Informed Consent Form

TITLE: Immunologic Responses to a Live Attenuated Oral Cholera Vaccine

NCT NUMBER: NCT03251495

IRB APPROVAL DATE: April 11, 2024

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: Immunologic Responses to a Live Attenuated Oral Cholera Vaccine

Principal Investigator: Nadine G. Rouphael, MD, MSc
School of Medicine, Division of Infectious Diseases
[redacted]

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

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?
Cholera is a life-threatening illness that causes diarrhea. Cholera is caused by eating or drinking the *Vibrio cholerae*. Each year, there are about 1.3 to 4.0 million cases of cholera worldwide, resulting in 21,000 to 143,000 deaths. The bacteria is spread through water or food that has stool in it. Up to 50 countries with limited access to clean water are more likely to have outbreaks. In the United States most cases are linked to travel to these countries; however, there are 10-15 cases acquired in the United States each year because of undercooked seafood. Cholera spreads very easily. Illness from cholera can vary from no symptoms to severe watery diarrhea that can cause death by dehydration in a healthy person within hours.

Vaxchora, (PaxVax, San Diego, CA), is a live attenuated cholera vaccine that protects against some cholera strains. It has been approved by the FDA since June 2016. Since October, 2016, this vaccine has been recommended for certain travelers 18 through 64 years of age going to cholera-affected areas. The purpose of this study is to look at the immune responses to the FDA approved cholera vaccine (Vaxchora®).

The purpose of the optional sub study is to understand gut immune responses, and see relationships between immune responses in the gut and the blood. This is done through upper gastrointestinal endoscopy or scope, also called Esophagogastroduodenoscopy (EGD).

You cannot be in this study if you:

- Are sick within 72 hours before vaccination
- Have any acute or chronic medical condition that, in the opinion of the principal investigator, would make vaccination unsafe or confuse the evaluation of immune response to study vaccination
- Have a suppressed immune system as a result of illness, immunosuppressive medication, chemotherapy, or radiation therapy within 3 years prior to study vaccination
- Have taken oral or parenteral corticosteroids of any dose within 30 days before study vaccination
- Reside with individuals under the age of 2 or with an immunocompromised individuals
- Have a known history of autoimmune disease
- Have a history of Guillain-Barre Syndrome
- Have plans to receive any vaccine from 28 days prior to study vaccination until 29 days after study vaccination
- Have previously received a cholera vaccine or have a known history of cholera infection
- Have donated blood or blood products within 56 days before study vaccination, plan to donate blood at any time during the 56-day duration of subject study participation, or plan to donate blood within 56 days after the last blood draw
- Have known hypersensitivity or allergy to any component of the vaccine or history of anaphylaxis with a vaccine or vaccine component
- Have allergy to tetracycline and/or ciprofloxacin
- Are pregnant or breastfeeding or plan to within one month of vaccination.
- Travelled to a cholera endemic area and had traveler's diarrhea in the previous 5 years
- Have abnormal stool pattern (fewer than 3 stools/ week or greater than 2 stools/ day) or regular use of laxatives in the last 6 months
- Have current or recent antibiotic use in the past 14 days
- Are healthcare workers who have direct contact with patients who are immunocompromised, have unstable medical conditions, or are under the age of 2
- Are childcare workers who have direct contact with children who are 2 years or younger.
- Work in the food industry
- Have received any vaccine within the previous 21 days
- Have a diagnosis of any small bowel disease.
- Have any contraindications to endoscopy/concerns of the anesthesiologist
- Have a BMI > 35 kg/m^2
- Are currently taking medications for the treatment of reflux or other diseases where anti acids medications are needed
- Have a history of *Helicobacter pylori* infection
- Have a History of bleeding disorders. For those with recent or current use of warfarin, aspirin, heparin, nonsteroidal anti-inflammatory drugs (NSAIDs) or other blood thinner/ anticoagulant medications, you must be able to abstain from these medications for at least 1 week prior to the EGD procedure or as otherwise instructed by the Gastroenterologist performing the procedure.

To be eligible for the Optional Sub Study arm:

- A responsible (18 years or older) must accompany you and must remain with you and accompany you home due to the sedation. You and a responsible adult can take a taxi/Uber/Lyft to your procedure, but the responsible adult must remain with you and must accompany you home.

This study plans to have 50 people sign this consent form, and be eligible and willing to receive the Cholera vaccine. We desire that 30 of these subjects also agree to do the sub study. To meet these goals, we expect up to 100 people may need to sign this consent document and be screened for the study.

What will I be asked to do?

The study lasts for about 13 months and requires 7 to 8 visits. The screening visit may or may not be done and happens between 45 and 7 days before visit 1. Visit 1 is the day of vaccination and the remaining visits occur 8 days (visit 2), 11 days (visit 3), 15 days (visit 4), 29 days (visit 5), 90 days (visit 6) (for selected volunteers), and 365 days (visit 7) after vaccination.

Screening/Baseline Visit (about 4 hours):

- Review and sign this consent document, if you choose
- Collect medical history and information about medications
- Measure oral temperature, pulse, blood pressure, height, and weight
- A urine pregnancy test will be done for females of child-bearing potential
- Agree to use 2 forms of birth control for 30 days after getting the vaccine
- A targeted physical exam may be done

Visit 1 Vaccine Visit (about 2 hours):

- Review and sign this consent document, if you choose
- Collect medical history and information about medications
- Measure oral temperature, pulse, blood pressure, height, and weight
- A urine pregnancy test will be done for females of child-bearing potential
- Agree to use 2 forms of birth control for 30 days after getting the vaccine
- A targeted physical exam may be done
- Collect blood samples for research laboratory testing
- Refrain from drinking for 1 hour before and 1 hour after getting the vaccine
- Drink a solution which contains the vaccine
- Stay at the clinic for 20 minutes after drinking the vaccine for observation
- Given memory aid to record any health changes you have for 7 days after the vaccine

Visit 2, 3, 4, 5, 6 (for selected volunteers), 7 Follow-Up (about 1 hour):

- Review changes to medical history and medications
- Review memory aid (for visit 2 only)
- Measure oral temperature, pulse, blood pressure
- Physical exam may be done
- Collect blood samples

Optional Sub study: Small Intestine Biopsy/EGD

You have the option to participate in a substudy which requires an upper gastrointestinal endoscopy or scope, also called Esophagogastroduodenoscopy (EGD). Normally a scope is used to help diagnose disorders such as gastroesophageal reflux disease, difficulty swallowing, etc. It can also be used for treatment (upper GI bleed, etc.). For the procedure, the doctor will pass a flexible tube with a light and a camera through the mouth into the stomach and upper part of the small intestine.

Up to 12 small intestine biopsies are performed through this EGD. A biopsy is when a needle is inserted to remove tissue. Before EGD, patients should take no food by mouth after midnight. If you have medications you need to keep taking, please discuss this with the study doctor. Most medications can be continued up to the time of EGD and are usually taken with a small sip of water. Some medications may need to be adjusted before EGD. The study doctor will tell you more about this.

All 30 people that agree to the sub study will have the EGD procedure done at Screening (Day 0). The EGD procedure will also be done on either Visit 5 (Day 29) or Visit 6 (Day 90). The procedure will be performed by a gastrointestinal specialist at the Emory GI suite, Dr. Steven Keilin.

As detailed below, after each EGD procedures there will be a scheduled follow-up phone call 7 days later. The study team will ask about any side affects you may have from the EGD procedure. The Emory GI suite will also call you 1 day after the procedure to check on you.

If you do not want to do this additional procedure, you can still be in the main study.

Screening/Baseline Visit (about 4 hours):

- Required if you do the optional substudy
- A small intestine biopsy using EGD will be done by a gastrointestinal specialist at Emory GI suite

Visit 0a Scheduled Phone Call Follow-Up (about 15 minutes)

- 7 days after EGD procedure
- Receive call from study team member to discuss any side effects from the EGD procedure

Visit 5 Follow-Up (about 4 hours):

- Done at visit 5
- A small intestine biopsy using EGD will be done by a gastrointestinal specialist at Emory GI suite

Visit 05a Scheduled Phone Call Follow-Up (about 15 minutes)

- 7 days after EGD procedure (visit 5)
- Receive call from study team member to discuss any side effects from the EGD procedure

Optional: Data/Sample Storage for Future Research

This study involves the collection of blood samples and, if you agree to the sub study, small intestine biopsies through EGD. With your agreement, the researchers may store these samples and research data from the main study for future medical research. You will be asked to consent separately at the end of this form for the retention and use of your leftover samples and accompanying data.

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

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

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

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

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 vaccine be provided?
The vaccine that you will take will be dispensed by the pharmacy and delivered to the principal investigator or study team member. They will provide the vaccine to you. If you have questions about the vaccine, you should ask the principal investigator or study team member.

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

What are the possible risks and discomforts?
There may be side effects from the study vaccine or procedures that are not known at this time. However, this vaccine is already FDA approved and is in use for current travelers to countries where there is cholera.

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

Vaccination: The most common side effects (incidence > 3%) reported by adults receiving Vaxchora were these:

- Tiredness (31%)
- Headache (29%)
- Abdominal pain (19%)
- Nausea/vomiting (18%)
- Lack of appetite (17%)
- Diarrhea (4%)

This vaccine is a live attenuated vaccine and has the potential to be spread to close household contacts. The following guidelines are to be followed:

- For at least 14 days following vaccination you should wash your hands thoroughly after using the bathroom and before preparing or handling food.
- You may not donate blood or blood products any time during the 56-day duration of subject study participation, or plan to donate blood within 56 days after the last blood draw.

If you are a woman: to protect against possible side effects of the study vaccine, women who are pregnant or nursing a child may not take part in this study. If you become pregnant, there may be risks to you, the embryo, or fetus. These risks are not yet known. If you are a woman of childbearing ability, you and the study doctor must agree on a method of birth control to use throughout the study. Two forms of birth control must be used to avoid pregnancy within one month of getting the vaccine. If you think that you have gotten pregnant during the study, you must tell the study doctor immediately. Pregnant women will be taken out of the study.

If you are a man: the effect of the study drug on sperm is not known. 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.

Optional Sub Study: Upper endoscopy biopsy (EGD):
Procedures include complications related to: sedation, endoscopy, and the biopsy extraction.

- Bleeding rarely occurs following diagnostic upper endoscopy (risk may be increased in patients with low blood platelet counts or if you have certain bleeding disorders). The risk is increased with use of anticoagulants and antiplatelet medications.
- Tearing of the gastrointestinal tract. 0.03% to 0.11% of the population have GI perforation following an EGD.
- Infection: Risk of infection related to gastrointestinal endoscopy is 0.03%. The risk of infection increases when additional procedures are performed as part of your endoscopy. Most infections are minor and can be treated with antibiotics.

Risks related to sedation: The following events were found to occur in 0.02 to 0.54% of the persons and mortality rates were 0.03 to 0.05 %:

- Shortness of breath
- Decreased blood pressure and/or heart rate
- A sudden drop in heart rate and blood pressure leading to fainting
- Below-normal level of oxygen in your blood
- Irregular heartbeat

The risk of these events are increased in patients with advanced age, underlying comorbid illness (especially pulmonary disease), sleep apnea, obesity, anemia, and dementia.

Will I benefit directly from the study?
This study is not designed to benefit you directly, but it is likely you will receive some level of immune protection from future *V. cholerae* exposures, however *V. cholerae* does not circulate in the US. This study is designed to learn more about the immune responses to the cholera vaccine. The study results may be used to help others in the future.

Will I be compensated for my time and effort?
You will receive $75 for visit 1 and $50 for all other completed study visits, to compensate you 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 $225 total, if you complete all study visits (not counting the additional compensation for sub study participation). 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.

Optional Sub Study: If you participate in the optional sub study, you will receive $350 for each EGD, to compensate you for your time and effort. You will receive $700 total for completing both EGD procedures (pre and post vaccination). If you do not finish the study, we will compensate you for the visits you have completed.

What are my other options?

You do not have to take part in this study. This is not a drug or treatment study so no treatment or care is available.

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

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

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

Certificate of Confidentiality

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

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

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

- Giving state public health officials information about certain infectious diseases,
- Giving law officials information about abuse of a child, elderly person or disabled person.
- Giving out information to prevent harm to you or others.

Giving the study sponsor or funders information about the study, including information for an audit or evaluation.

Storing and Sharing your Information

De-identified data from this study, including your de-identified genetic information, 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.

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, your genetic information has special legal protections called "privilege," which means that the information cannot be used as evidence in a court. By signing this form and allowing us to use and disclose your genetic information for the purposes described in this consent, you waive any privilege with regard to that genetic information, meaning that the information loses this legal protection.

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 may 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 may be put in any Emory Healthcare medical record you have now or any time during the study.

The results of some study tests and procedures will be used only for research purposes and will *not* be placed in your medical record. For this study, those items include pregnancy tests.

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

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

Incidental Findings from the Upper Gastrointestinal Endoscopy
You will receive an endoscopy for research purposes only. The research does not require the endoscopy results to be read for healthcare purposes. However, if the researchers are concerned about something they see on the scope they will let you know, and they will help you with next steps to address this finding. You or your insurance company will have to pay for a follow up evaluation if needed based on the incidental finding.

In Case of Injury
If you become ill or injured from being in the study, Emory will help you get medical treatment. Emory has not, however, set aside any money to pay you or to pay for this medical treatment. The only exception is if it is proven that

your injury or illness is directly caused by the negligence of an Emory employee. "Negligence" is the failure to follow a standard duty of care.

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

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

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

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

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

Authorization to Use and Disclose Protected Health Information

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

Main Study

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

- Demographic information including your e-mail (if you want to communicate with us in this manner)
- 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.
- Pregnancy test results and 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 also use and share your PHI to conduct normal business operations. We may share your PHI with other people and places that help us conduct or carry out the study, such as laboratories, data management centers, data monitors, contract research organizations, Institutional Review Boards (IRBs) and other study sites. If you leave the study, we may use your PHI to determine your health, vital status or contact information.

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

Authorization to Use PHI is Required to Participate:

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

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

- The Principal Investigator and the research staff will use and disclose your PHI to conduct the study
- Emory may use and disclose your PHI to get payment for study related treatment and to run normal business operations.
- The Principal Investigator and research staff will share your PHI with other people and groups to help conduct the study or to provide oversight for the study.
- NIH is the Sponsor of the study. The Sponsor may use and disclose your PHI to make sure the research is done correctly and to collect and analyze the results of the research. The Sponsor may disclose your PHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.
- 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 (OHRP) and the Food and Drug Administration (FDA)
    - Public health agencies
    - Research monitors and reviewer
    - Accreditation agencies

Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your PHI may be shared with that new institution and their oversight offices. PHI will be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent and HIPAA authorization.

Optional Sub Study: Small Intestine Biopsy/EGD

PHI That Will be Used/Disclosed for Optional Sub Study:
The PHI that we will use and/or disclose (share) for the optional sub study includes the same PHI from the main study.

Purposes for which your PHI will be Used/Disclosed for Optional Sub Study:
We will use and disclose your PHI for the conduct and oversight of the optional sub study.

Authorization for This Use of PHI is Required to Participate in Optional Sub Study, but Not in Main Study:
You do not have to authorize the use and disclosure of your PHI. If you do not authorize the use and disclosure of your PHI for the optional sub study, then you may not participate in the optional sub study. You can still be in the main research study even if you don't participate in the optional study.

People Who Will Use/Disclose Your PHI for Optional Sub Study:
The same people and groups who will use and disclose your PHI for the Main Study will also do so in connection with the optional sub study.

Optional: Data/Sample Storage for Future Use:

PHI That Will be Used/Disclosed for Optional Storage of Data/Samples for Future Research:
The PHI that we will use and/or disclose (share) for the optional storage of data and samples for future research use is the same PHI from the main study.

Purposes for which your PHI will be Used/Disclosed for Optional Storage of Data/Samples for Future Research:
We will use and disclose your PHI for the optional storage of data and samples for future research use of your PHI.

Authorization for This Use of PHI is Required to Participate in Optional Storage of Data/Samples for Future Research, but Not in Main Study:
You do not have to authorize the use and disclosure of your PHI. If you do not authorize the use and disclosure of your PHI for the optional storage of data and samples for future research use, then you may not participate in the storage of data and samples for future research use. You can still be in the main research study even if you don't participate in the optional storage of data and samples for future research use .

People Who Will Use/Disclose Your PHI for Optional Storage of Data/Samples for Future Research:
The same people and groups who will use and disclose your PHI for the Main Study will also do so in connection with the optional storage of data and samples for future research use.

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

Revoking Your Authorization
If you sign this form, at any time later you may revoke (take back) your permission to use your information. If you want to do this, you must contact the study team at: Nadine Rouphael, MD, [redacted].

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, and health care clearinghouses. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them.

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

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

Contact Information

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

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

Contact Dr. Steven Keilin at [redacted] for any concerns regarding the EGD procedure.

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.

TO BE FILLED OUT BY SUBJECT ONLY

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

_____

Name of Subject

_____ _____

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**

Consent and Authorization

Consent and HIPAA Authorization for optional sub study and contact for future research. Please place your initials below (select only ONE option):

Optional Sub Study: Small Intestine Biopsy/EGD

_____ YES, I agree to participate in the sub study, as described above to undergo EGD procedures and related follow-ups

_____ NO, I do not agree to participate in the sub study, as described above to undergo EGD procedures and related follow-ups

Optional: Data/Sample Storage for Future Use

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

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

_____ NO, you may not use my samples for other future research. Destroy my unused samples at the end of this study.

Optional: Contact for Future Studies & Database Storage

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

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