Informed Consent Form

TITLE: Yellow Fever Heavy Water: Turnover of Antigen Specific Lymphocytes and Monocytes After Immunization With the 17D Yellow Fever Vaccine

NCT NUMBER: NCT01290055

IRB APPROVAL DATE: November 27, 2023

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 about 303 people who are taking part in the study at Emory.

Why is this study being done?
This study is being done to answer the question: How does the body's immune system respond to the yellow fever vaccine, YFV-17D. You are being asked to be in this research study because you are a healthy individual between the ages of 18 and 45.

Do you have to be in the study?
It is your choice to join this research study. You do not have to be in it. Before you choose, take time to learn about the study.

What do you have to do if you choose to join this study?
If you qualify and choose to join the study, you will participate for up to 12 months (9-13 study visits). The researchers will ask you to do the following: receive a YFV-17D vaccine, drink heavy water, give blood and saliva samples, complete a heavy water diary. 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. If you are traveling to a yellow fever endemic area, you will benefit from being vaccinated with the YF-VAX® vaccine.

What are the risks or discomforts you should know about before deciding?
The study will take time. 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:

- risks of the YFV-1D vaccine, some of which include: redness or swelling at the injection site, muscle aches, allergic reaction
- risks of drinking heavy water, some of which include: dizziness or vertigo
- 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 possible risks and discomforts?"

Alternatives to Joining This Study
You can receive the YF-VAX® vaccine outside of the study. If you need this vaccine for travel purposes, please speak with your regular healthcare provider.

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. There is more information in the "Costs" section further below.

What Should You 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 such as how much time you will have to spend on the study, any words you do not understand and more details about study procedures. Make sure you understand which parts of the study are research and which are standard care that you could have even if you did not join the study. Take time to think about this and talk about it with your family and friends.

EMORY UNIVERSITY | Institutional Review Board
Research Administration

Emory University
Consent to be a Research Subject

Group 1 Consent

Title: Yellow Fever Heavy Water: Turnover of antigen specific lymphocytes and monocytes after immunization with the 17D yellow fever vaccine

IRB #: 46406

Principal Investigator: Srilatha Edupuganti, MD, MPH

Sponsor: National Institutes of Health (NIH) and Emory Vaccine Center

Introduction
You are being asked to be in a medical research study. This form tells you what you need to think about before you choose if you want to join the study. **It is your choice. If you choose to join, you can change your mind later and leave the study.** Your choice will not cause you to lose any medical benefits. If you choose not to join this study, your doctor will still treat you.

Before you decide:
- Read this form or have it read to you
- Listen to the study doctor or study staff explain the study to you
- Ask questions about anything that is not clear

You will get a copy of this form. Take your time to think about joining the study. You may wish to discuss it with family or friends. Do not sign this form if you still have questions or something does not 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?
This study is being done to investigate how the body's immune system reacts to a yellow fever vaccine called YFV-17D (YF-VAX®). This vaccine is usually given to adults who are traveling to high-risk yellow fever areas such as South America and Africa. Yellow fever is a mosquito-borne illness. Currently, CDC and World Health Organization (WHO) recommend yellow fever vaccination for persons 9 months of age or older who are traveling to or living in a country that is high-risk for yellow fever.

Your immune system is what protects you from disease. When you are infected by a bacteria or virus or get a vaccine, your immune system is activated in two ways: immediately and long-term. The immediate response is your body's way of defending itself from the current infection. The long-term response is what protects you from getting the disease again later on. Certain cells in your immune system are able to recognize foreign bacteria and viruses you have been exposed to before and fights them off before you can become sick.

The purpose of this study is to better understand how the immune system responds to YFV-17D. Specifically, we are studying part of the long-term part of the immune response called T cells. Memory T cells are infection-fighting white blood cells that can recognize foreign bacteria or viruses that were encountered during an earlier infection or vaccination. We will look at how memory T cells get processed by the body and their lifespan. This

research will be helpful in understanding the basic immunological responses to the YFV-17D vaccine, which can lead to the development of better, safer and effective vaccines in the future.

Heavy water (also known as deuterium labeled water or ^2H_2O) is physically and chemically very similar to ordinary drinking water. In water, two hydrogen atoms bond to an oxygen and create H_2O. However, in heavy water, deuterium atoms replace the hydrogen atoms. Deuterium is a form of hydrogen that possesses an extra neutron. This neutron gives the atom extra weight, hence the name “heavy water.” This extra weight can be detected in the lab with very sensitive instruments. Deuterium is in fact already in the water we drink daily. It is not radioactive, and it occurs naturally at a concentration of about 1 part per 5,000. Researchers have used heavy water since 1934 as a safe and effective tool in clinical trials. When a person drinks heavy water, it tags the cells in their blood. Then, researchers can take a blood sample and use those tagged cells in their tests. By tagging the T cells in this study, researchers can learn more about their lifespan and processing after YFV-17D vaccination.

You are being asked to participate in Group 1 of this study. This group is split up into three parts – Group 1a, Group 1b and Group 1c. The study staff will let you know if you will be in Group 1a, 1b or 1c.

What will you be asked to do?
If you decide to join this study and sign the consent form, your health, blood tests, medical history and travel history will be assessed to see if you meet the requirements for study participation. If you do, you will be asked to come back to the clinic for 8-12 more visits over the next 6-12 months. Each visit is described in more detail below:

Visit 1 - Screening
This visit will be completed the same day the consent form is signed. At this visit, you will be asked to complete the activities listed below:

- Tell us about your medical history, general health and any medications you are taking
- Tell about your previous and future travel plans
- Provide blood samples

HLA Testing: HLA antigens are a set of several genes that you inherit from your parents. There are many variations and combinations of HLA genes that a person can have. HLA genes make proteins that sit on the outside of all of your cells. Your immune system uses HLA antigens to tell your cells apart from other things that can get inside your body.

In order to be enrolled in this study, a participant must test positive for a certain type of HLA antigen called HLA-A02. The blood sample you provide at the screening visit will be tested for HLA-A02. Based on previous research, we expect about 20% of the people we screen for this study to test positive for HLA-A02. If you test positive for HLA-A02 and meet all other screening requirements, we will ask you to come back for an enrollment visit. If you test negative, you will not be eligible for this study. However, we can discuss other research studies with you if you would like.

HLA testing is a genetic test. We will only be testing your HLA genes. We will **not** be doing any genetic testing to determine hereditary diseases.

Visit 2 – Enrollment
If you are determined to be eligible for the study, we will ask you to come back into the clinic to complete the enrollment visit and receive the YFV-17D vaccination. You will be asked to complete the activities listed below:

Before Vaccination:

- You will be asked to read the vaccine information sheet for YFV per CDC guidelines.
- Tell us about your general health and current medications
- Have a physical exam done
- Provide blood samples
- If you were assigned female sex at birth, you will be asked to take a urine or serum pregnancy test. If the test is positive, you will not receive a vaccination

Vaccination:

All vaccinations will be given as a shot in the arm.

After Vaccination:

You will be observed for a minimum of 20 minutes for any allergic reactions to the vaccine. We will also give you a symptom diary for you to record any side effects that you experience for 7 days after vaccination.

Visits 3+ – Follow Up

The exact schedule of follow up visits and heavy water drinking will be determined by the group you are assigned to – Group 1a, 1b and 1c. The schedule of activities for each group is below.

Follow up visits may include the following activities:

- Tell us about your general health and current medications
- Provide blood and/or saliva samples
- Review your completed heavy water memory aid with study staff
- You will be assessed for any allergic reactions to the vaccine

Schedule of Activities – Group 1a

Visit #				1	2	3	4	5	6	7+
Day	**Day 0**	**Days 1-5**	**Days 6-14**	**Screening Visit**	**Enrollment Visit (Day 0)**	**Day 5**	**Day 14**	**Day 21**	**Day 28**	**Weeks 6, 10, 14, 18, 22**
Medical History, Vitals				X	X					
Physical Exam					X					
Urine Pregnancy Test					X					
Vaccination					X					
Heavy Water	Drink 50ml 2x/day	Drink 50ml 3x/day	Drink 50ml 2x/day			Bring Memory Aid & Symptom Diary to Clinic	Bring Memory Aid & Symptom Diary to Clinic			
Blood Sample				X	X		X	X	X	X
Saliva Sample						X	X			

Schedule of Activities – Group 1b

Visit #			1	2	3	4	5	6 & 7	8+
Day/Month	**Days 14-19**	**Days 20-28**	**Screening Visit**	**Enrollment Visit (Day 0)**	**Day 14**	**Day 21**	**Day 28**	**Weeks 6, 12**	**Months 6, 12**
Medical History, Vitals			X	X					
Physical Exam				X					
Urine Pregnancy Test				X					
Vaccination				X					
Heavy Water	Drink 50ml 3x/day	Drink 50ml 2x/day			Bring Symptom Diary to Clinic	Bring Memory Aid to Clinic	Bring Memory Aid to Clinic		
Blood Sample			X	X	X	X	X	X	X
Saliva Sample						X	X		

Blood sample on Day 14 may not be done based on the needs of the study at that time.

Schedule of Activities – Group 1c

Visit #				1	2	3	4	5	6	7+
Day/Month	**Day 0**	**Days 1-5**	**Days 6-28**	**Screening Visit**	**Enrollment Visit (Day 0)**	**Day 5**	**Day 14**	**Day 21**	**Day 28**	**Months 3, 6, 12**
Medical History, Vitals				X	X					
Physical Exam					X					
Urine Pregnancy Test					X					
Vaccination					X					
Deuterated Water (^2H_2O)	Drink 50ml 2x/day	Drink 50ml 3x/day	Drink 50ml 2x/day			Bring Memory Aid & Symptom Diary to Clinic	Bring Memory Aid & Symptom Diary to Clinic		Bring Memory Aid to Clinic	

Solicited Adverse Events						X	X			
Blood Sample				X	X		X	X	X	X
Saliva Sample						X	X		X	

Blood sample on Day 14 may not be done based on the needs of the study at that time.

How will your study vaccine and heavy water be provided?
The study vaccine and heavy water that you will take 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 provide the study vaccine and heavy water to you. If you have questions about the vaccine or heavy water, you should ask the principal investigator or study nurse. You may also call the pharmacy if you have questions about the vaccine or heavy water. The number for the pharmacy is included on your study drug package, if given one.

If you will take the heavy water home, keep it out of the reach of children or anyone else who may not be able to read or understand the label. Do **not** let anyone else drink the Heavy Water besides you.

Who owns your 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. If you leave the study, the data and samples that were already collected may still be used for this study.

What are the possible risks and discomforts?
YFV-17D Vaccination Risks
Participants receiving the Yellow Fever vaccination are required to read the Vaccine Information Sheet about the Yellow Fever vaccine. Participants may experience an allergic reaction to the vaccine. These allergic reactions are explained in the Vaccine Information Sheet. In some cases, these reactions can be serious. If you experience any of the following symptoms, please contact the study doctor, Dr. Edupuganti, using the contact information on the last page of this document.

Common, may occur up to a few hours after vaccination
- Redness, itching, swelling and/or bruising at the injection site

Common, may occur 5-10 days after vaccination
- Low-grade fever
- Mild headaches
- Muscle aches

Rare, may occur up to a few hours after vaccination
- Difficulty breathing
- Dizziness
- Fast heartbeat
- Hives
- Hoarseness
- Paleness, weakness
- Wheezing

Rare, may occur up to 30 days after vaccination
- Swelling of the brain, spinal cord or surrounding tissues

- Guillain-Barre syndrome: a disease in which a person's immune system damages the nerve cells causing muscle weakness and, sometimes, paralysis
- Internal organ dysfunction or failure

Some people have developed hepatitis (swelling of the liver) or encephalitis (swelling of the brain) after getting the YFV-17D vaccine, but this is rare. Most people who get these problems recover with no lasting effects. Very rarely, about 1 in 250,000 doses, YFV-17D vaccine has caused severe disease involving multiple body organs. Some of these people have died from the vaccine. The risk of serious disease and death after YFV-17D vaccine seems to be higher among people older than 60 years of age and among people who have had problems with their thymus gland.

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

Heavy Water Risks:
There are few side effects experienced by people who drink heavy water. These side effects are mild and often go away on their own after about 2 hours.

- Dizziness (3.3% of people)
- Vertigo (3.3% of people)

If you experience these side effects, we ask you that you rest quietly and refrain from driving or operating heavy machinery and contact the study team.

In very large amounts, heavy water can have adverse effects. However, a human weighing about 150 lbs. would need to drink more than 40 cups of heavy water rapidly to experience toxic effects. 40 cups is more than 150 times what you will be asked to drink at any given time as part of the study.

Taking daily doses of heavy water may also be inconvenient and will require some planning.

If it is biologically possible for you to become pregnant: To protect against possible side effects of the study vaccine and heavy water, people 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 person of childbearing ability, you must have a negative pregnancy test before receiving the vaccine or heavy water. You must also agree to use at least one form of effective birth control throughout the vaccination and heavy water period of the study. Effective methods include:

- Abstinence
- Condoms
- Intrauterine Devices (IUDs)
- Hormonal Shots/Implants
- Oral Contraceptives
- Contraceptive Patches
- NuvaRing

If you think that you have gotten pregnant during the study, you must tell the study doctor immediately. If you become pregnant, researchers may ask to monitor your health and the outcome of the pregnancy.

If it is biologically possible for you to make someone pregnant: There are no safety issues that we are aware of.

Blood Draw Risks:

You could faint or feel lightheaded from blood draws. The needle used for drawing blood can cause pain and bruising. Rarely, some people get an infection where the needle was put in their arm to draw the blood. To minimize this risk, only trained and qualified staff will draw your blood.

Saliva Sample Risks:
There are no risks in using the Salivette® saliva collection device.

Genetic Testing Risks:
We are planning to do genetic testing on your blood samples. We are not planning to do genetic tests to determine hereditary diseases. We will keep all genetic test results as part of research records, and they will not become part of your Emory medical record or shared with your doctor unless you give us permission to do so. It is possible that if others found out information about you that is learned from these tests (such as information about HLA type) it could cause you problems with your family (having a family member learn about a disease that may be passed on in families or learning who is the true parent or a child) or problems getting a job or insurance. The risk of this is extremely low because your results will not be part of your medical records.

Privacy Risks:
We will take several steps to protect your personal information. Although the risk is very low, it is possible that your personal information could be given to someone who should not have it.

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 you benefit from the study?
If you are traveling to yellow fever endemic areas, you will benefit from being vaccinated with YF-VAX® which is required for travel to some countries in Africa and South America. If you are not planning to travel, you will receive no benefit from this vaccine. There is no benefit from drinking heavy water. This study is designed to learn more about how the body's immune system responds to the YF-VAX® vaccine. The study results may be used to help others in the future.

Will you be paid for your time and effort?
You will get $75 for each completed study visit, for your time and effort. If you do not finish the study, we will compensate you for the visits you have completed. You will receive an additional one-time payment of $50 if you complete and bring back your heavy water diary as well as the empty vials. In the unlikely event we need to ask you to come back for more study visits than are listed on this consent form, you will receive $20 per visit.

At the screening visit, you will be compensated with a gift card.

Starting with the enrollment visit, compensation will be provided on a web based, reloadable, debit card (ClinCard) that automates reimbursements.

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 system.

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 your other options?
If you choose not to join this study, you can receive the YFV-17D vaccine outside of this study for travel purposes. Your regular healthcare provider can discuss receiving the vaccine outside of the study with you.

How will your 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.

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
We will store all the data and specimens that you provide using a code. We need this code so that we can keep track of your data over time. This code will not include information that can identify you (identifiers). Specifically, it will not include your name, initials, date of birth, or medical record number. We will keep a file that links this code to your identifiers in a secure location separate from the data.

We will not allow your name and any other fact that might point to you to appear when we present or publish the results of this study.

Your data and specimens may be useful for other research being done by investigators at Emory or elsewhere. We may share the data or specimens, linked by the study code, with other researchers at Emory, or with researchers at other institutions that maintain at least the same level of data security that we maintain at Emory. We will not share the link between the study code and your identity.

We may also place data in public databases accessible to researchers who agree to maintain data confidentiality, if we remove the study code and make sure the data are anonymized to a level that we believe that it is highly unlikely that anyone could identify you. Despite these measures, we cannot guarantee anonymity of your personal data.

We will use your specimens and data only for research. We will not sell them. However, the results of this research might someday lead to the development of products (such as a commercial cell line, a medical or genetic test, a drug, or other commercial product) that could be sold by a company. You will not receive money from the sale of any such product.

Returning Results to Participants/Incidental Findings
In general, we will not give you any individual results from the study of the samples you give us. If we find something of urgent medical importance to you, we will inform you, although we expect that this will be a very rare occurrence.

How is my Genetic Information Protected? What are the Risks?
The Genetic Information Nondiscrimination Act (GINA) is a federal law that generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that GINA does **not** protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance, and does not apply to employers with less than 15 employees.

In addition to GINA, the State of Georgia has laws that prohibit insurers from using genetic testing information for any non-treatment purpose. However, like GINA, this state law protection has exclusions: life insurance policies, disability income policies, accidental death or dismemberment policies, Medicare supplement policies, long-term care insurance policies, credit insurance policies, specified disease policies, hospital indemnity policies, blanket accident and sickness policies, franchise policies issued on an insurance policy written as a part of workers' compensation equivalent coverage, or other similar limited accident and sickness policies.

Privilege
In the State of Georgia, in some circumstances your genetic information may have special legal protections called "privilege." This means that the information cannot be used as evidence in a court. By allowing us to use and disclose your genetic information for this research study along with other information about you that genetic information used in the research may no longer have that legal protection. Other protections described in this form will still apply. There are also other confidentiality protections for research data in general under Georgia state law.

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

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

The results of tests and procedures done as part of this study 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 believe you have become ill or injured from this research, you should contact Dr. Sri Edupuganti at telephone number [redacted]. You should also let any health care provider who treats you know that you are in a research study.

If you get ill or injured from being in the study, Emory will help you to get medical treatment. Neither Emory nor the sponsor have set aside money to pay for this medical treatment. Your insurer will be billed for your treatment costs. If you do not have insurance, or if your insurance does not pay, then you will have to pay these costs.

For Emory, the only exception is if it is proven that your injury or illness is directly caused by the negligence of an Emory employee. “Negligence” is the failure to follow a standard duty of care. You do not give up any legal rights you may have by being in this study, including any right to bring a claim for negligence.

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.

If you leave the study before the last planned study visit, the researchers may ask you to complete some of the final steps such as lab work or imaging as applicable.
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:

- You do not follow instructions
- You are not able to keep scheduled appointments
- You have a study related injury
- You participate in any other experimental drug/vaccine research projects during the study
- The researchers think that staying in the study would be harmful to you
- The study is stopped by the study sponsor

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 funder(s), the Emory Institutional Review Board, the Emory Office of 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.

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
- 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 National Institutes of Health (NIH) and Emory Vaccine Center are 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.
- 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.
    - 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 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 Dr. Sri Edupuganti at [redacted]. After hours, you may call the Emory Hospital Paging Service at [redacted] and ask for The Hope Clinic Physician on Call.

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 404-712-0720 or 877-503-9797 or irb@emory.edu.

To tell the IRB about your experience as a research participant, fill out the Research Participant Survey at https://tinyurl.com/ycewgkke.

Consent and Authorization

TO BE FILLED OUT BY SUBJECT ONLY

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

Optional Storage of Specimens for Future Use Information

Your specimens will be protected the same way as the specimens for the main study. There are no additional risks or costs for allowing storage of specimens for future use than the ones already described for the main study (see sections above).

What is the purpose of storing specimens for future use?
Researchers will use the blood samples (also called specimens) collected in the main study to run tests and answer the questions being asked in this study. Once those tests are done, there may be leftover blood specimens. The researchers would like your permission to store the leftover specimens and use them in future research projects that are not part of this study. Allowing the storage of your specimens for future research is optional. You can still be in the main study even if you do not allow the storage and future use of your specimens.

The specimens will be stored at sites determined by the sponsor of this research, the National Institutes of Health and Emory Vaccine Center. Stored specimens will be used for research only. Future research projects may help the researchers better understand other diseases or the human immune system.

What will I be asked to do?
Since the stored specimens are leftover blood, the are no extra blood draws or study activities you will be asked to complete.

Will I benefit directly from the study?
The storage and use of your specimens for future research is not designed to benefit you directly. It is designed to learn more about how the body's immune system reacts to the YF-VAX® vaccine. The study results may be used to help others in the future.

Will I be compensated for my time and effort?
You will not be offered additional compensation for allowing the storage of specimens for future use.

What are my other options?
If you decide not to let the researchers store and use your specimens for future research, you can still participate in the main study.

Withdrawal from Storage of Specimens for Future Use
You have the right to remove your specimens from storage for future use at any time without penalty. You may stay in the main study even if you decide to no longer allow researchers to store your specimens for future use.

Contact Information
See contact information for the main study, above.

Consent and Authorization

Please initial below to indicate whether or not you agree to the optional storage of specimens for future use. You can still be in the main study even if you do not agree to take part in the option

_____ (Initials) **YES**, you may store and use my leftover samples for an indefinite period of time for future research as described above.

_____ (Initials) **NO**, you may not use my leftover samples for future research. Destroy my leftover samples at the end of this study.

TO BE FILLED OUT BY SUBJECT ONLY

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