Informed Consent Form

A Phase 1 Study to Evaluate the Safety and Immunogenicity of CDC-9 Inactivated Rotavirus Adjuvanted Vaccine for Intramuscular Administration in Healthy Adults

NCT# 06485258

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You Are Being Asked to Be in a Research Study

Concise presentation of key concepts

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

Why is this study being done?

This study is being done to answer the question: does a new experimental rotavirus vaccine stimulate the immune system, and is the vaccine safe? You are being asked to be in this research study because you are a healthy adult 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 approximately 9 months (13 study visits). The researchers will ask you to do the following: provide consent, provide medical and medication history, allow us to collect blood and possibly urine samples, allow us to perform a physical exam, receive three vaccinations, and report any side effects following vaccination in an e-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. This study is not intended to benefit you directly. The study results may be used to benefit others in the future.

What are the risks or discomforts you should know about before deciding?

The study will take time. The vaccine that is being tested may not work any better than current approved vaccines and may even cause harm. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious. Risks for this study include:

- discomfort, bruising, or lightheadedness from blood draws or vaccination
- adverse effects (side effects) of the study vaccine
- 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
Since this is not a treatment study, the alternative is not to participate.

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. Take time to think about this and talk about it with your family and friends.

Emory University
Consent to be a Research Subject

Title: A Phase 1 Study to Evaluate the Safety and Immunogenicity of Inactivated Rotavirus Adjuvanted Vaccine for Intramuscular Administration in Healthy Adults

IRB #: STUDY00007399

Principal Investigator: Christina Rostad, MD

Sponsor: Centers for Disease Control and Prevention

Study-Supporter: Bill & Melinda Gates Foundation

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?
The purpose of this study is to test an experimental rotavirus vaccine to see if it is safe and if it stimulates the immune system to make antibodies. Infection with rotavirus can cause symptoms such as watery diarrhea, vomiting (throwing up), and fever. Sometimes the symptoms are severe enough to require hospitalization or cause death. Rotavirus infection most commonly occurs in infants and children but can also affect adults. Children are at greater risk of having severe symptoms.

The experimental vaccine is investigational, meaning it is not approved by the FDA; however, the FDA is allowing this vaccine to be tested in this study. There are two vaccines approved by the FDA available for rotavirus. Both available vaccines are administered orally (taken by mouth) and contain live rotavirus. However, these vaccines do not work as effectively in preventing severe illness in some people, which may be related to oral administration. CDC-9 inactivated rotavirus vaccine (IRV) is a vaccine that is given as a shot and contains rotavirus that has been inactivated (killed) by heat. When given as a shot, the inactivated rotavirus cannot cause infection but instead trains the immune system to recognize and protect against rotavirus with subsequent exposure.

Approximately 110 people will enroll and be screened into this study and 50 of those people will be assigned to one of two groups. Both groups will have 25 people, who will receive three study vaccinations in total, each 28 days apart. The first group will receive a 3.75 µg dose of CDC-9 IRV or placebo, and the second group will receive a 7.5 µg dose of CDC-9 IRV or placebo.

At each of the study clinic visits, we will collect blood samples from you. The samples will be used for tests to assess your health and for research testing of the immune system in response to the study vaccine.

This study will take place at Emory Children's Center – Vaccine Research Clinic over approximately 9-10 months.

What will you be asked to do?

If you agree to participate, you will be assigned by chance, like flipping a coin, to receive either CDC-9 IRV or placebo. The placebo in this study is salt water without vaccine. If you receive placebo, it is not expected to result in an immune response to rotavirus. You will have an 80% chance (4 of 5) of receiving vaccine and a 20% chance (1 of 5) of receiving placebo. Half of the vaccine recipients will receive the 3.75 µg dose and half will receive the 7.5 µg dose. Neither you nor the study doctor will know which group you are in until the study is over. You will receive 3 doses of either the vaccine or the placebo. The second dose will occur about 1 month after the initial dose, and the third dose will occur about 2 months after the initial dose. Your involvement will last approximately 9-10 months.

Screening

You will have a screening visit to check if you are eligible to participate. The screening visit will take about 90 minutes and includes:

- Reviewing and signing the consent form if you agree to participate in the study
- Collecting information about your medical history, including medications you take & vaccination history
- Collecting vital signs (temperature, blood pressure, heart rate) and height and weight
- Having a physical exam
- Testing your blood to check your kidneys, pancreas, and liver functions, blood cell counts, and to perform testing for HIV, hepatitis B, and hepatitis C infections. The study doctor may be required by law to report the result of the HIV and hepatitis tests to the local health authority.
- For women who can become pregnant, a urine pregnancy test

If your blood or urine lab results are not within standard, normal ranges, you will not be able to participate in the study, and the study doctor may refer you to your regular medical provider.

Women who can become pregnant must agree to use an acceptable method of birth control from at least 30 days before the first study vaccination through 60 days after the last study vaccination. Acceptable birth control methods include abstinence from sexual activity that could lead to pregnancy; monogamous relationship with a partner who has had a vasectomy at least six months ago; documented status as being surgically sterile (hysterectomy, bilateral oophorectomy, tubal ligation/salpingectomy, or Essure® placement); intrauterine devices; and hormonal methods, including the birth control patch, shot (Depo-Provera), pills, the vaginal ring (NuvaRing), and the contraceptive implant (Nexplanon).

Men of childbearing potential must agree to use of condoms to ensure effective contraception with female partners of childbearing potential OR for female partners to use at least one acceptable primary form of contraception from first vaccination until 60 days after the last study vaccination. Men must also agree to not donate sperm, from the first study vaccination until 60 days after the last study vaccination.

General Study Visits
Study visits that include a study vaccination will generally last about 2-3 hours and other visits will generally last about 30 minutes. Visits may include:

- Questions about your recent medical history and medications, illnesses or symptoms, and side effects or reactions
- Collecting vital signs (heart rate, blood pressure, temperature)
- If applicable, reviewing use of birth control methods and pregnancy status
- Having a physical exam if needed
- Collection of blood samples at each of the study clinic visits (and, for women who can become pregnant, urine for pregnancy testing at each of the two study vaccination visits)
- Study vaccination or assessment of the site of a previous study vaccination
- Review of the e-diary

Study Vaccination Visits
Study vaccination visits will occur on Study Days 1, 29, and 57. At those visits, we will review your lab test results and medical history to confirm that you are eligible for a study vaccination.

You will be in one of two study groups which will each include 25 participants. You will receive an injection of the same dose of study vaccine or placebo in the deltoid (shoulder) muscle of your upper arm at each of the three study vaccination visits. You will stay in the clinic for at least 30 minutes after the study vaccination for study staff to check for any immediate reactions.

We will give you a thermometer and ruler with instructions to record your temperature and any side effects. The e-diary will be completed by accessing a website through a QR code (or by directly entering the website into an Internet browser) and will ask questions about your health or potential symptoms you might have after receiving the study vaccination. You will be trained by the study staff on how to complete the e-diary. You will enter information in the e-diary each day, preferably in the evening and at the same time of day, for 7 days after each injection. If a reported side effect continues beyond 7 days, you will be followed by trial staff at your next site visit or phone call. Your e-diary information will be reviewed by telephone or during site visits.

If you become sick or have any reactions after a study vaccination, you should immediately contact the study staff. We may ask you to come to the clinic for an extra study visit. The staff may perform additional research or safety procedures, if needed.

Follow-Up Visits
In addition to the study vaccination visits, you will also come to the clinic for follow up visits, on Days 8, 36, 64, 85, and 237. Follow-up visits in the clinic will take about 30 minutes. There will be four visits conducted over the telephone on Days 2, 30, 58, and 147, which will take less than 10 minutes.

The study staff may call you periodically during your study participation to check on your health status, to remind you of an upcoming visit, or for other reasons. We may also contact you by email or text message when appropriate.

Unscheduled Visits
You may be asked to come back to the study clinic at other times if needed, for example, if you have a reaction or illness that should be evaluated before the next scheduled visit. The study doctor will determine what activities will be needed after reviewing any symptoms that you are having.

Laboratory Testing of Specimens

We will test your blood to check your kidney, pancreas, and liver functions, blood cell counts, and to perform testing for HIV, hepatitis B, and hepatitis C infections at the screening visit. For individuals of childbearing potential, we will perform urine testing for pregnancy at the screening visit and prior to receipt of study vaccine. In addition to these tests, blood specimens will be collected from you throughout the study to test how the immune system responds to the study vaccine. We will look at your antibodies and how different cells of your immune system help to fight the virus. We will not perform any genetic testing.

Blood samples for these research tests may be sent to a central storage facility or sent directly to the research testing laboratories. These samples will not be labeled with your name or initials, or any other information that could readily identify you. These samples will be labeled only with a barcode and a unique tracking number (ID code) to help protect your confidentiality. Staff at the central storage facility and research testing laboratories will not know your identity, or even the study identifier you were assigned. We may remove the codes from your information or samples so that we cannot identify you and use these in other research. These deidentified samples may be shared with other researchers without your additional consent.

Extra Blood Samples

We will also collect extra blood samples at each visit (about 10 teaspoons or less depending upon the visit) to store and use for secondary research. Secondary research could test for a number of different things including but not limited to antibodies, other markers of recent infection, or immune responses. These samples will not be sold or used directly for production of any commercial product. No human genetic tests will be performed on your samples. **If you do not want to give leftover and extra samples for secondary research, you cannot be in this vaccine study.**

Samples will be stored indefinitely at a site determined by the CDC. Extra samples will be labeled only with a barcode and an ID code (not with your name, initials, or any other information that could readily identify you). These extra samples will be stored with the same confidentiality measures used for the main specimens.

If these samples are tested in the future, the results may be published. You will not be identified in such publication. In other words, the publication will not contain any information about you that would enable someone to determine your identity.

By signing and dating this consent form, you are agreeing to the collection, storage and future research use of your samples and information collected for this study. The results of any future research testing will be kept confidential in the same way as the results of other testing done for this study. The results of any future research will not be available to you or your regular doctor and will not be placed in your medical record.

Ask us if you have questions about how your blood samples may be used.

How will your study drug be provided?

The study drug (CDC-9 IRV vaccine) that you will take will be dispensed by the Investigational Drug Services pharmacy at Emory University and delivered to the principal investigator or study team member who will provide the study drug to you. If you have questions about the study drug, you should ask the principal investigator or study nurse.

Note: The research team for this study includes non-licensed team members who may obtain your consent or help guide you through the study. There are some kinds of questions only licensed clinicians can answer. For example,

detailed questions about drug interactions. If you have questions like these, the non-licensed coordinator will ask a licensed study team member to answer your questions.

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. Leftover and extra blood samples may be used in the future for research about this study vaccine and your body's response to this study vaccine. These blood samples might be used in new or different laboratory tests, to give information for the development of new vaccines, or for the studies of rotavirus or other infections, including using tests that have yet to be developed. You will not be contacted about the types of future research. You may change your mind about secondary research and withdraw consent for the storage and use of your coded samples or information at any time. You will need to contact the study doctor using the contact information listed on page 13 of this form. If you have visits after this, we will stop collecting extra blood.

If you leave the study, the data and samples that were already collected may still be used for this study. Your samples will be removed from future use when the vaccine study is completed. Only stored samples with an ID code and not used in this research can be removed or destroyed. Research that has already begun using your specimens cannot be withdrawn. For example, if some research with your specimens and data has already been completed, the information from that research may still be used. Also, for example, if the specimens and data have been shared already with other researchers, it might not be possible to withdraw the specimens and data.

What are the possible risks and discomforts?

There may be some risks to participation in this study. You may experience one or more of the risks or side effects explained below. You should discuss these with the study doctor or study staff. Many side effects go away shortly if treated, but in some cases, side effects can be serious, long lasting, or permanent. The study vaccine is experimental and has not been given to humans before and there may be risks that we do not know about right now. Side effects may occur more frequently with higher doses of the study vaccine or with the second or third dose compared with the first.

The possible risks of participating in this study include those associated with having blood drawn, reactions to the injection, adverse effects (side effects) of the study vaccine, and the possibility of a breach of confidentiality.

Risks of having blood drawn or getting the study vaccine injection

Having your blood taken can cause pain and may also cause lightheadedness or fainting. The needle stick can cause bruising, which can be prevented or reduced by putting pressure on the site for a few minutes after the needle is removed. Rarely, people can get an infection at the site of the blood draw. To reduce the risk of infection after the blood draw or study vaccine injection, the study doctor or study staff will wipe the area clean with alcohol and use sterile equipment.

Risks associated with study vaccination

After a study vaccination, a person might experience:

- Mild to moderate events:
    - A sore arm
    - Redness, swelling, hardness, or itching at injection site
    - Fever, chills, or fatigue (feeling tired)
    - Flu-like illness, runny nose, or cough
    - Headache, muscle aches, pain, and stiffness in the joints
    - Nausea or vomiting
    - Temporary abnormal lab test results
    - Fainting

- Swelling of lymph nodes in the neck or armpit

- Severe events could occur very rarely:
  - Any of the reactions listed above (such as pain or soreness) could be severe enough to prevent you from performing your activities of daily life for some period of time.
  - Rarely, an injection could cause ulceration (open sore), abscess (a pocket of pus caused by the body fighting infection) or necrosis (dead tissue) at the injection site.
  - Additionally, any reaction other than the above events could be severe.
  - A small number of people (about 1 in 4 million people) have an immediate allergic reaction called anaphylaxis (also known as allergic shock) after receiving vaccines or medications. This type of reaction may include symptoms such as:
    - Skin rash (hives)
    - Sweating
    - A feeling of dread
    - Swelling around the mouth, throat, and eyes
    - Wheezing
    - Difficulty breathing
    - Increased pulse
    - Fainting or feeling dizzy due to low blood pressure
    - Inability to breathe without assistance

If these reactions occur, emergency medications administered by study personnel can usually stop them. Most people who experience anaphylaxis recover completely. Rarely, people can die.

If you had an allergic reaction after being vaccinated in the past, or if you are allergic to any product, you must tell the study doctor or study staff before you decide to sign and date this informed consent form. If you have an allergy to some products, you will not be able to take part in this study. Serious allergic reactions can be life-threatening.

If it is biologically possible for you to become pregnant: to protect against possible side effects of the study drug, 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 an acceptable method of birth control to use from at least 30 days before the first study vaccination through 60 days after the last study vaccination. If you think that you have gotten pregnant during the study, you must tell the study doctor immediately. Pregnant women will not receive additional study product, but they will be followed for safety outcomes.

If it is biologically possible for you to make someone pregnant: the effect of the study drug on sperm is not known. To protect against possible side effects, you should not get a sexual partner pregnant while taking the study drug and for 60 days after the last vaccination. You must agree to use of condoms to ensure effective contraception with female partners of childbearing potential OR for female partners to use at least one acceptable primary form of contraception from first vaccination until 60 days after the last study vaccination. Men must also agree to not donate sperm, from the first study vaccination until 60 days after the last study vaccination.

Other risks
There is a small risk to people who have an unknown health problem at the screening visit. Your blood will be taken at the screening visit to check for health problems. We will review your results before giving you the first study vaccination.

There may be side effects from the study drug or procedures that are not known at this time.

There is a risk of loss of confidentiality of your information. You will read more about the protection of your information later in this consent form. Please ask us if you would like to know more about how your information will be protected while you are in this study.

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?

You will not benefit from joining the study. This study is designed to learn more about how the immune system responds to an experimental inactivated rotavirus vaccine. The study results may be used to help others in the future.

Will you be paid for your time and effort?

You will receive $100 for the screening visit and each completed vaccine visit, $50 for each completed follow-up study visit, and $30 for each completed week of e-diary entries to compensate you for your time and effort. If any unscheduled visits are required, then you will receive $20 in compensation per visit. If you do not finish the study, we will compensate you for the visits you have completed. You will get approximately $960 total if you complete all study visits.

We are planning to provide compensation to you by a personal payment card. We issue this to you 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. You will be paid following each time you complete a visit. 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.

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?

You can choose not to participate in this study.

If you choose to join this study, you may not be able to join other research studies. Discuss this with the researchers if you have concerns. You may wish to look on websites such as clinicaltrials.gov and ResearchMatch.org for other research studies you may want to join.

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.

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.

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 an uncommon occurrence.

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 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 vital signs, height, weight, physical examination findings, pregnancy

test results (if individual is of childbearing potential), laboratory test results (including results of HIV, Hepatitis B, and Hepatitis C tests), information entered in the e-diary, or adverse event or serious adverse event assessments.

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

In Case of Injury

If you get ill or injured from this research, contact the person listed in the contact section of this form. Emory will help you get immediate medical care. However, Emory, CDC, and the Bill & Melinda Gates Foundation do not have programs to pay for this medical care or compensate you if you are hurt from being in this study.

The costs for any treatment or hospital care you receive as the result of a study-related injury that are not covered by a health insurer will be billed to you.

You do not give up any legal rights you may have by being in this study, including any right to pursue a claim through the legal system.

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:

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

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 Emory Institutional Review Board, the Emory Office of Compliance, and the Food & Drug Administration. 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 and give you study related treatment.
- Emory may use and disclose your information to get payment for study related activities and to run normal business operations.
- 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.
- Centers for Disease Control and Prevention is the Sponsor and the Bill & Melinda Gates Foundation is the Supporter of the study. The Sponsor and Supporter 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 research team may use and disclose your information, including disclosure to insurance carriers to administer payment for subject injury.
- 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.
    - Other researchers and centers that are a part of this study.
    - Government agencies that regulate the research including Office for Human Research Protections and Food & Drug Administration.
    - Public health agencies.
    - Research monitors and reviewer.
    - Accreditation agencies.
    - The contract research organization, Peachtree Solutions.
- 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 research and recruiting team at [redacted] or [redacted].

For emergencies: Contact the 24-hour emergency number at [redacted].

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 [redacted] or [redacted]

To tell the IRB about your experience as a research participant, fill out the Research Participant Survey at [redacted]

TO BE FILLED OUT BY SUBJECT ONLY

Future Use Acknowledgement

_____ (Initials) I understand, if I take part in this study, that my blood samples will be stored indefinitely and may be used for future research as described above.

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 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**

Contact For Future Studies:

We may want to contact you in the future to ask if you would like to participate in another related study or in future unrelated studies. If you agree, we would like to keep your name, date of birth, address, phone number and e-mail address on file. This information will be kept confidential and will not be shared with other investigators at this or other institutions.

Please initial your decision about permission for us to contact you in the future for upcoming studies (initial only ONE option):

_____YES, you may contact me in the future by telephone, e-mail, text messaging or postal mail to inform me of upcoming studies.

_____NO, you may not contact me in the future regarding upcoming studies.