Informed Consent Cover Page

Official Title: Evaluation of Human Immune Responses to Influenza Virus Vaccination in Healthy Volunteers

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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: Evaluation of Human Immune Responses to Influenza Virus Vaccination in Healthy Volunteers

Principal Investigator: Aneesh Mehta, MD and Rafi Ahmed, PhD

Sponsor: **National Institutes of Health**

Investigator-Sponsor: Aneesh Mehta, MD and Rafi Ahmed, PhD

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.

The results of this study may be published in a scientific journal. In the event of publication, the journal will not receive any information about you nor will any information that can identify you be published in the article.

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 may search this Web site at any time.

What is the purpose of this study?
The purpose of this study is to evaluate the immune response of the killed flu vaccine in healthy subjects. You are being asked to participate in this study because you are a healthy volunteer.

Influenza ("Flu") infection carries a risk of serious illness. The immune system is your body's defense against all sorts of infections and foreign invaders. When you get the flu vaccine, you are getting a dose of killed (inactivated) flu virus. Your immune system then builds protective responses against the flu virus. Later, if you get exposed to the flu, these responses help attack and kill the virus. You may not get sick at all, or you may have a much shorter or milder illness.

Doctors recommend an Influenza (Flu) vaccine for healthcare workers, people with certain conditions that increase their risk of complications from the flu (for example lung or heart disease), people with weakened immune systems, and people in close contact with people with weakened immune systems or other high risk conditions. The Centers for Disease Control and Prevention (CDC), the American College of Physicians, The American Academy of Family Physicians, and the American College of Obstetricians and Gynecologists all recommend that everyone older than 6 months of age received an influenza vaccine annually unless there are medical contraindications. A contraindication is a medical condition that prevents vaccine from being administered.

The "killed" flu vaccine is a vaccine made from an inactivated influenza virus that has been split apart and modified in such a way as to not be able to grow at all in a human. The killed flu vaccine is given as an injection into your arm.

The study will measure the way your immune system responds standard FDA approved licensed seasonal flu vaccine by measuring the immune response in your blood over a period of time, in this study for six months post (after) vaccination. Researchers expect to see a change in your immune system before and after receiving flu vaccine. It is possible that by measuring these differences, they can better understand how the body responds to flu vaccination and how long the immunity lasts. This is important because it could help make more effective flu vaccines in the future.

This study will enroll 10 healthy control volunteers per year for 5 separate years, who have not received the flu vaccine within the current flu vaccination season, with a total maximum enrollment of 70 volunteers.

What will I be asked to do?

You will be asked to attend all clinic visits involved in this study. There are seven clinic visits altogether, including the screening and enrollment visits, and 5 follow-up visits. The total length of your participation in the study will be 6 months.

Pre-Enrollment Screening:

You will be seen for your visits in the outpatient Atlanta Clinical & Translational Science Institute (ACTSI) in Emory University Hospital, or in the Transplant Clinic on the 6th floor of Emory Clinic B. The ACTSI is sometimes called the "GCRC," they are the same clinic. You will be asked to read and sign this consent form, volunteering to participate in this study. We will ask you some questions about your health and what vaccines you may have had in the past to ensure that you are a healthy volunteer. We will write down what medicines you are taking. You will have your height and weight taken. You will have your blood pressure, pulse and temperature recorded. You will have blood work drawn to determine if you have normal blood counts and normal blood chemistries. For these tests you will have about 1 tablespoon of blood drawn. If your lab tests are normal for this study, you will next be enrolled at "Day 0," usually within a couple of weeks of the screening visit.

To be included in this study, you must meet the following criteria:

For inclusion into the study, a subject must satisfy all of the following criteria:

1. Male or female subjects between 18 and 49 years of age
2. Subjects capable of providing written informed consent prior to initiation of any study procedures. Subjects able to understand and comply with planned study procedures and be available for all study visits
3. Screening labs within normal limits per the laboratory normal ranges or considered to be clinically insignificant by the investigator. Normal laboratory ranges are as listed below:

    A. Hematology:

    - Hemoglobin: Male- 12.9-16.1g/dl; Female- 11.4-14.4 gm/dL
    - White blood cells (WBC): Male- 4.2-9.2/uL, Female- 4-10/µL;

- Platelet count: 150-400 µL

B. Chemistries:

- Kidney function: Glomerular filtration rate (GFR) >/= 60;
- Liver enzymes: Albumin >/= 3.5 g/dL; ALT <66 u/L; AST <62 u/L

4. Subjects who have not received the seasonal influenza vaccine in the current flu season and are not suspected to have had an influenza infection in the current flu season.
5. Negative pregnancy test in females of childbearing potential at screening. Pregnancy will be re-tested on day of vaccination (day 0) if conducted > 14 days from screening visit.

You may not be included in the study if you meet any of the following exclusion criteria:

1. Known infection with HIV, HCV, or HBV. This information will be obtained verbally from the patient.
2. If female, active pregnancy or breast-feeding or plans to become pregnant during study participation.
3. Chronic medical conditions that cause immunodeficiency or that require medications which could alter immune function such as immunosuppressants and immunoenhancers.
4. Have any medical disease or condition that, in the opinion of the site principal investigator or appropriate sub-investigator, is a contraindication to study participation. This includes any acute or chronic medical disease or condition, defined as persisting 3 months (defined as 90 days) or longer, that would place the subject at an unacceptable risk of injury, render the subject unable to meet the requirements of the protocol, or may interfere with the evaluation of responses or the subject's successful completion of this study
5. Have an acute illness as determined by the site principal investigator or appropriate sub-investigator, within 72 hours prior to study vaccination. An acute illness which is nearly resolved with only minor residual symptoms remaining is allowable if, in the opinion of the site principal investigator or appropriate sub-investigator, the residual symptoms will not interfere with the ability to assess safety parameters as required by the protocol.
6. Persons taking anticoagulants, long-term aspirin therapy, or long-term systemic steroids (greater than 3 months in the past 12 months and any within 30 days).
7. Have known hypersensitivity or allergy to eggs, egg or chicken protein or other components of the study vaccine;
8. Have a known latex allergy;
9. Have a history of severe reactions following previous immunization with licensed influenza virus vaccines
10. Have a history of Guillain-Barre syndrome
11. Subjects who had or are suspected to have had an influenza infection in the current influenza season
12. Subjects who, at screening, have abnormal vital signs and/or physical exam, including a temperature ≥ 38.0 C, Systolic blood pressure ≤90 or≥160 mmHg, pulse ≤ 60 or > 110 beats per minute, new rash, signs of infection.
13. Subjects who have already received the seasonal influenza vaccine in the current influenza vaccination season.

Any person participating in the study who develops criteria for exclusion will be withdrawn from the study.

Day 0 – Enrollment
You will have your blood pressure, pulse and temperature recorded. Up to 48 ml (approximately 3 tablespoons) of blood will be drawn to test for baseline labs antibody levels. If you are a woman of childbearing potential, and it has been more than 14 days since your screening, you will have additional urine pregnancy test to confirm that you are not pregnant before you are administered the flu vaccine. Although the flu vaccine is safe for pregnant women, this particular study does not allow the enrollment of pregnant women.

You will receive the standard licensed FDA approved killed influenza vaccine available for the current flu season, which will be given by an injection (shot) into your upper arm. When you receive the shot, there may be slight pain and burning during the injection and your arm may feel sore for a few hours after the shot. There is a small chance that the vaccine may cause a slight fever or a sense of feeling mildly ill.

One purpose of this research is to collect, store, and use your samples for research. The lab will not give the results to you or this clinic, and the results will not become part of your study record. Your specimens will be protected with the same level of confidentiality as your medical records, described in the Confidentiality section below. Please mark your initials below to indicate whether you agree or do not agree to future use of your specimens.

_____YES, I give permission for my specimens to be stored for future use in similar studies by these investigators and by other investigators at this or other institutions.

_____NO, I DO NOT give permission for my specimens to be stored for future use in similar studies by these investigators and by other investigators at this or other institutions

Visits: 2-5
You will be asked to come back to have blood drawn 5 more times: day 7, day 14, day 28, day 90 and day 180* after you have received the flu vaccine. You will come to the Atlanta Clinical & Translational Science Institute located on the ground floor of Emory University Hospital for these visits. The amount of blood drawn at each follow up visit varies and is detailed in the chart below. Please note that due to research being halted due to COVID-19, your Day 180 visit will be delayed for approximately 90 days

	Follow up Visit Number/ Day				
	1 (Day 7)	2 (Day 14)	3 (Day 28)	4 (Day 90)	5 (Day 180*)
Amount of Blood to be drawn at each visit	96ml 6tbs	96ml 6tbs	64ml 4tbs	64ml 4tbs	64ml 4tbs

Over seven visits, a total of 448 ml (about 1.8 cups) of blood will be drawn from your arm. At each visit you will have your temperature recorded. At each visit, you will be asked about any changes in your health or changes in the medicines you are taking.

The results of the study will not be disclosed to the doctors taking care of you. No decisions regarding your medical care will be based on the results obtained in this study.

After the initial testing is completed, we ask your permission to store any unused blood for use in future tests that may be developed. You will be asked to sign a separate consent to store unused blood specimens. You may participate in the main part of the study without consenting to storing blood samples. If new studies are identified, the consent and the protocol will be updated and submitted to the appropriate regulatory authorities, ethics committees, and Institutional Review Board (IRB) for approval. You will be asked to sign the new informed consent form before additional tests are done on the stored samples.

You will also have the following procedures performed at visits 2-5

- You will be asked if there have been any updates or changes to your medical history since your last visit.
- You will be asked about any new medications or changes in your medication regime since your last visit.
- You will be asked if you have experienced any Adverse Events (negative changes in your physical health). If the answer is yes, you will be asked additional questions by the principal investigator so that they may determine the severity of the event.
- If you have previously indicated that you experienced an adverse event, the doctor will ask you follow up questions to see if you are still experiencing the problem or if it has gotten better.
- You will have your vital signs checked. This includes Blood Pressure, temperature, and pulse. You will be asked not to eat or drink anything 10 minutes prior to your oral temperature being taken.
- If you are a woman of childbearing potential, and it has been more than 14 days since your last visit, you will have a urine pregnancy test to confirm that you are not pregnant.

Unscheduled Visits

An unscheduled visit is one that occurs outside the scheduled visits for any reason. Because of the nature of this study, we do not expect for there to be a need for any unscheduled visits. In the event that an unscheduled visit is necessary, the following procedures may occur and are dictated by the reason for the visit and at the Principal Investigator's discretion.

- A Medical history will be reviewed and updated as appropriate.
- All concomitant medications taken since the study visit will be recorded on the appropriate data collection form. Previously recorded medications will be updated as appropriate.
- Study personnel will discuss with you any Adverse Events and record the information you provide. Previously recorded AE/SAEs will be updated as appropriate.
- You may have your vital signs, including oral temperature, pulse, blood pressure and taken be obtained.
- You may have a targeted physical examination performed by a study clinician licensed to make medical diagnoses and listed on the Form FDA 1572 as the site principal investigator or sub-investigator.
- You may have approximately 10 mL (.67 tbl sp)of blood collected for clinical laboratory testing if deemed necessary by Dr. Mehta or a designee

- If you are a woman of childbearing potential, and it has been more than 14 days since your last visit, you will have a urine pregnancy test to confirm that you are not pregnant.

How will my vaccine be provided?
The flu vaccine that you will be given will be dispensed by the pharmacy and delivered to the principal investigator or study team member. The principal investigator or health care providers on the research team will administer the vaccine to you. The killed flu vaccine is given as an injection into your arm. If you have questions about the vaccine, you should ask the principal investigator or study nurse. You may also call the pharmacy if you have questions about the medicine. The number for the pharmacy is included on your medicine package.

Who owns my study information and samples?
If you join this study, you will be donating your samples and study information. Any tissue, blood, cell, or other biological samples that you provide as a participant in this research study are donations of these samples. You will not receive any compensation if your samples or information to make a new product. Upon your donation, these samples, and any data, discoveries, materials or other products that come from the samples will be the exclusive, permanent property of the sponsor, NIH. You will not have any property rights in the samples, nor will you have any property rights in or be entitled to compensation of any type for any products, data, or other items or information that is developed from the samples.

If you withdraw from the study, data and samples that were already collected may be still be used for this study. You may, at any time request that Dr. Ahmed destroy your sample, and Dr. Ahmed will make all reasonable attempts to honor your request.

If you decide later that you no longer wish to have any remaining samples stored you may contact Dr. Ahmed at 404-727-4700 to request stored specimens destroyed.

What are the possible risks and discomforts?

The most common risks and discomforts expected in this study are:
Blood Draws - You may experience discomfort and bruising from the needle stick required to draw the blood sample.
Flu Vaccine - There are some common, expected reactions to the killed flu vaccine. Some of the common reactions to the killed flu vaccine are discomfort and bruising at the site of the shot, your arm may feel stiff or achy for a few hours, sore throat, headache, chills, and fatigue

The less common risks and discomforts expected in this study are:
Blood Draws - There is a small chance of infection and bleeding at site of the needle stick. You may have redness or skin irritation where the Band-Aid or tape is placed over the site.
Flu Vaccine - A few people experience mild fever and body aches for 24 hours after getting the flu shot.

Rare but possible risks include:
Flu Vaccine - Very rarely, people have a serious allergic reaction to the flu vaccine. You should not receive the flu shot if you are allergic to chicken, eggs, or Thimerosal (a preservative in contact lens solutions). Associated with the 1976 flu vaccine, a few subjects experienced temporary paralysis, a condition known as Guillain-Barre syndrome. However, this syndrome has not been seen with the more modern influenza vaccine preparations. You will receive a Center of Disease Control and Prevention "What You Need to Know" handout at the time of vaccination.

Flu vaccine and pregnancy:
Flu vaccination is administered as standard of care for pregnant women. One study of influenza vaccination of approximately 2,000 pregnant women demonstrated no adverse fetal effects associated with influenza vaccine. However, if you are a woman, to assure your safety and that of an unborn baby, if you are pregnant or planning to

become pregnant during the time this research is being conducted, you will not be able to participate in this voluntary research. If you become pregnant during your participation in this study, you and your baby will be followed for monthly safety monitoring until your baby is born.

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

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 so 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 may not benefit you directly. We may learn new things that will help others.
In addition, obtaining the flu vaccine may provide protective immunity against the seasonal influenza strains within the vaccine.

Will I be compensated for my time and effort?
For your time, inconvenience, travel and parking, you will be paid $30 per visit from the baseline time point through day 90 (up to five times). Please note that due to research being halted due to COVID-19, your Day 180 visit will be delayed for approximately 90 days. At visit 6 (the intended Day 180 visit), you will receive $30 for the visit and an additional $30 for completion of the study for a total of $60 for visit 6 (the intended Day 180 visit). The total amount your time and travel will be compensated will be up to $210 for completion of all scheduled study visits.

What are my other options?
You are free to choose whether or not to participate in this study. The alternative to choosing to be in this study is to not be in the study. Your participation is completely voluntary and you have the right to refuse to be in this study.

How will you protect my private information that you collect in this study?
Emory will keep any research records that it creates private to the extent that this is required to do so by law. Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

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

Confidentiality
Certain offices and people other than the researchers may look at your medical charts and study records. Government agencies and Emory employees overseeing proper study conduct may look at your study records. These offices include the Office for Human Research Protections, the Emory Institutional Review Board, the Emory Office of Research Compliance, and the Office for Clinical Research. Study sponsors 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 description of this clinical study 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.

To help us further protect your privacy, the investigators have a Certificate of Confidentiality from the Department of Health and Human Services (DHHS).

With this Certificate, the investigators cannot be forced (for example, by court subpoena) to disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, other proceedings, or be used as evidence. Disclosure will be necessary, however, upon request of DHHS for audit or program evaluation purposes, or to other government agencies related to communicable diseases.

The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities for information required by local or state law.

The Certificate of Confidentiality cannot be used for information in your medical records.
A Certificate of Confidentiality does not prevent disclosure of your information to the NIH, Food and Drug Administration (FDA), or federal funding agency.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your consent to receive research information, then the investigator may not use the Certificate to withhold that information. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others. The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of child abuse and neglect, or serious harm to the subject or others.

Medical Record

Research Information Will Go Into the Medical Record:

If you are or have been an Emory Healthcare patient, you have an Emory Healthcare medical record. If you are not and have never been an Emory Healthcare patient, you do not have one. Please note that an Emory Healthcare medical record will be created if you have any services or procedures done by an Emory provider or facility for this study.

If you agree to be in this study, a copy of the consent form and HIPAA subject form that you sign will be placed in your Emory Healthcare medical record.

Emory Healthcare may create study information about you that can help Emory Healthcare take care of you. For example, the results of study tests or procedures. These useful study results will be placed in your Emory Healthcare medical record. Anyone who has access to your medical record will be able to have access to all the study information placed there. The confidentiality of the study information in your medical record will be protected by laws like the HIPAA Privacy Rule. On the other hand, some state and federal laws and rules may not protect the research information from disclosure.

The researchers will review the results of certain study tests and procedures only for the research. The researchers will not be looking at the results of these tests and procedures to make decisions about your personal health or treatment. For this study, those things include: vital signs (blood pressure, heart rate, weight, and height), results of the screening laboratory tests (blood cell counts, blood chemistry) and record of administration of the vaccine.

Emory does not control results from tests and procedures done at other places, so these results would not be placed in your Emory Healthcare medical record. They will not likely be available to Emory Healthcare to help take care of you. Emory also does not have control over any other medical records that you may have with other healthcare providers. Emory will not send any test or procedure results from the study to these providers. If you decide to be in this study, it is up to you to let them know.

In Case of Injury

If you get ill or injured from being in the study, Emory would help you get medical treatment. You should let the study doctor know right away that you are ill or injured. If you believe you have become ill or injured from this study, you should contact Dr. Aneesh Mehta at telephone number 404-686-1000 or Dr. Rafi Ahmed at 404-727-4700. You should also let any health care provider who treats you know that you are in a research study.

The NIH will not pay for treatment or provide any compensation in the case of injury. You do not give up any legal rights by signing this form..

Your insurance will be billed for any costs of medical treatment for your injury or illness that Emory does not pay. Your insurer may be told that you are in a research study. If you do not have insurance, or if your insurance does not pay, then you will have to pay these costs.

Emory has not set aside any money to pay you or to pay for your treatment if you get ill or injured from being in the study. The only exception to this policy is if it is proved that your injury or illness is directly caused by the negligence of an Emory employee.

Emory will keep any research records that it creates private to the extent that this is required to do so by law.

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

If you believe you were injured by the vaccine used in the study, you may be eligible for compensation through the National Vaccine Injury Compensation Program. You can get information about this program by calling 1-800-338-2382. Alternatively, you can use the internet to contact the program at http://www.hrsa.gov/gethealthcare/conditions/compensation.html

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.

Withdrawal from the Study

You can stop at any time after giving your consent. This decision will not affect in any way your current or future medical care or any other benefits to which you are otherwise entitled. In the event that you do withdraw from this study, the information you have already provided will be kept in a confidential manner. You have the right to leave a study at any time without penalty.

Reasons why you may be taken off study without your consent:
You may be removed from the study without your consent at any time. Reasons why you may be removed from the study include, but are not limited to, the following:

- Your doctor determines that it is in your best interest not to take part.

- You are unable to complete required study tests
- The study is stopped by the Institution, the Sponsor(s), or other health authorities

If you are removed from the study, Dr. Mehta or his designee will contact you to discuss the study stopping procedures.

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 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.

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. 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). If you leave the study, we may use your PHI to determine your health, vital status or contact information. We will use and disclose your PHI for the administration and payment of any costs relating to subject injury from the study.

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. We will also comply with legal requests or orders that require us to disclose your PHI. These include subpoenas or court orders.

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 or receive research-related treatment.

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 and give you study related treatment.
- 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.

- Government agencies that regulate the research including: Office for Human Research Protections

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 write to:

Aneesh K. Mehta, MD
Division of Infectious Diseases
Emory University School of Medicine
101 Woodruff Circle, WMRB 2101
Atlanta, GA 30322

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 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 or 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

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 and/or for other purposes besides this study.

Contact Information

Contact Dr. Aneesh Mehta (404-686-1000) aneesh.mehta@emory.edu or Shine Thomas (404-712-2004) with questions or concerns involving your clinical procedures, tests, results or visits: and Dr. Rafi Ahmed (404-727-4700) rahmed@emory.edu with questions or concerns that are non-clinical regarding the basic scope and purpose of the study.

- 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 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 print your name and sign below if you agree to be in this 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 consent to keep.

_____
Name of Subject

_____ _____
Signature of Subject Date Time

_____
Witness Name (if person is illiterate)

_____ _____
Witness Signature Date Time

_____ _____
Name of Person Conducting Informed Consent Discussion

Date Time

_____
Signature of Person Conducting Informed Consent Discussion

Statement of Person Obtaining Consent:

I have discussed, in detail, the informed consent document for this research study with the participant including the purpose of the study and its risks and benefits. I have answered all the participant's questions clearly. It is my opinion that the participant understands the risks, benefits, and procedures involved with participation in this research study.

_____ _____

Name of Investigator or designee Signature

_____

Date

After the study is done, we wish to store any remaining blood samples for use in future tests. As this study progresses, new tests may be developed. Researchers could use these samples to learn more about the body's response to vaccines. If new studies are identified, the consent and the protocol will be updated and submitted to the appropriate regulatory authorities, ethics committees, and IRBs for approval. You will be asked to sign the new informed consent form before additional tests are done on the stored samples. These samples will not be sold or shared with any other researchers.

Information concerning the confidentiality, use and disclosure of your health information contained in the main consent form applies to this part as well. We will make every attempt to insure that your personal information will be kept confidential. Stored specimens will be labeled only with your unique study number and information linking you to your blood sample will be stored separately.

You understand and agree that any tissue, blood, cell, or other biological samples that you provide as a participant in this research study are donations of these samples. Upon your donation, these samples, and any data, discoveries, materials or other products that come from the samples will be the exclusive, permanent property of the sponsor, NIH. You will not have any property rights in the samples, nor will you have any property rights in or be entitled to compensation of any type for any products, data, or other items or information that is developed from the samples. Nevertheless, you may, at any time request that Dr. Ahmed destroy your sample, and Dr. Ahmed will make all reasonable attempts to honor your request.

If you decide later that you no longer wish to have any remaining samples stored you may contact Dr. Ahmed at 404-727-4700 to have stored specimens destroyed.

If you're willing to allow us to store any remaining blood samples for use in future immunologic research, please sign below.

_____

Name of Subject

_____ _____

Signature of Subject Date/Time

_____ _____

Signature of Person Conducting Informed Consent Discussion Date/Time