Title: Systems Biology of Zoster Vaccine Recombinant, Adjuvanted

NCT#: NCT04047979

Date: 10/22/2021

# You Are Being Asked to Be in a Research Study

## What Is a Research Study?

The main purpose of research studies is to gain knowledge. This knowledge may be used to help others. Research studies are not intended to benefit you directly, though some might.

## Do I Have to Do This?

**No. Being in this study is entirely your choice. If you decide to join this study, you can change your mind later on and withdraw from the research study.**

Taking part in a study is separate from medical care. The decision to join or not join the research study will not affect your status as a patient.

## What Is This Document?

This form is an informed consent document. It will describe the study risks, procedures, and any costs to you.

This form is also a HIPAA Authorization document. It will describe how your health information will be used and by whom.

Signing this form indicates you are willing to take part in the study and allow your health information to be used.

## What Should I Do Next?

1. Read this form, or have it read to you.
2. Make sure the study doctor or study staff explains the study to you.
3. Ask questions (e.g., time commitment, unfamiliar words, specific procedures, etc.)
4. If there will be medical treatment, know which parts are research and which are standard care.
5. Take time to consider this and talk about it with your family and friends.

**Emory University**
**Consent to be a Research Subject / HIPAA Authorization**

**Title**: Systems Biology of Zoster Vaccine Recombinant, Adjuvanted (Shingrix®)

**Principal Investigator:** Nadine Rouphael, MD, MSc
Emory University School of Medicine,
The Hope Clinic, 500 Irvin Court, Suite 200
Decatur, GA 30030

**Sponsor:** National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH)

**Dr. Bali Pulendran serves as the overall Principal Investigator for the overall grant funding the current study Dr. Pulendran serves as consultant for GlaxoSmithKline, the manufacturer of the Shingrix vaccine used in this study. Dr. Pulendran receives compensation for his services. The terms of this arrangement have been reviewed and approved by Emory University in accordance with its conflict of interest policies.**

## Introduction

You are being asked to be in a medical research study. This form is designed to tell you everything you need to think about before you decide if you want to be a part of the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.** The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.

Before making your decision:

- Please carefully read this form or have it read to you
- Please listen to the study doctor or study staff explain the study to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form you will not give up any legal rights.

A description of this clinical trial will be available on http://www.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.

## What is the purpose of this study?

The purpose of the study is to better understand how the immune system responds to the new herpes zoster (shingles) vaccine (Shingrix®). We will be looking at some markers in the blood after vaccination with Shingrix®.

Varicella zoster virus (VZV) can cause two diseases: chicken pox (varicella) and herpes zoster (shingles). The primary infection with VZV causes chicken pox, a widespread rash with fever, mostly in childhood. The virus can then remain in a person's body and has the ability to reactivate later in life causing shingles. Shingles is a painful rash, occurring mostly in older people or those who have a weakened immune system. After the rash goes away, individuals may have ongoing pain in the same area.

The study will be an open label clinical trial in healthy older adults. There will be two groups of participants: those aged 50 to 60 years or those who are 70 years old and above. Everyone will receive two doses of the vaccine. This will help us compare the immune response to the herpes zoster vaccine in different age groups of older adults.

We plan to have 60 people receive the study vaccine at the Hope Clinic. To get 60 people who are eligible to receive the vaccine, about 100 people may need to sign the consent form and be screened for the study.

You cannot be in this study if you:

- Are a woman able to bear children
- Are sick within 72 hours before vaccination
- Received blood products within 6 months before or 6 months after vaccination
- Received any vaccine within 4 weeks before or 4 weeks after vaccination
- Have any acute or chronic medical condition that the study doctor thinks may harm you or confuse the study
- Have a history of bleeding disorders
- Are taking any retroviral therapy with activity against herpes viruses (acyclovir, famciclovir, valacyclovir, etc.) within 3 days before or 14 days after vaccination
- Use oral or parenteral corticosteroids of any dose for >2 weeks within 90 days before vaccination
- Have a suppressed immune system as a result of illness, immunosuppressive medication, chemotherapy, or radiation therapy within 3 years before vaccination
- Have a history of HIV, hepatitis B or C, tuberculosis, or transplant (bone marrow, hematopoietic stem cell, or solid organ transplant)
- Have severe reactions to prior vaccinations, including severe allergic reactions (anaphylaxis)
- Have any allergy to any component of the vaccine
- Have received any experimental drug or vaccine within 12 months before vaccination
- Have previously received any shingles or varicella vaccine or immunoglobulin
- Have a history of shingles

**What will I be asked to do?**

The study lasts for 6 months and requires 13-14 visits. Visits 1 and 7 are the vaccination visits, visits 2-6 and 8-13 are follow-ups during which blood will be drawn. The study will have an optional visit anytime after 9 months from the first vaccination during which blood collection will be done.

Screening Visit:

- Time: about 1 ½ -2 hour
- Consent for participation in the study if you choose
- Collect your medical history, medications, and vaccinations
- Measure oral temperature, pulse, blood pressure, height, and weight
- Physical exam may be done
- You will receive a stool collection kit and instructions on how to collect a stool sample

FirstVaccination Visit Time: about 1 ½ hour

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- Measure oral temperature, pulse, blood pressure, Review eligibility
- Review changes to medical history, mediciations and vaccine history
- Physical exam may be done
- Collect blood samples for immune analysis and provide stool
- Receive 1st dose of vaccine
- Stay at clinic for 15 minutes after getting vaccine

- Get memory aid to record any health changes you have for 7 days after the vaccine

The Screening and Vaccination Visits may be combined into one visit if all activities can be completed in one visit. A combined Screening and Vaccination Visit may take about 2- 2 ½ hours.

Visits 2-6 and 8-13: Follow-up:

- Time: about 30 minutes
- Review changes to medical history and medications
- Oral temperature, pulse, blood pressure may be measured
- Physical exam may be done
- Collect blood samples
- Review memory aid (for visits 2, 3, 4, 8, 9, 10)

Visit 7: 2nd Vaccination (This visit is for 2 hours):

- Time: about 2 hour
- Review changes to medical history and medications
- Measure oral temperature, pulse, blood pressure
- Physical exam may be done
- Collect blood samples.
- Receive 2nd dose of vaccine
- Stay at clinic for 15 minutes after getting vaccine
- Get memory aid to record any health changes you have for 7 days after the vaccine

**Missed Vaccination visit:**

If you miss the second vaccination due to the CoVID-19 pandemic, we may contact you to return for the missed vaccination visit, If you have not received the second dose from an outside source. Ideally the second dose is given 2-6 months apart, if more than 6 months have elapsed since the first dose of the vaccine the Centers for Disease Control and Prevention (CDC) recommends that the second dose be given as soon as possible. During the second vaccination visit we will review the consent form with you and complete the same procedures and assessments as outlined under Visit 7: 2nd vaccination visit. After the visit you will be asked to return for regular follow up visits as scheduled.

**Optional: Blood Sample Storage for Future Research**

This study involves the collection of blood samples. With your agreement, the researchers may store these samples from the main study for future medical research. You will be asked to consent separately at the end of this form for the retention and use of your leftover samples.

These samples could be used to further explore the markers of immune response to this adjuvanted vaccine. Your samples will not be sold or used directly for production of any commercial product. Reports about future research done with your samples will NOT be kept in your health records.

If you do not agree to this future research, your samples will be used only for the main study and destroyed after analysis. If consent is not given for use of the samples for future use, you can still participate in the main study.

All blood samples collected from you will be stored in secure facilities during the study and will be destroyed on completion of the study analyses. Coded samples may be stored at the Pulendran Lab at Stanford University or Sette Lab at La Jolla Institute. If you have agreed for your samples to be used for future research, then they will be stored indefinitely. You can ask for your samples to be destroyed before this point. However, data derived from samples will continue to be kept and used for the purposes agreed to by you in this document. To ensure privacy, your name and other identifying information will not be attached to the samples released for research purposes or any data derived from your samples; instead, you will only be identified by the subject ID code, which will not allow the lab or third parties to know your identity.

If you decide to leave the study at any time but do not ask for your samples to be destroyed, the researchers may continue to use your samples for the reasons allowed by you in this document.

**How will my vaccine be provided**?
The vaccine that you get will be dispensed by the pharmacy and delivered to the principal investigator or study team member. They will provide the vaccine to you intramuscularly, as a shot, in the deltoid muscle of either arm. If you have questions about the vaccine, you should ask the principal investigator or study team member.

**Who owns my study information and samples?**
If you join this study, you will be donating your samples and study information. You will not receive any compensation if your samples or information are used to make a new product. If you withdraw from the study, data and samples that were already collected may be still be used for this study.

**What are the possible risks and discomforts?**
There may be side effects from the study vaccine or procedures that are not known at this time.

**Blood Draw**
Some people may get lightheaded or faint during or just after having blood drawn. Having your blood drawn can be painful and can cause bruising. Bruising can be prevented or reduced by putting pressure on the site for a few minutes after the blood is drawn. It is possible to get an infection where the study doctor or study staff draw your blood, but this is very rare. To reduce the risk of infection, the study doctor or study staff will wipe the area clean with alcohol and use sterile equipment.

**Vaccination**
The potential risks of receiving Shingrix® vaccine include but are not limited to:
- Vaccine site reactions: pain (78%), redness (38.1%), and swelling (25.9%)
- General body reactions: muscle pain (myalgia) (44.7%), tiredness (fatigue) (44.5%), headache (37.7%), shivering (26.8%), fever (20.5%), and gastrointestinal symptoms (17.3%).

The majority of these reactions lasted 2 to 3 days.

**If you are a woman**: to protect against possible side effects of the vaccine, women who are of childbearing potential, pregnant, or nursing a child may not take part in this study.

**If you are a man:** the effect of the vaccine on sperm is not known. To protect against possible side effects, if you are a man you should not get a sexual partner pregnant while getting study vaccine and for 2 months after the last dose. You and the study doctor should agree on a method of birth control to use throughout the study.

It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

**Will I benefit directly from the study?**

This study is not designed to benefit you directly. However, you will gain some protection against the development of herpes zoster (shingles). This study is designed to learn more about the body's response to the Shingrix® herpes zoster vaccine. The study results may help others in the future.

**Will I be compensated for my time and effort?**

You will get $75 for each of the vaccination visits and $50 for screening and follow-up visits to compensate you for your time and travel. If you do not finish the study, we will compensate you for the visits you have completed. If you complete all study visits, you could receive a total compensation of $750. You will be compensated $50, if you opt to come in for the optional visit that will occur anytime after 9 months from the first vaccination.

Our preferred method of compensation will be the use of Clincards. We would also like the option of compensating you in the form of cash, check or gift card if ClinCard is not available. All payments are made using a personal payment card. We issue this to you for free. The payment card is a prepaid debit card. It can be used exactly like a MasterCard.

We load money onto your card electronically every time you need to be paid. The card scheme is run by Greenphire, an independent company specializing in payments for research studies and clinical trials. To issue your card, we need to give Greenphire some of your personal information. Banks and other financial institutions can access this information if they need to verify your identity when you use your card.

Emory University is required by law to report any payments we make to the IRS. To do this, Emory University Department of Finance needs to keep your Social Security Number on file. We are asking you to allow us to communicate your name, address, date of birth, research study name and Social Security Number to Greenphire and Emory University Department of Finance. If you want to receive e-mail or text alerts when payments are made to you, we will ask you to provide your e-mail or phone number as well. All of this information will be stored on computers owned by Greenphire. Greenphire will not have access to any other information collected during this study. Full instructions about using your card are included when we issue it. Please ask if you have any questions or concerns about the card scheme.

You will be asked to fill out a tax form, including your Social Security or Taxpayer Identification Number, in order to be reimbursed, depending on the amount and method of payment. Some payment methods involve mail coming to your house, which may be seen by others in your household. You can decline payment if you are concerned about confidentiality, or you can talk to the study team to see if there are other payment options.

**What are my other options?**

You do not have to take part in this study. If you decide not to participate, you can discuss with your health care provider and get the vaccine as part of your regular medical care.

Taking part in this study, however, may make you unable to participate in some other research studies, if they exclude people who have taken certain treatments. You should discuss this with the researchers if you have concerns. You may wish to research other study options at websites like clinicaltrials.gov and ResearchMatch.org.

**How will you protect my private information that you collect in this study?**

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.

**Certificate of Confidentiality**

There is a Certificate of Confidentiality from the National Institutes of Health for this Study. The Certificate of Confidentiality helps us to keep others from learning that you participated in this study. Emory will rely on the Certificate of Confidentiality to refuse to give out study information that identifies you. For example, if Emory received a subpoena for study records, it would not give out information that identifies you.

The Certificate of Confidentiality does not stop you or someone else, like a member of your family, from giving out information about your participation in this study. For example, if you let your insurance company know that you are in this study, and you agree to give the insurance company research information, then the investigator cannot use the Certificate to withhold this information. This means you and your family also need to protect your own privacy.

The Certificate does not stop Emory from making the following disclosures about you:

- Giving state public health officials information about certain infectious diseases,
- Giving law officials information about abuse of a child, elderly person or disabled person.
- Giving out information to prevent harm to you or others.
- Giving the study sponsor or funders information about the study, including information for an audit or evaluation.

**Storing and Sharing your Information**

De-identified data from this study, may be shared with the research community at large to advance science and health. Data from this study may be placed into public databases where, in addition to having no direct identifiers, researchers will need to sign data use agreements before accessing the data. We will remove or code any personal information that could identify you before your information is shared. This will ensure that, by current scientific standards and known methods, it is extremely unlikely that anyone would be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

**Medical Record**

If you have been an Emory Healthcare patient before, then you already have an Emory Healthcare medical record. If you have never been an Emory Healthcare patient, you do not have one. An Emory Healthcare medical record will be made for you if an Emory provider or facility gives you any services or procedures for this study.

Copies of the consent form/HIPAA authorization that you sign will be put in any Emory Healthcare medical record you have now or any time during the study.

The results of some study tests and procedures will be used only for research purposes and will *not* be placed in your medical record.

Tests and procedures done at non-Emory places may not become part of your Emory medical record. Also, if you decide to be in this study, it is up to you to let your other health providers know.

To comply with Georgia State Law we will document in the Georgia Registry of Immunization Transactions and Services (GRITS) that you have received the herpes zoster (Shingrix®) vaccine.

**In Case of Injury**
If you get ill or injured from being in the study, Emory will help you get medical treatment. Emory and the sponsor have not, however, set aside any money to pay you or to pay for this medical treatment. The only exception is if it is proven that your injury or illness is directly caused by the negligence of an Emory or sponsor employee. "Negligence" is the failure to follow a standard duty of care.

If you become ill or injured from being in this study, your insurer will be billed for your treatment costs. If you do not have insurance, or if your insurer does not pay, then you will have to pay these costs.

If you believe you have become ill or injured from this research, you should contact Dr. Nadine Rouphael at telephone number [redacted]. You should also let any health care provider who treats you know that you are in a research study.

**Costs**
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. If the study procedures result in any medical complications that would not fall under "injury" as discussed above, the cost of treatment for those complications may be charged to you or your insurance.

**Withdrawal from the Study**
You have the right to leave a study at any time without penalty.

The researchers also have the right to stop your participation in this study without your consent for any reason, especially if they believe it is in your best interest or if you were to object to any future changes that may be made in the study plan.

## Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. We call your health information that identifies you, your "protected health information" or "PHI." To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA). We refer to all of these laws as the "Privacy Rules." Here we let you know how we will use and disclose your PHI for the main study.

**PHI that Will be Used/Disclosed:**
The PHI that we will use or share for the main research study includes:

- Medical information about you including your medical history and present/past medications
- Results of exams, procedures and tests you have before and during the study
- Laboratory test results
- Pregnancy test results
- Personal information such as: name, date of birth, social security number, address, phone number, email, and date of study visits

**Purposes for Which Your PHI Will be Used/Disclosed:**
We will use and share your PHI for the conduct and oversight of the research study. We will use and share your PHI to provide you with study related treatment and for payment for such treatment. We will also use and share your PHI to conduct normal business operations. We may share your PHI with other people and places that help us conduct or carry out the study, such as laboratories, data management centers, data monitors,

contract research organizations, Institutional Review Boards (IRBs) and other study sites. If you leave the study, we may use your PHI to determine your health, vital status or contact information.

**Use and Disclosure of Your Information That is Required by Law**:
We will use and disclose your PHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults.

**Authorization to Use PHI is Required to Participate**:
By signing this form, you give us permission to use and share your PHI as described in this document. You do not have to sign this form to authorize the use and disclosure of your PHI. If you do not sign this form, then you may not participate in the research study.

**People Who will Use/Disclose Your PHI:**
The following people and groups will use and disclose your PHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your PHI to conduct the study.
- Emory may use and disclose your PHI to get payment for study related treatment and to run normal business operations.
- The Principal Investigator and research staff will share your PHI with other people and groups to help conduct the study or to provide oversight for the study.
- NIH/NIAID is the Sponsor of the study. The Sponsor may use and disclose your PHI to make sure the research is done correctly and to collect and analyze the results of the research. The Sponsor may disclose your PHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.
- Bali Pulendran at Stanford University may use your PHI to conduct the study
- Alex Sette at La Jolla Institute may use your PHI to conduct the study
- Greenphire operates ClinCard and uses the personal information listed above to put study payments onto the ClinCard.
- The following people and groups will use your PHI 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; Food and Drug Administration
    - Public health agencies
    - Research monitors and reviewer
    - Accreditation agencies
- Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your PHI may be shared with that new institution and their oversight offices. PHI will be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent and HIPAA authorization.

**Expiration of Your Authorization**
Your PHI will be used until this research study ends.

**Revoking Your Authorization**

If you sign this form, at any time later you may revoke (take back) your permission to use your information. If you want to do this, you must contact the study team at: The Hope Clinic, 500 Irvin Court, Suite 200, Decatur, GA 30030.

At that point, the researchers would not collect any more of your PHI. But they may use or disclose the information you already gave them so they can follow the law, protect your safety, or make sure that the study was done properly and the data is correct. If you revoke your authorization you will not be able to stay in the main study.

**Other Items You Should Know about Your Privacy**
Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them. The Sponsor, and people and companies working with the Sponsor on this study are not covered by the Privacy Rules. They will only use and disclose your information as described in this Consent and Authorization.

To maintain the integrity of this research study, you generally will not have access to your PHI related to this research until the study is complete. When the study ends, and at your request, you generally will have access to your PHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your PHI. Once we do this, the remaining information will not be subject to the Privacy Rules. Information without identifiers may be used or disclosed with other people or organizations for purposes besides this study.

**Contact for Future Studies & Database Storage**
We may want to contact you in the future to see if you are interested in participating in other studies. If and when you are contacted, you can decide then if you want to participate or not in new studies. In order to be able to contact you in the future, we will need to store your information in a secure password protected database. We may contact you about future studies by telephone, e-mail, text or mail. Please note that these methods of communication may not be secure.

The risk to you is a potential loss of privacy; however, your privacy is very important to us and we have safeguards in place to protect your information.

We plan to store in the database selected information including but not limited to the following: your name, gender, date of birth, address, telephone number, e-mail, studies that you either screened for or enrolled in, and health information and sexual orientation so that we can match you with a study that best fits you and contact you in the future. Your decision regarding future contact will not affect your participation in this study.

**Contact Information**
Contact Dr. Nadine Rouphael at [redacted] or the 24 hour emergency phone number at [redacted] during business hours. For evening/weekend hours – [redacted] (Emory Hospital Paging Service, ask for the physician on call for the [redacted]).

- if you have any questions about this study or your part in it,
- if you feel you have had a research-related injury or a bad reaction to the study drug, or
- if you have questions, concerns or complaints about the research

Contact the Emory Institutional Review Board at [redacted]

- if you have questions about your rights as a research participant.
- if you have questions, concerns or complaints about the research.
- You may also let the IRB know about your experience as a research participant through our Research Participant Survey at http://www.surveymonkey.com/s/6ZDMW75.

**Consent and Authorization**

Please ***initial*** below if you opt to participate in the following:

**Optional: Blood Sample Storage for Future Use:**

_____YES, you may store my unused coded (identified as described above) samples for an indefinite period of time for future research as described above.

_____YES, you may store my unused samples for an indefinite period of time for future research as described above, but you must remove any information that could identify it as mine (labeling it only by study and group). If we remove information that can identify you from the sample, if you decide in the future that you would like to have it removed from research, we will be unable to do so as we will not know which sample is yours.

_____NO, you may not use my samples for other future research. Destroy my unused samples at the end of this study.

**Optional: Contact for Future Studies & Database Storage**

Please place your initials below (select only ONE option):

_____YES, you may contact me about future studies and store my information in a secure password protected database.

_____ NO, you may not contact me about future studies and store my information in a secure password protected database.

***TO BE FILLED OUT BY SUBJECT ONLY***

Please **print** your name, **sign**, and **date** below if you agree to be in this research study. By signing this consent and authorization form, you will not give up any of your legal rights. We will give you a copy of the signed form to keep.

_____

**Name of Subject**

_____ _____ **AM / PM**

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

***TO BE FILLED OUT BY STUDY TEAM ONLY***

_____

**Name of Person Conducting Informed Consent Discussion**

_____ _____ **AM / PM**

**Signature of Person Conducting Informed Consent Discussion** **Date** **Time**