Informed Consent Form

A Phase 1 Study to Evaluate the Safety and Immunogenicity of an Inactivated Rotavirus Vaccine for Intradermal Administration by Microneedle Patch in Healthy Adults

NCT# 06962904

Document IRB Approval Date: 5/26/2025

EMORY UNIVERSITY | Institutional Review Board
Research Administration

Consent to be a Research Subject

You are being asked to join a research study. You do not have to join.
Please read this form carefully before you decide.

Study Title	A Phase 1 Study to Evaluate the Safety and Immunogenicity of an Inactivated Rotavirus Vaccine for Intradermal Administration by Microneedle Patch in Healthy Adults
IRB #	STUDY00008061
Principal Investigator	Christina Rostad, MD
Study Contact	Christina Rostad, MD
Study Contact Phone	Emory Children's Center – Vaccine Research Center (ECC-VRC) 404-727-4044 24-hour emergency number: [redacted]
Sponsor or Funding Source	Centers for Disease Control and Prevention

Key Points

This section contains some key points that will help you decide if you want to join this study. There are more details about the study after this section. If you do not understand something, please ask someone.

Purpose	This study is being done to learn more about a new experimental rotavirus vaccine given via microneedle patch: is the vaccine safe and will it stimulate the immune system?
Length of Time	If you join this study, you will have 13 study visits, including 9 in-person visits at Emory Children's Center– Vaccine Research Clinic and 4 phone calls. Each visit may last about 3 hours if it is a vaccine visit,30 minutes if it is an in-person follow-up visit, and 10-15 minutes if it is a

	phone call. The total amount of time you could be in the study is approximately 9 months.
Research Procedures	You will be asked to provide consent, provide medical and medication history, allow us to collect blood and possibly urine samples, allow us to perform a physical exam, receive three vaccinations, take photographs of vaccine application site before and after vaccination, and report any side effects following vaccination in an e-diary. All of these procedures will be paid for by the study. 80% of participants will receive the study vaccine, and 20% of participants will receive placebo.
Risks	The study will take time. The vaccine that is being tested may not work any better than current approved vaccines and may even cause harm. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious. Risks for this study include: • discomfort, bruising, or lightheadedness from blood draws • adverse effects (side effects) of the study vaccine • loss of privacy • breach of confidentiality You can find a full list of expected risks, their frequency and severity in the section titled “What are the risks of this study?”
Benefits	You will not benefit from taking part in this study.
Other Options	You do not have to join this study.

The rest of this form tells you more about this study.

Why have I been given this form?

To see if you are interested in taking part in a research study. A research study is a planned study to learn about a topic.

Do I have to join this study?

No. Being in research is voluntary. It is your choice. If you don't want to take part in the study, there will be no penalty. You will not lose your current benefits. The study team will explain the study to you. Please ask questions. Take your time deciding if you want to take part in this study. You can talk to others about the study. If you choose to join, you can change your mind later and leave the study. If you choose not to join this study, your doctor will still treat you.

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

This trial will be registered and may report results on ClinicalTrials.gov, a publicly available registry of clinical trials.

Why is this study being done?

The purpose of this study is to test an experimental rotavirus vaccine to see if it is safe and if it stimulates the immune system to make antibodies. Infection with rotavirus can cause symptoms such as watery diarrhea, vomiting (throwing up), and fever. Sometimes the symptoms are severe enough to require hospitalization or cause death. Rotavirus infection most commonly occurs in infants and children but can also affect adults. Children are at greater risk of having severe symptoms.

Most vaccines are currently given by injection. This involves use of a needle and syringe with trained staff. This can make it hard to give vaccines in areas of the world where there is a shortage of trained healthcare workers. Needles are medical waste that requires special handling. They can also cause accidental needle sticks after use.

Technology has improved with new methods for giving vaccines. One new method that we will test in this study is called a microneedle patch. The microneedles used in this study are very small, may cause less pain than usual syringes and needles, and can also solve some of the problems that occur with needle and syringes. Microneedles used in this study will be made of a mixture of the study vaccine and inactive ingredients (similar to sugar) that are crystallized into a point. When the microneedle patch is applied to the skin, the point goes through the surface of the skin and dissolves over a period of minutes.

Microneedle patches have a history of safe use in humans. The most common side effects are itching and/or mild redness that gets better after a few days. A study using the microneedle patch to deliver the influenza vaccine to healthy adults showed it was safe with no serious adverse events (SAEs) related to the patch reported.

This is the first time this vaccine is being tested in humans in a microneedle patch. This vaccine is experimental. This means that the vaccine is not approved by the Food and Drug Administration (FDA). Until now, the vaccine has mostly been tested in animals.

There are two vaccines approved by the FDA available for rotavirus. Both available vaccines are administered orally (taken by mouth) and contain live rotavirus. However, these vaccines do not work as effectively in preventing severe illness in some people, which may be related to oral administration. CDC-9 inactivated rotavirus vaccine (IRV) is a vaccine that is given as a microneedle patch and contains rotavirus that has been inactivated (killed) by heat. When given as a microneedle patch, the inactivated rotavirus cannot cause infection but instead trains the immune system to recognize and protect against rotavirus with subsequent exposure.

How long would I be in the study?

This study will take place at Emory Children's Center – Vaccine Research Clinic over approximately 9-10 months, and you will have approximately 13 study visits.

At each of the study clinic visits, we will collect blood samples from you. The samples will be used for tests to assess your health and for research testing of the immune system in response to the study vaccine.

Who is paying for this study?

This study is being paid for by the Centers for Disease Control and Prevention.

How many people will take part in this study?

Approximately 110 people will enroll and be screened into this study and 50 of those people will be assigned to one of two groups. Both groups will have 25 people, who will receive three study vaccinations in total, each 28 days apart. The first group will receive a 3.75 µg dose of CDC-9 IRV or placebo through microneedle patch, and the second group will receive a 7.5 µg dose of CDC-9 IRV or placebo through microneedle patch.

Do the Emory researchers conducting this study have financial interests I should know about?

No.

What will I be asked to do?

If you agree to participate, you will be assigned by chance, like flipping a coin, to receive either CDC-9 IRV or placebo. The placebo in this study is a microneedle patch without vaccine. If you receive placebo, it is not expected to result in an immune response to rotavirus. You will have an 80% chance (4 of 5) of receiving vaccine and a 20% chance (1 of 5) of receiving placebo. Half of the vaccine recipients will receive the 3.75 µg dose and half will receive the 7.5 µg dose. Neither you nor the study doctor will know whether you received CDC-9 IRV or placebo until the study is over. You will receive 3 doses of either the vaccine or the placebo. The second dose will occur about 1 month after the initial dose, and the third dose will occur about 2 months after the initial dose. Your involvement will last approximately 9-10 months.

<u>Screening</u>

You will have a screening visit to check if you are eligible to participate. The screening visit will take about 90 minutes and includes:

- Reviewing and signing the consent form if you agree to participate in the study

- Collecting information about your medical history, including medications you take & vaccination history
- Collecting vital signs (temperature, blood pressure, heart rate) and height and weight
- Having a physical exam
- Testing your blood to check your kidneys, pancreas, and liver functions, blood cell counts, and to perform testing for HIV, hepatitis B, and hepatitis C infections. The study doctor may be required by law to report the result of the HIV and hepatitis tests to the local health authority.
- For women who can become pregnant, a urine pregnancy test

If your blood or urine lab results are not within standard, normal ranges, you will not be able to participate in the study, and the study doctor may refer you to your regular medical provider.

Women who can become pregnant must agree to use an acceptable method of birth control from at least 30 days before the first study vaccination through 60 days after the last study vaccination. Acceptable birth control methods include abstinence from sexual activity that could lead to pregnancy; monogamous relationship with a partner who has had a vasectomy at least six months ago; documented status as being surgically sterile (hysterectomy, bilateral oophorectomy, tubal ligation/salpingectomy, or Essure® placement); intrauterine devices; and hormonal methods, including the birth control patch, shot (Depo-Provera), pills, the vaginal ring (NuvaRing), and the contraceptive implant (Nexplanon).

Men of childbearing potential must agree to use of condoms to ensure effective contraception with female partners of childbearing potential OR for female partners to use at least one acceptable primary form of contraception from first vaccination until 60 days after the last study vaccination. Men must also agree to not donate sperm, from the first study vaccination until 60 days after the last study vaccination.

We will test your blood to check your kidney, pancreas, and liver functions, blood cell counts, and to perform testing for HIV, hepatitis B, and hepatitis C infections at the screening visit. For women of childbearing potential, we will perform urine testing for pregnancy at the screening visit and prior to receipt of study vaccine. In addition to these tests, blood specimens will be collected from you throughout the study to test how the immune system responds to the study vaccine. We will look at your antibodies and how different cells of your immune system help to fight the virus. We will not perform any genetic testing.

<u>Study procedures</u>

Study visits that include a study vaccination will generally last about 2-3 hours and other visits will generally last about 30 minutes. Visits may include:

- Questions about your recent medical history and medications, illnesses or symptoms, and side effects or reactions
- Collecting vital signs (heart rate, blood pressure, temperature)
- If applicable, reviewing use of birth control methods and pregnancy status
- Having a physical exam if needed
- Collection of blood samples at each of the study clinic visits (and, for women who can become pregnant, urine for pregnancy testing at each of the three study vaccination

visits)
- Study vaccination or assessment of the site of a previous study vaccination
- Photography of the patch application site
- Completion of an acceptability questionnaire to tell us how you feel about the microneedle patch
- Review of the e-diary

Study vaccination visits will occur on Study Days 1, 29, and 57. At those visits, we will review your lab test results and medical history to confirm that you are eligible for a study vaccination.

You will be in one of two study groups which will each include 25 participants. You will have a microneedle patch applied to the wrist area of the same dose of study vaccine or placebo at each of the three study vaccination visits. You will stay in the clinic for at least 30 minutes after the patch removal for study staff to check for any immediate reactions. A photograph may be taken of your wrist before and after the patch is applied to document any changes to the skin. You will also complete an acceptability questionnaire to tell us how you feel about the microneedle patch.

Photographs of the patch application site will be taken at all in-person clinic visits. These photographs only serve to document any changes to the skin where the patch was applied. Photographs will only contain the wrist area where the patch will be applied or was applied and will not include the face or anything identifiable (e.g., jewelry and watches will be removed, and markings/tattoos covered if necessary). Photographs will be stored using a coded identifier (subject ID) and will not have a name, date of birth, or any other information that can link the photo back to you.

We will give you a thermometer and ruler with instructions to record your temperature and any side effects. The e-diary will be completed by accessing a website through a link sent to your email and will ask questions about your health or potential symptoms you might have after receiving the study vaccination. You will be trained by the study staff on how to complete the e-diary. You will enter information in the e-diary each day, preferably in the evening and at the same time of day, for 7 days after each vaccination. If a reported side effect continues beyond 7 days, you will be followed by trial staff at your next site visit or phone call. Your e-diary information will be reviewed by telephone or during site visits.

If you become sick or have any reactions after a study vaccination, you should immediately contact the study staff. We may ask you to come to the clinic for an extra study visit. The staff may perform additional research or safety procedures, if needed.

Blood samples for these research tests may be sent to a central storage facility or sent directly to the research testing laboratories. These samples will not be labeled with your name or initials, or any other information that could readily identify you. These samples will be labeled only with a barcode and a unique tracking number (ID code) to help protect your confidentiality. Staff at the central storage facility and research testing laboratories will not know your identity, or even the study identifier you were assigned. We may remove the codes from your information or samples so that we cannot identify you and use these in other research. These deidentified samples may be shared with other researchers without your additional consent.

We will also collect extra blood samples at each visit (about 7 teaspoons or less depending upon the visit) to store and use for secondary research. Secondary research could test for a number of different things including but not limited to antibodies, other markers of recent infection, or immune responses. These samples will not be sold or used directly for production of any commercial product. No human genetic tests will be performed on your samples. **If you do not want to give leftover and extra samples for secondary research, you cannot be in this vaccine study.**

Samples will be stored indefinitely at Emory Children's Center and at a site determined by the CDC. Extra samples will be labeled only with a barcode and an ID code (not with your name, initials, or any other information that could readily identify you). These extra samples will be stored with the same confidentiality measures used for the main specimens.

If these samples are tested in the future, the results may be published. You will not be identified in such publication. In other words, the publication will not contain any information about you that would enable someone to determine your identity.

By signing and dating this consent form, you are agreeing to the collection, storage and future research use of your samples and information collected for this study. The results of any future research testing will be kept confidential in the same way as the results of other testing done for this study. 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.

Ask us if you have questions about how your blood samples may be used.

Follow-up procedures

In addition to the study vaccination visits, you will also come to the clinic for follow-up visits, on Days 8, 36, 64, 85, and 237. Follow-up visits in the clinic will take about 30 minutes. There will be four visits conducted over the telephone on Days 2, 30, 58, and 147, which will take less than 10 minutes.

The study staff may call you periodically during your study participation to check on your health status, to remind you of an upcoming visit, or for other reasons. We may also contact you by email or text message when appropriate.

You may be asked to come back to the study clinic at other times if needed, for example, if you have a reaction or illness that should be evaluated before the next scheduled visit. The study doctor will determine what activities will be needed after reviewing any symptoms that you are having.

Study Chart

You will receive a dose of the study vaccine or placebo every 28 days for 3 doses in this study.

Visit	Screening visit	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9	Visit 10	Visit 11	Visit 12
Study calendar	**Day 0 (or earlier)**	**Day 1**	**Day 2**	**Day 8**	**Day 29**	**Day 30**	**Day 36**	**Day 57**	**Day 58**	**Day 64**	**Day 85**	**Day 147**	**Day 237**
Review medical history, meds, & vaccines	✓	✓	☎	✓	✓	☎	✓	✓	☎	✓	✓	☎	✓
Vital signs and physical exam	✓	✓		✓	✓		✓	✓		✓	✓		✓
Blood draw	💧	💧		💧	💧		💧	💧		💧	💧		💧
Microneedle patch application		▒			▒			▒					
Photograph of patch site		📷		📷	📷		📷	📷		📷	📷		📷
Acceptability questionnaire		✓			✓			✓			✓		✓

Where will the research procedures take place?

Study procedures will be done at Emory Children's Center – Vaccine Research Clinic.

What if I have questions about my study vaccine?

The study vaccine (CDC-9 IRV vaccine) that you will take will be dispensed by the Investigational Drug Services pharmacy at Emory University and delivered to the principal investigator or study team member who will provide the study vaccine to you. If you have questions about the study vaccine, you should ask the principal investigator or study nurse.

The study team includes non-licensed team members who may obtain your consent or help guide you through the study. There are some kinds of questions only licensed clinicians can answer. For example, detailed questions about drug interactions. If you have questions like these, the non-licensed coordinator will ask a licensed study team member to answer your questions.

What are the risks of this study?

There may be some risks to participation in this study. You may experience one or more of the risks or side effects explained below. You should discuss these with the study doctor or study staff. Many side effects go away shortly if treated, but in some cases, side effects can be serious, long lasting, or permanent. The study vaccine is experimental and there may be risks that we do not know about right now. Side effects may occur more frequently with higher doses of the study vaccine or with the second or third dose compared with the first.

The possible risks of participating in this study include those associated with having blood drawn, reactions to the microneedle patch, adverse effects (side effects) of the study vaccine, and the possibility of a breach of confidentiality.

Risks of having blood drawn

Having your blood taken can cause pain and may also cause lightheadedness or fainting. The needle stick can cause bruising, which can be prevented or reduced by putting pressure on the site for a few minutes after the needle is removed. Rarely, people can get an infection at the site of the blood draw. To reduce the risk of infection after the blood draw, the study doctor or study staff will wipe the area clean with alcohol and use sterile equipment.

Risks associated with microneedle patch application

There may be side effects from the microneedle patch containing study vaccine that are not known at this time. Based on previous studies using a microneedle patch, the most common risks and discomforts expected in this study are:

- Pain or tenderness at patch administration site
- Skin irritation including mild redness or swelling of the skin at the site of the patch

placement. In previous studies, this went away after several hours but sometimes took days to disappear.
- Discoloration or darkening of the skin at the site of the patch placement. In previous studies, this almost completely resolved by 180 days.
- Itching that occurs while the patch is on the skin or after removal.

Risks associated with study vaccination

After a study vaccination, a person might experience:

- Mild to moderate events:
  - Pain or tenderness
  - Redness, swelling, hardness, or itching at microneedle patch site
  - Fever, chills, or fatigue (feeling tired)
  - Headache, muscle aches, pain, and stiffness in the joints
  - Nausea or vomiting
  - Temporary abnormal lab test results
  - Swelling of lymph nodes around the elbow or armpit
- Severe events could occur very rarely:
  - Any of the reactions listed above (such as pain or tenderness) could be severe enough to prevent you from performing your activities of daily life for some period of time.
  - Rarely, the patch could cause bleeding, bruising, permanent discoloration, or scarring at the application site.
  - Additionally, any reaction other than the above events could be severe.
  - A small number of people (about 1 in 4 million people) have an immediate allergic reaction called anaphylaxis (also known as allergic shock) after receiving vaccines or medications. This type of reaction may include symptoms such as:
    - Skin rash (hives)
    - Sweating
    - A feeling of dread
    - Swelling around the mouth, throat, and eyes
    - Wheezing
    - Difficulty breathing
    - Increased pulse
    - Fainting or feeling dizzy due to low blood pressure
    - Inability to breathe without assistance

If these reactions occur, emergency medications administered by study personnel can usually stop them. Most people who experience anaphylaxis recover completely. Rarely, people can die.

If you had an allergic reaction after being vaccinated in the past, or if you are allergic to any product, you must tell the study doctor or study staff before you decide to sign and date this informed consent form. If you have an allergy to some products, you will not be able to take part in this study. Serious allergic reactions can be life-threatening.

If it is biologically possible for you to become pregnant: to protect against possible side effects of the study vaccine, women who are pregnant or nursing a child may not take part in this study. If you become pregnant, there may be risks to you, the embryo, or fetus. These risks are not yet known. If you are a woman of childbearing ability, you and the study doctor must agree on a method of birth control to use throughout the study. If you think that you have gotten pregnant during the study, you must tell the study doctor immediately. Pregnant women will not receive additional study product, but they will be followed for safety outcomes.

If it is biologically possible for you to make someone pregnant: the effect of the study vaccine on sperm is not known. To protect against possible side effects, you should not get a sexual partner pregnant while taking the study vaccine and for 60 days after the last vaccination. You and the study doctor should agree on a method of birth control to use throughout the study.

Other risks

There is a small risk to people who have an unknown health problem at the screening visit. Your blood will be taken at the screening visit to check for health problems. We will review your results before giving you the first study vaccination.

There may be side effects from the study vaccine study or procedures that are not known at this time.

There is a risk of loss of confidentiality of your information. You will read more about the protection of your information later in this consent form. Please ask us if you would like to know more about how your information will be protected while you are in this study.

Researchers may learn something new during the study that may affect your choice to be in the study. If this happens, they will tell you about it. Then you can choose if you want to stay in this study. You may be asked to sign a new form if you choose to stay in the study.

Will I benefit from the study?

There will be no direct benefit from taking part in the study. What is learned from this study may help others in the future.

Will I be paid for my time and effort?

You will receive $100 for the screening visit and each completed vaccine visit, $50 for each completed follow-up study visit, and $30 for each completed week of e-diary entries to compensate you for your time and effort. If any unscheduled visits are required, then you will receive $20 in compensation per visit. If you do not finish the study, we will compensate you for the visits you have completed. You will get approximately $940 total if you complete all study visits.

Emory may be required to report your payment(s) to the IRS depending on how much you receive in a year. You must give the researchers a valid Social Security number or Taxpayer Identification

Number for IRS reporting purposes. If you do not, your amount may be reduced because taxes are taken out. Please talk to your study team for more details.

A company called Greenphire is working on behalf of the study to compensate participants. Greenphire will need to collect certain personal information about you to set up your account. The company will see this study title but will not any research-related information about you.

We reserve the right to change the method of payment if Clincard is unavailable.

Who owns my study data and samples?

If you join this study, you will be donating your samples and data. You will not be paid if your samples or data are used to make a new product. Leftover and extra blood samples may be used in the future for research about this study vaccine and your body's response to this study vaccine. These blood samples might be used in new or different laboratory tests, to give information for the development of new vaccines, or for the studies of rotavirus or other infections, including using tests that have yet to be developed. You will not be contacted about the types of future research. You may change your mind about secondary research and withdraw consent for the storage and use of your coded samples or information at any time. You will need to contact the study doctor using the contact information listed on page 17 of this form. If you have visits after this, we will stop collecting extra blood.

If you leave the study, the data and samples that were already collected may still be used for this study. Your samples will be removed from future use when the vaccine study is completed. Only stored samples with an ID code and not used in this research can be removed or destroyed. Research that has already begun using your specimens cannot be withdrawn. For example, if some research with your specimens and data has already been completed, the information from that research may still be used. Also, for example, if the specimens and data have been shared already with other researchers, it might not be possible to withdraw the specimens and data.

What are my other options?

Your option is to not join the study.

If you choose to join this study, you may not be able to join other research studies. Discuss this with the researchers if you have concerns. You may wish to look on websites such as ClinicalTrials.gov and ResearchMatch.org for other research studies you may want to join.

How will my private information be protected?

Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

Study records can be opened by court order. They also may be provided in response to a subpoena or a request for the production of documents.

What is a Certificate of Confidentiality?

This research project has a Certificate of Confidentiality from the Centers for Disease Control and Prevention (CDC). Unless you say it is okay, researchers cannot release information that may identify you for a legal action, a lawsuit, or as evidence. This protection applies to requests from federal, state, or local civil, criminal, administrative, legislative, or other proceedings. As an example, the Certificate would protect your information from a court subpoena. There are some important things that you need to know. The Certificate DOES NOT protect your information if a federal, state, or local law says it must be reported. For example, some laws require reporting of abuse, communicable diseases, and threats of harm to yourself or others. The Certificate CANNOT BE USED to stop a federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop reporting required by the U.S. Food and Drug Administration (FDA). The Certificate also DOES NOT stop your information from being used for other research if allowed by federal regulations.

Researchers may release your information when you say it is okay. For example, you may give them permission to release information to insurers, your doctors, or any other person not connected with the research. The Certificate of Confidentiality does not stop you from releasing your own information. It also does not stop you from getting copies of your own information.

Will my data be stored, shared with other researchers, or used to make new products?

This study is collecting data and specimens from you. We would like to make your data and specimens available for other research studies that may be done in the future. The research may be about similar diseases or conditions to this study. However, research could also be about unrelated diseases, conditions, or other types of research. These studies may be done by researchers at this institution or other institutions, including commercial entities. Our goal is to make more research possible. We plan to keep your data and specimens indefinitely.

Your de-identified data and specimens may be shared with other collaborating researchers. However, your data and specimens will only be shared with researchers conducting IRB-approved studies. The researchers will only have access to de-identified data and specimens and must agree not to try to identify you.

We will protect the confidentiality of your information to the extent possible. Your data and specimens will be coded to protect your identity before they are shared with other researchers. Emory will have a code key that can be used to link to your identifying information. The code key

will be securely stored. However, there remains a possibility that someone could identify you. There is also the possibility that unauthorized people might access your data and specimens. In either case, we cannot reduce the risk to zero.

The use of your data and specimens may lead to new tests, drugs, devices, or other products or services with commercial value. These products or services could be patented and licensed. There are no plans to provide any payment to you should this occur.

Will clinically relevant research results be shared with me?

In general, we will not give you any individual results from the study of the samples you give us.

It is possible that we will discover something that is unrelated to the purpose of this study. If we believe that the information is of urgent medical importance, we will share this information with you.

How will my participation affect my medical record?

If you do not already have an electronic medical record where this research will take place, one may be created for you if you enroll in this study. We do this so that Emory can track your participation in this study for safety and quality reasons. The information in your medical record will be protected by laws like the HIPAA privacy rule. In research studies, it is possible that all, some, or no study test results or procedures will be documented in your medical record. For this study, those items include vital signs, height, weight, physical examination findings, pregnancy test results (if individual is of childbearing potential), laboratory test results (including results of HIV, Hepatitis B, and Hepatitis C tests), information entered in the e-diary, or adverse event or serious adverse event assessments.

Please ask your study team if you have questions about this.

What if I am injured in this study?

If you get ill or injured from this research, contact the person listed in the contact section of this form.

Emory will help you get immediate medical care. However, Emory and the Centers for Disease Control and Prevention do not have programs (or do not plan) to pay for this medical care or compensate you if you are hurt from being in this study.

The costs for any treatment or hospital care you receive from a study-related injury not covered by a health insurer may be billed to you if you do not have insurance. You will be responsible for deductibles, co- payments, and co-insurance.

There are no plans to pay you or give you other compensation for the injury. You do not give up any legal rights you may have by being in this study, including any right to pursue a claim through the legal system.

Will there be any costs to me if I join the study?

There will be no costs to you for participating in this study, other than basic expenses like transportation. You will not be charged for any of the research activities.

Can I leave the study after I join the study?

You have the right to leave a study at any time without penalty.

The researchers also have the right to take you out of the study without your consent for any reason. They may do this if they believe it is in your best interest or if you do not agree to changes that may be made in the study.

These are some reasons why the researchers may take you out of the study:

- Reasons related to you (for example, if you move to another city or if you do not agree to receive your study vaccination)
- Reasons related to your health (for example, if you have a serious reaction to the study vaccine)
- Because the entire study is stopped (the sponsor may stop the study at any time)
- If you do not later consent to any future changes that may be made to how the study is done
- If you become pregnant
- Any other reason

Confidentiality

Certain offices and people other than the researchers may look at study records. Government agencies and Emory employees overseeing proper study conduct may look at your study records. These offices include the Office for Human Research Protections, the Emory Institutional Review Board, the Emory Office of Compliance, and the Food & Drug Administration. Study funders may also look at your study records. Emory will keep any research records we create private to the extent we are required to do so by law. A study number rather than your name will be used on study records wherever possible. Your name and other facts that might point to you will not appear when we present this study or publish its results.

People Who will Use/Disclose Your Information:

The following people and groups will use and disclose your information in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your information to conduct the study and give you study related treatment.

- Emory may use and disclose your information to get payment for study related activities and to run normal business operations.
- The Principal Investigator and research staff will share your information with other people and groups to help conduct the study or to provide oversight for the study.
- The Centers for Disease Control and Prevention is the Sponsor of the study. The Sponsor may use and disclose your information to make sure the research is done correctly and to collect and analyze the results of the research. The Sponsor may disclose your information to other people and groups like study monitors to help conduct the study or to provide oversight for the study.
- Micron Biomedical is providing the microneedle patches for the study and will collect the used patches for analysis. Micron may use and disclose your information to collect and analyze the results of the research.
- The research team may use and disclose your information, including disclosure to insurance carriers to administer payment for subject injury.
- The following people and groups will use your information to make sure the research is done correctly and safely:
    - Emory offices that are part of the Human Research Participant Protection Program and those that are involved in study administration and billing. These include the Emory IRB, the Emory Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
    - Other researchers and centers that are a part of this study.
    - Government agencies that regulate the research including Office for Human Research Protections and Food & Drug Administration.
    - Public health agencies.
    - Research monitors and reviewers, including independent study monitors or monitors from a contract research organization.
    - Accreditation agencies.
- Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your information may be shared with that new institution and their oversight offices. Information will be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent.

Contact Information

If you have questions about the study procedures, appointments, research-related injuries or bad reactions, or other questions or concerns about the research or your part in it, contact the research and recruiting team at [redacted] or [redacted].

For emergencies: Contact the 24-hour emergency number at [redacted].

This study has been reviewed by an ethics committee to ensure the protection of research participants. If you have questions about your **rights as a research participant**, or if you have **complaints** about the research or an issue you would rather discuss with someone outside the research team, contact the Emory Institutional Review Board at [redacted] or [redacted].

To tell the IRB about your experience as a research participant, fill out the Research Participant Survey at [redacted] or scan the QR code to fill out the survey.

[redacted]

EMORY UNIVERSITY | Institutional Review Board
Research Administration

Consent

TO BE FILLED OUT BY SUBJECT ONLY

Future Use Acknowledgement

_____ (Initials) I understand, if I take part in this study, that my blood samples will be stored indefinitely and may be used for future research as described above.

If you choose to be in this research study: print your name, sign, and date below. You will not give up any of your legal rights by signing this form. We will give you a copy of the signed form to keep.

_____

Name of Subject

_____ _____

Signature of Subject (18 or older and able to consent) **Date and Time**

TO BE FILLED OUT BY STUDY TEAM ONLY

_____

Name of person conducting informed consent discussion

_____ _____

Signature of person conducting informed consent discussion **Date and Time**

Contact For Future Studies:

We may want to contact you in the future to ask if you would like to participate in another related study or in future unrelated studies. If you agree, we would like to keep your name, date of birth, address, phone number and e-mail address on file. This information will be kept confidential and will not be shared with other investigators at this or other institutions.

Please initial your decision about permission for us to contact you in the future for upcoming studies (initial only ONE option):

_____YES, you may contact me in the future by telephone, e-mail, text messaging or postal mail to inform me of upcoming studies.

_____NO, you may not contact me in the future regarding upcoming studies.