.

By signing this consent form, you allow for the collection of extra samples. You should have consented first to the storage and future research use of your blood and nasal samples and information for research, excluding your protected health information. Stored extra/leftover blood and nasal samples will be used

for research purposes only. At any time during this study or after this study is over, stored extra/leftover blood and nasal samples may be shared with other investigators, institutions, or drug companies without additional consent. No information will be provided that could easily identify you.

After enrollment, you may withdraw your consent for the collection and storage of samples for secondary research at any time by providing written notice to the investigator or study staff. No "extra samples" will be collected. Samples collected for this vaccine study may not be destroyed. However, samples collected or stored for secondary research may be destroyed after the vaccine study is completed. Samples released for secondary research before you withdrew consent may not be able to be destroyed.
Your samples and/or data may be stored and shared for future research without additional informed consent if identifiable private information, such as your name and medical record number, are removed. If your identifying information is removed from your samples or data, we will no longer be able to identify and destroy them. The samples will not be sold or used directly for production of any commercial product. However, the research studies in the future that use your data and samples may result in commercial profit. You will not be compensated for the use of your data and samples other than what is described in this consent form.

There are no benefits to you in the collection, storage and future use of your blood and nasal samples. The results of any future research will not be available to you or your regular doctor and will not be placed in your medical record. Future research tests may benefit others by leading to new approaches in the development of vaccines or treatments for flu illness.

The results of any future testing will be kept confidential in the same way as the results of other testing done for this study. If these blood or nasal samples are tested in the future, the results may be published. You will not be identified in such publications. Please feel free to ask the study staff any questions you may have about how your blood and nasal samples may be used.

HOW LONG WILL I BE IN THIS STUDY?
Your participation in this study will last up to approximately 394 days (13.5 months), not including the screening period that will take place up to 14 days prior to Visit 1.

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ADULT
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You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled. However, if you decide to stop participating in the study, we encourage you to talk to your doctor first. Any clinically relevant results will be shared with you, which may include adverse effects discovered as a result of the administration of this vaccine. These results will be shared at the end of the trial and when all data analysis is complete. Information is also available at **www.clinicaltrials.gov**.

WHAT ARE THE RISKS OF THE STUDY?
While on the study, you are at risk for some side effects. You should discuss these with the study doctor or study staff. Many side effects go away shortly after a vaccine is given, but in some cases, side effects can be serious, long lasting, or permanent.

Study risk is minimized by starting with a low dose and by first testing each dose of vaccine in just two participants and pausing before enrolling the remaining participants receiving that dose.

This investigational influenza vaccine, DCVC H1 HA mRNA-LNP, has never been tested in humans. There may be risks that we do not know about, which include your health getting worse or even death. Side effects that have been reported with similar mRNA vaccine include at the injection site:

- Pain
- Tenderness
- Swelling (hardness)
- Redness
- Swelling of the lymph nodes on the same arm of the injection

General side effects include:

- Fatigue
- Headache
- Muscle pain
- Joint pain
- Chills
- Nausea
- Vomiting
- Fever

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- Feeling unwell

There is a small possibility that an mRNA vaccine could cause a severe allergic reaction occurring shortly after getting a dose of vaccine. A severe allergic reaction could be life-threatening. Participants with a prior history of severe allergic reaction after a previous dose of any influenza vaccine or mRNA vaccine or to a vaccine component will not be allowed to receive vaccine.

Signs of severe allergic reaction can include:

- Difficulty breathing
- Shortness of breath
- Wheezing
- Sudden drop in blood pressure
- Swelling around the mouth, throat, or eye
- Facial and throat swelling
- Fast pulse or irregular heartbeat
- A rash
- Sweating
- Dizziness
- Weakness

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received mRNA-LNP COVID-19 vaccines (Pfizer-BioNTech and Moderna). These events have occurred particularly in adolescents and young adults after the second dose.

In a population-based cohort study the incidence of acute myocarditis was noted to be almost 6 per 1 million individuals after the second dose. Myocarditis reporting rates among males 12-29 years of age have been noted to be about 40 cases per million second doses of mRNA COVID-19 vaccines. In most of these people, symptoms began within a few days following receipt of the second dose of the vaccine. The chance of having this occur is low. Symptoms include:

- Chest pain

- Shortness of breath
- Palpitations (fast beating or fluttering heart)

More serious problems including a potential small risk of Guillain-Barré Syndrome or other neurologic conditions such as a paralysis of the facial nerve, encephalitis (inflammation of the brain), encephalomyelitis (inflammation of the brain and spinal cord), and seizures have been rarely described after mRNA vaccines. Guillain-Barré Syndrome is a disorder of the immune system where the nerves are attacked by immune cells that causes weakness and tingling in arms and legs.

In laboratory animals, abnormalities associated with increased clotting were seen following administration of the HA protein. Study participants will be closely monitored via blood draws for changes in prothrombin time (PT), activated partial thromboplastin time (APPT), and fibrinogen levels. These are ways to measure how your blood is clotting.

Available data from short-term follow-up suggest that most individuals have had resolution of symptoms, but information is not yet available about potential long-term effects. In addition, there may be other possible unknown side effects of mRNA-LNP vaccines. Serious and unexpected side effects may also occur. Should a severe allergic reaction occur immediately following vaccination, medications to treat such a reaction will be immediately available for administration according to standard guidelines at the study site.

<u>Seasonal Influenza Vaccine/Shot (IIV4) Risks</u>
IIV4 risks include minor problems such as:

- Soreness, redness, swelling, or pain where the shot was given
- Hoarseness of the voice
- Sore, red or itchy eyes
- Cough
- Fever
- Body aches
- Headache
- Itching
- Fatigue

All of these side effects usually occur within 1-2 days of vaccination and usually resolve without treatment. More serious problems including a small increased risk of Guillain-Barré Syndrome estimated at 1 or 2 additional cases per million people vaccinated can occur. In addition, IIV4 rarely can cause a severe allergic reaction, or anaphylaxis, which is estimated at ~1 in one million doses of IIV4 administered.

Participants with a prior history of severe allergic reaction after a previous dose of any influenza vaccine or to a vaccine component, including egg protein, and participants with a history of Guillain-Barré Syndrome will be excluded from study enrollment.

Should a severe allergic reaction occur immediately following vaccination, medications to treat such a reaction will be immediately available for administration according to standard guidelines at the study site.

Risks related to Nasal Absorption or Nasal Swab Sampling
Obtaining a nasal absorption or nasal swab sample can cause discomfort in the nostrils, a nosebleed, tickling in the throat, coughing, sneezing, or watery eyes at the time of collection.

Risks of electrocardiogram (ECG)
The electrodes of an ECG may feel cold when applied; possible side effects of the ECG are skin irritation, itching and redness from the ECG electrode pads. This type of irritation usually resolves by itself, but topical medication is occasionally required.

Risks related to blood draws
Risks associated with drawing blood from your arm include momentary discomfort and/or bruising. Infection, excess bleeding, clotting, or fainting are also possible, although unlikely.

If I Catch Influenza, Could the Antibodies Produced Following Vaccination Make It Worse?
For other vaccines tested in animals against similar viruses (but not influenza), there have been reports of the illness being more severe in the animals that received the product than in those animals that did not. So far, this has not been seen with influenza. It remains important for you to contact your study

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doctor if you develop symptoms that might be caused by influenza (for example, fever, cough, shortness of breath).

Female and/or Male Contraception Language

If you are currently pregnant, plan to become pregnant at least 30 days prior to or 30 days after receiving study product, or are breastfeeding a child, you cannot be in this study.

Female Risks

Influenza infection during pregnancy is associated with an increased risk of complications for mothers and babies, including an increased risk of maternal death; pregnant women are advised to get an approved flu vaccine during pregnancy. In addition, the effects of the study vaccine on a developing pregnancy or breast feeding infant are not known. For these reasons, women who are pregnant, planning a pregnancy, or breastfeeding are not allowed to participate in this study.

Being a part of this study while pregnant may expose the unborn child to significant risks, some of which may be currently unforeseeable. Therefore, pregnant women will be excluded from the study. If you are a woman of childbearing potential, a blood pregnancy test will be done. If sexually active, you must agree to use appropriate contraceptive measures for the 30 days before you receive the vaccination until 30 days after you receive the second vaccination. A urine pregnancy test will be done at the vaccination visit (Visit 1).

You and your partner must agree to either abstain completely from vaginal intercourse during the study and for 30 days after study vaccination, or use a highly effective method to include (a) partner vasectomy, (b) bilateral tubal ligation, (c) intrauterine devices (IUDs), (d) hormonal implants (such as Implanon) (e) other hormonal methods (birth control pills, injections, patches, vaginal rings), or (f) true abstinence. If you and your partner are not currently using one of these methods your study doctor will discuss options with you, given your medical condition, your personal preferences, and the level of effectiveness required for this study.

Because no birth control method is 100% effective, you should notify your study doctor immediately if you think there is any chance you could be pregnant, even if you have had a recent negative pregnancy test. If you do become pregnant during the study, your study doctor will notify the sponsor. You will be

followed for the duration of the pregnancy to better understand the potential effects of the study drug on the outcome of your pregnancy.

Male Risks
The effects of the study vaccination on a developing pregnancy that began immediately after the father was vaccinated are not known. In addition, the antibodies produced may be present in semen and transmitted to a partner during sexual activity.

If you are receiving DCVC H1 HA mRNA-LNP and able to father children and your partner is a woman who could possibly become pregnant (she has not completed menopause, or has not had a hysterectomy and/or both tubes and/or both ovaries removed), you must agree to either abstain completely from vaginal intercourse or use a condom every time you have vaginal intercourse during intervention period for at least 90 days after study vaccination, even if you have had a vasectomy (because vasectomy does not prevent transmission of drug in semen) or your partner is using another method of birth control. If your partner is currently pregnant, breastfeeding, or becomes pregnant during the study, you must use a condom for all types of intercourse to prevent transmission.

Males must agree to refrain from donating sperm at least 90 days after receiving study product.

You should inform your partner about your participation in this study and the potential risks to a pregnancy. If your partner does become pregnant during the study or within 90 days of the study vaccination, you should notify the study doctor or staff immediately. Your partner may be asked for her permission to collect information on her health during the pregnancy and, if appropriate, on the health of the baby. The study doctor may share this information with the sponsor and the Institutional Review Board (IRB), a group of people who review research studies to protect the rights and welfare of research participants. If additional consent is not provided by your pregnant partner, the pregnancy outcome and date of delivery may be requested from the research participant.

There may be risks, discomforts, drug interactions or side effects that are not yet known.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
If you agree to take part in this study, there will be no direct medical benefit to you. As this is a first-in-human trial, it is unknown whether the study product, DCVC H1 HA mRNA-LNP, will help to protect

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participants from influenza disease or, if it does, how long that protection may last. If you receive the study product, DCVC H1 HA mRNA-LNP, it is recommended that you receive a licensed influenza vaccine no sooner than 60 days following the last study product vaccination and when it is recommended during the influenza season. The immunogenicity comparator IIV4 (seasonal flu vaccine/shot) may offer some protection against influenza infection for the strains of influenza contained in the vaccine.

We hope that in the future the information learned from this study will benefit other people.

WILL MY HEALTH INFORMATION BE USED DURING THIS STUDY?

The Federal Health Insurance Portability and Accountability Act (HIPAA) requires University of Iowa Health Care to obtain your permission for the research team to access or create "protected health information" about you for purposes of this research study. Protected health information is information that personally identifies you and relates to your past, present, or future physical or mental health condition or care. We will access or create health information about you, as described in this document, for purposes of this research study. Once University of Iowa Health Care has disclosed your protected health information to us, it may no longer be protected by the Federal HIPAA privacy regulations, but we will continue to protect your confidentiality as described under "Confidentiality."

We may share your health information related to this study with other parties including federal government regulatory agencies, the University of Iowa Institutional Review Boards and support staff, and

- Your study doctor and other study team members;
- The U.S. Food and Drug Administration [FDA];
- The National Institutes of Health [NIH];
- those contracted by the NIH, such as Emmes Company, Inc and Technical Resources International (TRI) pharmacovigilance and study monitoring groups
- auditing departments of the University of Iowa

You cannot participate in this study unless you permit us to use your protected health information. If you choose *not* to allow us to use your protected health information, we will discuss any non-research alternatives available to you. Your decision will not affect your right to medical care that is not

research-related. Your signature on this Consent Document authorizes University of Iowa Health Care to give us permission to use or create health information about you.

Although you may not be allowed to see study information until after this study is over, you may be given access to your health care records by contacting your health care provider. Your permission for us to access or create protected health information about you for purposes of this study has no expiration date. You may withdraw your permission for us to use your health information for this research study by sending a written notice to Patricia Winokur, MD, University of Iowa, Carver College of Medicine, 451 Newton Rd., Iowa City, IA 52242. However, we may still use your health information that was collected before withdrawing your permission. Also, if we have sent your health information to a third party, such as the study sponsor, or we have removed your identifying information, it may not be possible to prevent its future use. You will receive a copy of this signed document.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?
Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

As part of the study, results of your study-related laboratory tests and procedures may be reported to NIAID and its affiliates. In addition, your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives from the FDA, representatives and affiliates of NIAID, the Duke University Health System (DUHS) IRB, and others as appropriate. If any of these groups review your research record, they may also need to review your entire medical record.

As part of this study, you will be asked to have certain tests and/or procedures performed. These test results will be recorded in your medical record and will be reported to representatives and affiliates of NIAID. Positive hepatitis B, hepatitis C, and HIV results will be reported to the Iowa Department of Public Health. The test results will be kept confidential to the extent permissible under the law. Results of tests and studies done solely for this research study and not as part of your regular care will not be included in your medical record.

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The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1) there is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);
2) you have consented to the disclosure, including for your medical treatment; or
3) the research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project or for information that is required by the FDA.

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

All of the blood, urine and procedures are being done only because you are in this study. The study results for labs processed locally such as HIV and hepatitis B, will be available in your medical record. Laboratory results that are sent out of the University of Iowa, will not be a part of your research or medical record.

The study results will be retained in your research record for at least six years after the study is completed or for two years after study product licensure, whichever is longer. At that time either the research information not already in your medical record may be destroyed or information identifying you will be removed from such study results at the University of Iowa. Any research information in your medical record will be kept indefinitely.

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This information may be further disclosed by the sponsor of this study. If disclosed by the sponsor, the information is no longer covered by federal privacy regulations.

If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by federal privacy regulations.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

A description of this clinical trial will be available on https://clinicaltrials.gov/ as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people, such as those indicated below, may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you. Reviewers may include:

- Federal government regulatory agencies
- The FDA
- The NIH and those contracted by the NIH, such as Emmes Company, Inc and Technical Resources International (TRI) pharmacovigilance and study monitoring groups
- Auditing departments of the University of Iowa
- The DUHS IRB (a committee that reviews and approves research studies) and other representatives of this organization

To help protect your confidentiality, we will use ID numbers on research data. The data will be stored in locked cabinets and/or offices when not in use. Only research team members who are involved in the conduct, oversight, or auditing of this study will have access to the research data.

Electronic data will be stored in password protected computers and websites. For this study, each blood and nasal sample will be labeled with a barcode and a unique tracking number to protect our confidentiality. Personnel at the central storage and testing lab will not know your identity or the volunteer ID assigned to you for the study.

The University of Iowa generally requires that we document in your medical record chart that you are participating in this study. If you do not have a medical record in University of Iowa Heath Care, we will create one for you. The information included in the chart will provide contact information for the research team and information about the risks associated with this study. We will keep this Consent Document in our research files; it will not be placed in your medical record chart.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of the University of Iowa, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

WHAT ARE THE COSTS TO YOU?

It will not cost you anything to take part in this study. You will not have to pay for any study tests, procedures or study visits and they will not be charged to your insurance carrier.

WHAT ABOUT COMPENSATION?

You will be paid for being in this research study. You will need to provide your social security number (SSN) in order for us to pay you. You may choose to participate without being paid if you do not wish to provide your social security number (SSN) for this purpose. You may also need to provide your address if a check will be mailed to you. If your social security number is obtained for payment purposes only, it will not be retained for research purposes.

You will be reimbursed up to $650 for your expenses related to your participation (gas, and time). You will receive $50 for the screening visit, $50 for the vaccination visit and $50 for each of the follow up in-person visits. You will receive compensation for the study activities that are completed.

Consent to Participate in a Research Study
ADULT
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Payment received as compensation for participation in research is considered taxable income to the research participant. If payment to an individual totals $600 or more in any one calendar year, Duke University is required to report this information to the Internal Revenue Service (IRS). Research participant payments adding up to $600 or more during any calendar year will result in a 1099 (Miscellaneous Income) form being issued to the individual and a copy sent to the IRS.

WHAT ABOUT RESEARCH RELATED INJURIES?

- If you are injured or become ill from taking part in this study, medical treatment is available at the University of Iowa Hospitals and Clinics.
- The University of Iowa does not plan to provide free medical care or payment for treatment of any illness or injury resulting from this study unless it is the direct result of proven negligence by a University employee.
- If you experience a research-related illness or injury, you and/or your medical or hospital insurance carrier will be responsible for the cost of treatment.

For questions about the study or research-related injury, contact Dr. Patricia Winokur at (319) 384-4590 during regular business hours and at (319) 356-1616*)*, after hours and on weekends and holidays.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?

You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes unless the data concern an adverse event (a bad effect) related to the study. If such an adverse event occurs, we may need to review your entire medical record. All data that have already been collected for study purposes, and any new information about an adverse event related to the study, will be sent to the study sponsor.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at the University of Iowa. If you do decide to withdraw, we ask that you contact Dr. Winokur in writing and let her know that you are withdrawing from the study.

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Her mailing address is:
University of Iowa, Carver College of Medicine,
451 Newton Rd., Iowa City, IA 52242

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

Your doctor may decide to take you off this study if your condition gets worse, if you have serious side effects, or if your study doctor determines that it is no longer in your best interest to continue. The sponsor or regulatory agencies may stop this study at any time without your consent. Reasons why this might occur include:

- You are unable or unwilling to follow the instructions of the study;
- Participant becomes pregnant prior to study product dosing;
- The study doctor decides that the study is not in your best interest or that you are no longer eligible to be in the study; or
- The study is stopped by the study sponsor, an institutional review board (IRB), or by a government or regulatory agency.

If this occurs, you will be notified and your study doctor will discuss other options with you.

If you agree to allow your blood and nasal samples to be kept for future research by signing the biorepository protocol consent ((Pro00104290), DMID Protocol No. 19-0025) with identifying information that could link your sample to you, you are free to change your mind at any time. We ask that you contact Dr. Winokur in writing and let her know you are withdrawing your permission for your identifiable samples to be used for future research. At that time, we will ask you to indicate in writing if you want the unused identifiable blood and nasal samples destroyed or if your samples (having all identifying information removed that would link the sample to you) could be used for other research.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Patricia Winokur at (319) 384-4590 during regular business hours and at (319) 356-1616*)*, after hours and on weekends and holidays.

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For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

Locally, if you have questions, concerns, or complaints about your rights as a research subject or about research related injury, please contact the Human Subjects Office, 105 Hardin Library for the Health Sciences, 600 Newton Rd, The University of Iowa, Iowa City, IA 52242-1098, (319) 335-6564, or e-mail irb@uiowa.edu. General information about being a research subject can be found by clicking “Info for Public” on the Human Subjects Office web site, http://hso.research.uiowa.edu/. To offer input about your experiences as a research subject or to speak to someone other than the research staff, call the Human Subjects Office at the number above.

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STATEMENT OF CONSENT
"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

Participant's Name (printed): _____

_____	_____	_____
(Signature of Participant)	(Date)	(Time)

Statement of Person Who Obtained Consent

I have discussed the above points with the participant. It is my opinion that the participant understands the risks, benefits, and procedures involved with participation in this research study.

_____	_____	_____
(Signature of Person who Obtained Consent)	(Date)	(Time)

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