You Are Being Asked to Be in a Research Study

Concise presentation of key concepts

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study you will be one of 50 people who are being studied, at Emory.

Why is this study being done?

This study is being done to compare a new rabies vaccine (ChAd155-RG) with an existing rabies vaccine (RabAvert). The study is being done to answer the question: Is the new vaccine, ChAd155-RG, as safe as the existing vaccine, RabAvert? This study will also assess the antibody response to both vaccines. You are being asked to be in this research study because you are in good health and between the ages of 18-49 years old.

Do you have to be in the study?

It is your decision to be part of this research study. You do not have to be in it. Before you make your decision, you should take time to learn about the study.

What do I have to do if I choose to participate in this study?

If you are eligible and want to be part of the study, you will participate for 13 months (12-13 study visits). The researchers will ask you to do the following:

- give information about your medical and travel history including medications and vaccines you have received,
- have your vital signs, height, and weight measured,
- allow study health care providers to do physical exams,
- have blood drawn for safety and research tests,
- give urine for a safety test
- for females able to bear children: give urine for pregnancy tests (if you are able to bear children) and use birth control before and after you get the study vaccine,
- receive several study vaccines that could be RabAvert, ChAd155-RG, or placebo
- undergo testing for COVID-19 if indicated based on your symptoms
- record your symptoms on a memory aid after you get the vaccine.

ALL of these procedures will be paid for by the study.

How is this study going to help you?

If you are in the study, you will be helping the researchers answer the study question.

What are the risks or discomforts I should know about before making a decision?

The study will take time. The vaccine that is being tested may not work 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 – for this study, these include risks due to unanticipated test results, local and generalized vaccine reactions to study vaccines, blood draw. Some vaccine reactions may overlap with symptoms of COVID-19, and you may need to undergo testing for COVID-19 during the study using a research-based test. Other risks include loss of privacy and breach of confidentiality. A full list of expected risks, their frequency and severity are in the "What are the possible risks and discomforts?" section of this document.

Alternatives to Joining This Study

Since this is not a treatment study, the alternative is to not be in the study.

Costs

You WILL NOT have to pay for any of the study procedures. There is more information in the cost section below.

What Should I Do Next?

Read this form, or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions (e.g., about exact time commitment, about unfamiliar words, more details on specific procedures, etc.). Take time to consider this, and talk about it with your family and friends.

Emory University
Consent to be a Research Subject

Title: DMID 17-0089 A Phase 1, Dosage-Escalation Study of the Safety and Immunogenicity of a Novel Rabies Vaccine ChAd155-RG vs. the Comparator RABAVERT Vaccine in Healthy Adult Subjects

Principal Investigator: Varun K. Phadke, MD
Emory University School of Medicine,
The Hope Clinic, 500 Irvin Court, Suite 200
Decatur, GA 30030

Sponsor: National Institute of Allergy and Infectious Disease (NIAID)

Study-Supporter: ReiThera/GlaxoSmithKline Vaccines

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?

Rabies is an acute, progressive disease caused by a virus. Rabies causes encephalitis (inflammation of the brain). This infection can occur after exposure to the saliva of an infected animal. Rabies is almost always fatal and no standard treatment exists.

There are FDA approved vaccines that have been available in the U.S. for decades that can prevent rabies. In the US, two vaccines are currently available. One is called RABAVERT. This vaccine has an inactivated form of rabies virus made from chick embryos. To prevent rabies, RABAVERT is given in a 3 dose series over several weeks. A 4 dose series is recommended when someone has been exposed to rabies. Depending on the

exposure, another treatment can be given using rabies immunoglobulin (RIG) (antibodies against the rabies virus). Almost everyone that gets the recommended series of vaccines has a good immune response.

Even with RABAVERT, rabies remains widespread throughout the world. This is largely because rabies vaccines are not readily available, especially in countries with a high rate of animal rabies. The recommended rabies vaccine schedule is complicated and expensive. New vaccines are needed. New vaccines against rabies should be safe, affordable, and work as well as current vaccines. New rabies vaccines should need less doses to reduce the inconvenience and costs.

Some rabies vaccines, available outside the US, use a chemically weakened virus not related to rabies. This virus transports parts of the rabies virus to create an immune response to rabies. These vaccines are called modified live viral-vectored rabies vaccines and can be given as 1 dose. These rabies vaccines have been successful in animals for decades. Scientists think a similar approach could be used against human rabies.

A recently developed rabies vaccine using a live viral-vectored chimpanzee adenovirus will be tested in this study. The vaccine, ChAd155-RG, has a viral vector (the chimpanzee adenovirus). It has been changed so the virus cannot replicate. This vector carries inactivated parts of rabies virus. The ChAd155-RG vaccine has been tested in animals and was found effective.

You are being asked to take part in a research study for a new rabies vaccine. **The main purpose of this study is to compare an existing rabies vaccine (RABAVERT) to a new vaccine (ChAd155-RG).**

This trial will see if data from previous studies for ChAd155-RG can be repeated.

This study is being conducted at Emory University Hope Clinic. It is a Phase I, observer blinded, dosage-escalation trial. A phase I clinical trial tests the safety, side effects, best dose, and timing of a new vaccine. Observer blinded means that study team members that will be assessing you throughout the study will not know what vaccine you will receive. A dose escalation trial means the study will start by giving a lower dose of the study vaccine to participants. These participants will be observed for safety before a higher dose is given to another group of participants. The higher dose of the study vaccine is double the lower dose.

About 50 participants will sign the consent and qualify to get the shots. We expect we will need about 150 people to sign the consent and screen for the study to find 50 who qualify.

What will I be asked to do?

To qualify for this study you must:

- be 18-49 years old
- be in good general health
- follow the instructions you are given
- come to the clinic for all study visits
- tell us about any changes in your health or the way you feel
- tell us if you want to stop taking part in this study at any time
- agree to not be in any other research studies or plan to be
- have not donated blood or blood products recently and agree to not donate blood or blood products during the study

There will be 50 participants in this study, and 38 will receive the new vaccine and 12 will receive the existing vaccine. If you are enrolled into the study, you will be randomized (assigned by chance) to one of the study

groups in the table below. There is about a 3 in 4 chance that you will be in a group that will receive the new vaccine (ChAd155-RG). Groups A, B, and C will receive the ChAd155-RG vaccine. There is about a 1 in 4 chance you will receive the FDA approved vaccine (RABAVERT). Group D will receive the RABAVERT vaccine. Regardless of which group you are assigned to, you will get 4 vaccine shots over a 4 week period. Some of the 4 shots will be the assigned vaccine and some will be placebo (a placebo is an inactive substance that looks like the study drug injection).

You and the study team will not know which study group you are in. Only the study staff who gives you the shot will know. The study doctor can find out which group you are in if it is necessary to know for your health. If this happens, the study doctor may not be able to tell you, which study group you are in until after the study is over.

Study Group	**Number of Participants**	**Vaccine**	**Vaccine Dose**
A	14	ChAd155-RG	$5x10^{10}$ viral particles
B	14	ChAd155-RG	$1x10^{11}$ viral particles
C	10	ChAd155-RG	$1x10^{11}$ viral particles
D	12	RABAVERT	1 mL

In general, this study requires the following:

- 1 or more screening visits
- Up to 11 clinic visits over about 13 months
- Review of medical history, medications, and recent travel
- Height and weight measurements
- Vital signs measurement including: oral temperature, blood pressure, heart rate
- Physical exams (no pelvic or rectal exam)
- Females able to bear children: urine and serum pregnancy tests
- Urine collection for urine dipstick
- Blood draws for:
    - Safety Labs: blood counts, kidney and liver function
    - Screening Labs: Hepatitis B & C test, HIV test (only performed at the initial screening visit)
    - Research Tests: rabies immune responses to the vaccine
    - Developer Tests: immune responses to the vaccine vector
    - Developer Tests: to assess early immune and protein responses to the vaccine
    - Future Use (optional)
- 4 vaccine shots in the upper arm at 4 different visits
- Specimen collection for COVID-19 testing (only if indicated based on symptoms)
- Wait at the clinic for at least 30 minutes after each vaccine
- Document reactions to vaccine on a memory aid we give to you, with a ruler and thermometer

Each study visit is described below:

Visit 00A: Screening Visit (Day -28 to -1)

The screening visit checks if you qualify for this study. At the screening visit, the following will happen:

- Review and sign this informed consent form, if you choose

- Review your medical history, medications, and recent travel
- Obtain vital signs
- Obtain height and weight
- Complete physical exam
- Urine collection for urine dipstick
- Blood collection for Safety and Screening labs, about 2 tablespoons
- Females able to bear children: blood pregnancy test

To be in the study all safety and screening labs must come back normal and pregnancy test must be negative. If you qualify, you must be available to receive the first study shot within 28 days of this visit.

Visit 00B: Screening Visit (Day -28 to -1)

Another screening visit may be done if tests need to be repeated. At the screening visit, the following will happen:

- Review safety labs
- Update medical history and medications, if any changes
- Obtain vital signs
- Obtain height and weight
- Targeted physical exam, if needed
- Urine collection for urine dipstick
- Blood collection for safety labs, about 2 tablespoons

Visit 1, 3, 4, 6: Vaccine Visits (Day 1, 8, 15, 22)

At the vaccine visits, the following will happen:

- Review safety labs
- Update medical history and medications, if any changes
- Assess adverse events and new onset chronic medical conditions, if any
- Obtain vital signs
- Targeted physical exam, if needed
- Females able to bear children: urine pregnancy test
- Randomized to study group: A, B, C, or D (1st vaccine visit)
- Review of memory aid and examine arm that received vaccine (2nd, 3rd, 4th vaccine visits)
- Blood collection for:
    - Safety labs: Visits 3, 6
    - Research tests: Visits 1, 3, 4, 6
    - Developer tests: Visits 1, 3, 4, 6
    - Future use (optional): Visits 1, 4
- Blood collection amount:
    - 1st vaccine: about 5 tablespoons
    - 2nd & 4th vaccine: about 3 tablespoons
    - 3rd vaccine: about 5 tablespoons
- Assess planned injection site for any local symptoms prior to vaccination
- Receive vaccine into the deltoid muscle – sequential injections will be given in alternating arms
- Wait for at least 30 minutes at clinic to watch for any reaction to vaccine
- Receive a memory aid, ruler, and thermometer to record reactions to the vaccine.

Visit 2, 5, 7, 9, 10, 11: Follow-Up Visit (Day 2, 16, 29, 91, 181, 381)

At the follow-up visits, the following will happen:

- Update medical history and medications, if any changes
- Assess adverse events and new onset chronic medical conditions, if any
- Obtain vital signs
- Targeted physical exam, if needed
- Review of memory aid and examine arm that received vaccine (Visits 2, 5, 7)
- Blood collection for:
    - Safety labs: Visits 2, 5
    - Research tests: Visits 7, 9, 10, 11
    - Developer tests: Visits 2, 5, 7
    - Future use (optional): Visits 7, 9, 10, 11
- Blood collection amount:
    - Visit 2, 5: about 2 tablespoons
    - Visit 7: about 5 tablespoons
    - Visit 9, 10, 11: about 3 tablespoons

Visit 8: Follow-Up Phone Call (Day 50)

At the follow-up phone call, the following will happen:

- Update medical history and medications, if any changes

Early Termination & Unscheduled Visits

If you get at least one study vaccine shot, we will ask you to stay in this study for about 12 months after your last study vaccine to review your health. We will ask you to have blood samples taken about 4 weeks and 12 months after your last study vaccine to measure your immune responses.

At the early termination and unscheduled visits, the following may happen:

- Update medical history and medications, if any changes
- Obtain vital signs
- Targeted physical exam, if needed
- Review of memory aid and examine arm that received vaccine
- Blood collection for:
    - Safety labs
    - Research tests (early termination visits only)

Laboratory Testing of Blood Samples

The total amount of blood collected across all study clinic visits is up to approximately 34 tablespoons.

Blood samples will be labeled only with a study identifier and will not be labeled with your name or initials, or any other information that could readily identify you. Information about your blood samples for clinical testing will be kept confidential to the best of our and the sponsor's ability, and as required by law.

The research tests will measure immune responses to the ChAd155-RG/RABAVERT vaccine shot. Giving blood samples for these tests will not benefit you. The results of these tests are useful only for research purposes. Your individual results will not be available to you or your regular doctor.

Research blood samples will be labeled only with a barcode and a unique tracking number to help protect your information. Blood samples for the research tests will be sent to a storage facility and then sent to the research testing labs. Some blood for developer assays will be sent to the GlaxoSmithKline Vaccines for testing. Staff at the storage facility, the research testing labs or GlaxoSmithKline Vaccines will not know your identity, or even the study identifier you were assigned. Some blood samples for certain research tests may stay at one of the sites doing this study.

OPTIONAL: Future Research

We would like your permission to collect blood samples from you for future research studies. This includes additional planned research tests to measure immune responses to the ChAd155-RG/RABAVERT vaccine shot.

After the planned lab tests are done, there may be left over blood samples. We would also like your permission to keep any remaining samples to use in possible future research studies. These residual samples will be stored indefinitely at a site determined by the sponsor, NIH and may be shared with investigators at other sites or institutions. Some information about you, such as gender, age, health history, or ethnicity may be shared with other investigators. Electronic files associated with these samples will be password protected. Only people who are involved in the conduct, oversight, or auditing of this study will be allowed access. No human genetic testing will be performed on specimens

There is a risk of loss of confidentiality if you agree to future use of your samples. To reduce this risk, your samples will be labeled only by a code (your study subject number) and will not be labeled with your name or initials. Only the study team can link the samples back to you. Any identifying information about you will be kept confidential to the extent permitted by law.

Storing your samples for future use may not benefit you directly. You can decide if you want your samples to be stored and used for future research. Your decision about your samples will not affect your participation in this study or other studies or your medical care at this institution.

You may withdraw your permission to use your blood samples for future research at any time. However, we may continue to use any data generated from your samples before you withdrew your permission. In order to revoke (take back) your authorization, you may contact Dr. Varun Phadke at the Hope Clinic and we will honor your request.

OPTIONAL: Contact for Future Studies

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 data base. 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.

How will my vaccines be provided?
The vaccine that you will receive will be dispensed by the pharmacy and delivered to the principal investigator or study team member. The principal investigator or health care providers on his/her research team will give the vaccine to you. If you have questions about the vaccine, you should ask the principal investigator or 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?
While in this study, you are at risk for some side effects. Many side effects go away shortly after a vaccine is given, but in some cases, side effects may be serious, long lasting or permanent.

SCREENING
In this study you will be tested for Hepatitis B, Hepatitis C, and HIV. An unexpected positive result, or any other concerning health condition brought to your attention during screening, may cause stress and anxiety. The study team will refer you to medical care, as needed. A positive result on any of these tests will exclude you from participation in the study. Positive tests will be reported to the Public Health Department as required by state law.

RABAVERT VACCINE
RABAVERT was FDA approved in 1997. RABAVERT is generally well-tolerated. Potential risks related to RABAVERT include severe, rare disorders of the nervous system, such as:

- inflammation of the brain and surrounding tissues
- a loss of function or sensation of the nerves in a part of the body
- a loss or reduced function of muscle
- Guillain-Barre syndrome
- inflammation of the spinal cord
- optic nerve inflammation
- multiple sclerosis
- dizziness or syncope (fainting)
- visual disturbances

Data from 1997 to 2005 reported 336 adverse events (AE) for 1.1 million RABAVERT doses administered (0.03% of all doses). Of these, 13 were events related to the nervous system (4% of all the AEs). There was no pattern in the type or time of onset of symptoms to show a clear connection with the vaccine.

RABAVERT is reactogenic (can cause symptoms related to the body's response to the vaccine) in healthy people, causing

- Local reactions:
    - Pain at injection site (34%), lymph node swelling near injection site (15%), tissue swelling near injection site, and redness near injection site
- General reactions:
    - Malaise (generally feeling unwell) (15%), dizziness (15%), headache (10%), nausea, fever, muscle or joint aches, hot flush, rapid heartbeat, and lip, tongue, or limb swelling

ChAd155-RG VECTOR VACCINE

Chimpanzee adenovirus (ChAd) vectors can be associated with:

- Local reactions:
  - Pain, tenderness, redness, swelling
- General reactions:
  - Fatigue, muscle aches, joint aches
  - Flu-like symptoms such as fever, chills, and headache

In recent clinical trials that also used a related ChAd vector, there were no vaccine-related serious events or reactions (no hospitalizations or life-threatening events). Most experiences or reactions were mild and resolved without treatment within 48 hours after vaccine shot. The most common reactions were fatigue and headache.

The ChAd155 vector used in this trial has been tested in humans in a Phase 1 trial. There were no vaccine-related serious events or reactions. The most common reactions that affected daily activities were:

- local injection site pain (100% of vaccine recipients vs. 5% of placebo recipients)
- fatigue (50% of high-dose vaccine recipients vs. 37% of placebo recipients)
- headache (34% of high-dose vaccine recipients vs. 0% of placebo recipients)

The doses of the ChAd155 vector being used in this trial are double the doses used in the previous Phase 1 trial.

In recent studies of COVID-19 vaccines that use an adenovirus vector, there were a small number of individuals who experienced rare but serious blood clotting events. These events occurred after the Oxford-AstraZeneca COVID-19 vaccine, which uses a chimpanzee adenovirus, and the Johnson and Johnson/Janssen COVID-19 vaccine, which uses a human adenovirus. The cause of these rare blood clotting events is not fully understood and may or may not be related to the adenovirus vectors used in those vaccines. Additionally, the adenovirus vectors used in these COVID-19 vaccines are from different families of adenoviruses than the one being used in the vaccine being tested in this study, ChAd155. In published studies of vaccines based on adenoviruses related to ChAd155 there have been no blood clotting events, though these studies are smaller than the number of people who have received a COVID-19 vaccine.

The CDC and FDA did recommend a brief pause in the use of the Johnson & Johnson/Janssen COVID-19 vaccine to better understand the risk of these clotting events, and found that they are rare, occurring at a rate of about 7 per 1 million women between 18 and 49 years old who receive the Johnson & Johnson/Janssen COVID-19 vaccine. The rate is even lower for older women and men. All of the blood clotting events occurred in the first three weeks after receiving the vaccine. The CDC and FDA have since recommended that the use of this vaccine resume with a warning about the small risk of blot clots associated with low platelet counts among women ages 18 to 49 years.

If you choose to participate in this study, we will be monitoring for any blood clots that occur for the first four weeks after you receive any study injections.

ALLERGIC REACTION

A small number of people (about 1 in 4 million) have immediate and serious allergic reactions to licensed vaccines called anaphylaxis (also known as allergic shock). These reactions can be:

- skin rash (hives)
- swelling around the mouth, throat and eyes
- difficulty breathing

- a fast heartbeat
- fainting due to decrease in blood pressure

If these reactions happen, emergency medications can be given. These medications can usually stop the reactions. Most people who have anaphylaxis get better completely. People can die, but not very often. We do not expect this to happen in this study. You will stay at the clinic for at least 30 minutes after the vaccine shot so we can monitor you for any severe reactions.

BLOOD DRAW AND INTRAMUSCULAR INJECTION

Having blood drawn or getting a vaccine in your arm can cause

- pain
- bruising
- light headedness and fainting
- rarely, an infection
- very rarely, nerve injury

The study team does their best to reduce these risks by:

- applying pressure to the blood draw site for several minutes
- having you lay down for blood draw
- using sterile techniques

COVID-19 TESTING

Having your nasopharynx or oropharynx sampled with a swab can cause

- discomfort
- rarely, transient nose-bleeding

For women:

If you are a woman, you cannot take part in this study if you are:

- pregnant
- planning to become pregnant during this study
- nursing a child

If you become pregnant, there may be risks to you, the embryo, the fetus, or the nursing infant after birth. These risks are not yet known. Because of this, you must have a negative urine or blood pregnancy test at screening and before each of your study vaccine shots. Also, you should not donate eggs from the start of screening to ≥60 days after the last vaccination.

If you are able to become pregnant, you must meet one of the conditions below for 28 days before your 1st study vaccine until at least 60 days after your last study vaccine:

- abstinence or no sex with a male
- monogamous relationship with a man who had a vasectomy at least 6 months before your 1st study vaccine
- oral contraceptives ("the pill")
- IUDs
- birth control implants under the skin
- birth control injections
- birth control patch
- vaginal ring

- condoms and diaphragms/cervical cap with spermicide ("double barrier" method)

Some methods of birth control will not work when you are taking certain drugs or medications. Be aware you can still become pregnant even if you use an acceptable birth control method. You should not plan to breastfeed from the time of your first study vaccine until 60 days after your last study vaccine.

If you become pregnant during this study, report this to us immediately. You will not get any more study vaccines. With your permission, we will ask you to come back to the clinic for all the study visits to follow you for safety. We will also about your health and the outcome of your pregnancy. This information may be shared with the sponsor and Institutional Review Board (IRB), a group of people who review clinical research studies to protect the rights and welfare of research participants.

For men:
The effect of the study drug on sperm is not known. If you are a man you should not donate sperm from the start of screening to ≥60 days after the last vaccination. Also you should avoid getting a partner pregnant by meeting one of the conditions below for 28 days before your 1st study vaccine until at least 60 days after your last study vaccine:

- had a vasectomy
- abstinence or no sex with a female or no sex with a female able to bear children
- condoms or diaphragms/cervical cap with spermicide
- if the female partner meets a condition above, single-barrier method is acceptable

New Information
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. This study may help us learn more about the study vaccine. You may receive some immune protection against rabies. There is no guarantee the rabies vaccines will be safe or will protect you from rabies infection.

Will I be compensated for my time and effort?
You will be compensated for each completed study visit, for your time and effort:

- $75 for screening visit(s) (1-2 visits)
- $75 for each vaccine visit (4 visits)
- $50 for each follow-up visit (6 visits)
- $20 for scheduled phone call (1)
- $20 for unscheduled or early termination visits, if needed

You will get between $695 - $770 if you complete all study visits. If you do not finish the study, we will compensate you for the visits you have completed.

Our preferred method of compensation will be the use of Clincards. 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 such as: name, date of birth, social security number, address, phone number, email, and date of study visits. 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.

We would also like the option of compensating you in the form of cash, check or gift card if ClinCard accessibility is not available. 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. You will need to fill out a W-9 form.

What are my other options?
This is not a treatment study. You can choose not to be in this study. You can also choose to leave this study at any time after signing the consent form.

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.

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 Food and Drug Administration, the Office for Human Research Protections, the funder(s), the Emory Institutional Review Board, the Emory Office of Research Compliance. 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.

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 all 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.

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. In general, no long-term medical care or financial compensation for research-related injuries will be provided by the NIH or the Federal Government. 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. Varun Phadke at (Hope Clinic) telephone number (404) 712-1370. 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

If you choose not to do this study or if you decide to stop later, your benefits, services and rights will not change. If you stop this study early, we may ask you some questions about being in this study. To help you leave this study safely, we may ask you to do more tests.

The study doctor or sponsor may withdraw you from this study at any time, without your consent. You could be removed from this study for any of the following reasons:

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

Contact Information

Contact Dr. Varun Phadke at 404-712-1370 during business hours. For evening/weekend hours call: 404-686-1000 (Emory Hospital Paging Service, ask for the physician on call for the Hope Clinic, pager number 13068):

- 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 vaccine, or
- if you have questions, concerns or complaints about the research

Contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu:

- 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** your decision about each of the optional study parts detailed above. Indicate only ONE option for each part.

OPTIONAL: Future Research

_____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 dose group).

_____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

_____YES, you may contact me about future studies

_____ NO, you may not contact me about future studies.

TO BE FILLED OUT BY SUBJECT ONLY

Please **print** your name, **sign**, and **date** below if you agree to be in the main study. By signing this consent 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

_____ _____

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

_____ _____

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