Sentinel Cohort for the Response to Emerging Antimicrobial Resistance With Containment Microbiota Restoration Therapy Trial

Short study title: Sentinel Cohort REACT

NCT Number: NCT05780801

Date: April 17, 2023

STUDY00005467

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 up to 20 people who are being studied at Emory.

Why is this study being done?

This study is being done to answer the question: can microbiome therapies safely reduce colonization with antibiotic-resistant bacteria in hospitals like this one? You are being asked to be in this research study because you have a history of antibiotic-resistant bacteria in your gut.

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. Your choice will not affect your access to medical care for your condition. 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 about 7 months (3-5 study visits over 1 month followed by 6 months of monthly phone calls). The researchers will perform a medical history review, physical exam, and urine pregnancy test (if there is a chance you could get pregnant) to ensure that you are eligible to participate. If you choose to participate you will be asked to do the following: provide stool or rectal swabs. You will also be given human-derived bacteria and other microbes (microbiome therapeutic) via an existing feeding tube or rectal enema. 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. We are conducting this study because smaller studies have shown that microbiome therapies may help to remove antibiotic resistant bacteria (decolonize) from your body without antibiotics. So, you may benefit by reducing or eliminating colonization with antibiotic resistant bacteria.

What are the risks or discomforts you should know about before deciding?
The study will take time. The drug that is being tested may not work any better than regular care and may even cause harm. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious. For this study, these include

- Nausea
- Abdominal discomfort/cramping
- Diarrhea
- Risk of transmitted infection (including with a new antibiotic resistant bacteria) or health problem from the microbiota donor
- 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
There is no approved alternative treatment to treat intestinal colonization with antibiotic resistant bacteria. The alternative to participating is to not participate.

Costs
The study sponsor will pay for certain items and services that you may receive if you take part in this study. You will have to pay for the items or services for which the study sponsor does not pay. The sponsor will not pay for your regular medical care.

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

What Should You Do Next?
Read this form, or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions such as how much time you will have to spend on the study, any words you do not understand and more details about study procedures. Make sure you understand which parts of the study are research and which are standard care that you would have even if you did not join the study. Take time to think about this and talk about it with your family and friends.

EMORY UNIVERSITY | Institutional Review Board
Research Administration

Emory University
Consent to be a Research Subject / HIPAA Authorization

Title: Response to Emerging Antimicrobial resistance with ring Containment microbiota Therapy (REACT)

IRB #: STUDY00005467

Principal Investigator: [redacted]

Investigator-Sponsor: [redacted]

Study-Supporter: U.S. Centers for Disease Control & Prevention (CDC)
source: U54CK000601

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. This research consent form will explain why this research study is being done, what is involved in participating in the research study, the possible risks and benefits of participation, alternatives to participation, and your rights as a research participant. **It is entirely your choice to participate. 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.

You are invited to take part in this clinical trial, a type of medical research study, because you have tested positive by rectal swab or stool culture for an antibiotic resistant bacterium. We call this type of bacteria a Multi-Drug Resistant Organism (or MDRO for short) because the bacteria cannot be killed by many drugs and often requires treatment with IV antibiotics. Having MDRO colonization in the gut means the bacteria are present but often not causing symptoms. One problem of MDRO colonization is that even without causing symptoms now, it can make it more likely that you get an infection later or even pass the MDRO to others.

To be part of this study, participants must have colonization with one or more of these MDROs:

- ***C. difficile****: Clostridioides difficile* (you will hear us say "C. diff" for short),
- **CRE: C**arbapenem-**r**esistant ***E****nterobacteriaceae* (you will hear us say "C-R-E" for short),
- **ESBL: E**xtended **S**pectrum **B**eta-**L**actamase (you will hear us say "E-S-B-L" for short),
- **VRE: V**ancomycin-**r**esistant ***E****nterococcus* (you will hear us say "V-R-E" for short), or
- **CRPA**: **C**arbapenem-**R**esistant *Pseudomonas aeruginosa* (you will hear us say "C-R-P-A" for short)

This research study is studying the transfer of good bacteria to people who have MDRO colonization. The good bacteria will come from stool, which is donated by a healthy person who undergoes laboratory tests of blood, urine, and stool and risk factor screening similar to blood donors.

In this study, the research name for the stool, or study agent, is:

- **A**llogeneic **H**uman **S**tool in **G**lycerol (10%) (AHSG)

The microbiome therapeutic, which will be delivered as AHSG into your rectum as an enema or through an already existing feeding tube, is a type of intervention called:

- **Microbiome therapeutic** (you will hear us say "M-T" for short)

For purposes of this research, you will be referred to as a "participant" or "subject". It is expected that about 20 people will take part in this research study. Emory University School of Medicine and the Centers for Disease Control and Prevention are supporting this research study by providing funding. Participating in this study will take between 2 and 4 weeks followed by another 24 weeks of monthly follow up by telephone to see if you are doing well.

Before making your decision, we encourage you to please:

- 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 might 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.

If you decide to participate: please sign and date at the end of this form. We will give you a copy so that you can refer to it while you are involved in this research study. You can change your mind later on and withdraw from the research study. You will not give up any legal rights by signing this form.

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 better understand the efficacy and safety of microbiome therapies (MT) in patients with Multidrug Resistant Organism (MDRO) colonization who are admitted to hospitals like Emory Long Term Acute Care (ELTAC). This use of MT has been studied in other small studies to treat MDRO colonization, but this is the first time that investigators are also studying the effect of MT on transmission of the MDRO to other patients. This study will test the safety of the MT for this use and in patients like you, and how well it works to help design larger studies.

We believe, based on several studies published over the last 10 years, that the MT may help eliminate resistant bacteria that colonize the gut and later cause you to have an infection or be passed to other people. The use of MT for your condition was identified after observing success in patients who have *Clostridium difficile* (often called "C. diff") diarrhea AND other bacteria that are resistant to antibiotics. It was shown that a type of MT called fecal microbiota transplant (FMT) can eliminate both the *C. difficile* AND the other resistant bacteria. However, at this time, MTs are not approved by the U.S. Food and Drug Administration (FDA) and can only be performed in research studies such as this one under the care of a physician after discussing the risks and potential side effects.

Up to 20 people will participate in this study. The entire study will take a total of five years to complete but it will take between 2 to 4 weeks for each participant to complete followed by 6 months of monthly follow up to determine the safety of MT in people like you.

What will you be asked to do?

You will be in this research study for 2-4 weeks plus 24 weeks of follow up by email, phone, or medical record review.

The research doctor may decide to take you off the research study intervention for many reasons, including if:

- It is considered to be in your best interest
- The study treatment or procedures are found to be unsafe or ineffective
- There is any problem with following study treatments and procedures
- You are a female and become pregnant or plan to become pregnant
- Your condition worsens
- A decision is made to close the study
- Other unforeseen reasons make it necessary to stop your participation in the research study

If you are removed from the research study, the research doctor will explain to you why you were removed. In addition, you can stop participating in the research study at any time, however, the FDA requires that any information collected up to the point of your withdrawal cannot be removed from the study. If you decide to stop participating in this research study, we encourage you to talk to the research doctor and your primary doctor first.

What is a perirectal swab?

This study includes tests of changes in the bacteria and viruses that live in your gut, which will mainly be done with stool samples. If you are unable to produce a stool sample (as sometimes it is hard to tell when you will be able to have a bowel movement), we may ask to collect a perirectal swab. This swab is similar to wiping your anus with a piece of toilet tissue.

What is involved in the MAIN study intervention?

The MT will be given to you either through an existing feeding tube or a rectal retention enema. A rectal retention enema is a minor procedure in which a nurse or physician inserts a small tube into the rectum to infuse the product into the rectum. The procedure does not require sedation and will be performed in your hospital room. There are some additional preparatory and post-procedure considerations:

- **Pre-medication**: If you do not have a history of constipation and if the MT is not given through a feeding tube, you may be pre-medicated with a drug (loperamide) to help your body retain the enema for longer.
- **Microbiome Therapeutic (MT)**: You will receive 250mL (less than a 12 ounce soda can) of the MT via an existing feeding tube or rectal enema with the rate adjusted to your tolerance.
- **Observation period**: At the end of the MT administration, you will be observed by the study team for at least one hour to see how you are doing.

Since MT is not FDA approved, the study intervention will not be available to you after the study ends.

What does the study schedule look like?

Sometimes it is hard to keep track of all of the details and procedures that are part of a research study. We will describe them in this consent form and you can refer to this at any time during the research study.

Schedule of Events for Study Participants in FMT Group							
	Day 0	**Day 1, 2, 3, 4, 5, 6**	**Day 7**	**Day 14**	**Day 21**	**Day 28**	**Monthly Follow-up x 6**
Stool sample or rectal swab	✓		✓	✓	✓	✓	
Physical exam	✓						
Targeted Symptom Review	✓	✓	✓	✓	✓	✓	
Medical History Review	✓	✓	✓	✓	✓	✓	✓
Medication Review	✓	✓	✓	✓	✓	✓	✓
Environmental (room) swabbing	✓		✓	✓	✓	✓	
Urine pregnancy test	✓						
Microbiome Therapy (MT)	✓						
Quality of Life Survey	✓					✓	✓
Phone call, text message, email or bedside visit							✓

Day 0 (hospital room):

These screening tests may show that you are not eligible to participate in the research study. However, if you do meet the eligibility criteria, you can refer to this consent form for information about what to expect during and between study visits. The study team will also give you a copy of the schedule of events table from this consent form.

This visit will involve the following:

- **Medical history:** your medical record will be reviewed to collect information about your health, demographics, prior surgeries, and allergies. If you are currently taking systemic antibiotics for treatment of an infection or if you are taking preventative antibiotics, these will need to be stopped at least 2 days before your first MT.
- **Physical exam**: you will receive a modified physical exam, assessment of vital signs (blood pressure, heart rate, temperature, respiratory rate or oxygen saturation), and weight.
- **Urine Pregnancy Test:** If you are a woman of childbearing potential, you will have a pregnancy test performed. If the test is positive, your participation will be on hold until after you are no longer pregnant or breastfeeding.
- **MDRO analyses,** which includes the following tests:
    - **Stool sample or swab culture:** stool or perirectal swab sampling, which involves providing a stool sample or wiping a swab against your anus like a piece of toilet tissue. You will be informed of whether the culture results showed any MDRO growth (but not which MDROs in particular since there is no approved therapy for colonization) if you request to be notified.
    - **Stool metagenomic sequencing**: Stool metagenomic sequencing is the analysis of genetic material from the bacteria, viruses and fungi present in your stool. Samples collected from your stool will be sent for metagenomic sequencing to look at all of the types of bacteria, viruses and fungi found in your stool.

You will not be informed of these results and the results do not affect your eligibility. The samples may be stored for up to 10 years.

- **Environmental surface sampling:** environmental surface composites (e.g. bedside table, bedrail, phone; toilet seat, bathroom sink drain trap, or bedside commode as applicable; doorhandle, hand hygiene pump) will be sampled from your room for culture and metagenomic sequencing. You will not be informed of these results and the results do not affect eligibility for your study participation. The samples may be stored for up to 10 years.

- **Microbiome Therapeutic administration (MT)**
  - **Pre-medication (if no feeding tube)**: If you do not have a history of constipation, you may be pre-medicated with a drug (loperamide) to help retain the enema.
  - **Microbiome therapeutic (MT) delivery**: You will receive 250mL (less thana 12 ounce soda can) of the MT via an existing feeding tube or rectal enema with the rate adjusted to your tolerance.
  - **Observation period**: At the end of the infusion, you will be observed by the study team for at least one hour to see how you are doing.

Days 1, 2, 3, 4, 5, and 6 (hospital room):

- **Adverse event and concomitant medication review**: the study team will discuss any symptoms you might be experiencing, and any changes to your medications.

Days 7, 14, 21, 28 (hospital room):

- **Adverse event and concomitant medication review**: the study team will discuss any symptoms you might be experiencing, and any changes to your medications.
- **MDRO analyses,** which includes the following tests:
  - **Stool sample or swab culture:** stool or perirectal swab sampling, which involves providing a stool sample or wiping a swab against your anus like a piece of toilet tissue. You will be informed of whether the culture results showed any MDRO growth (but not which MDROs in particular since there is no approved therapy for colonization) if you request to be notified.
  - **Stool metagenomic sequencing**: Stool metagenomic sequencing is the analysis of genetic material from the bacteria, viruses and fungi present in your stool. Samples collected from your stool will be sent for metagenomic sequencing to look at all of the types of bacteria, viruses and fungi found in your stool. You will not be informed of these results and the results do not affect your eligibility. The samples may be stored for up to 10 years.
    Environmental surface sampling: environmental surface composites (e.g. bedside table, bedrail, phone; toilet seat, bathroom sink drain trap, or bedside commode as applicable; doorhandle, hand hygiene pump) will be sampled from your room for culture and metagenomic sequencing. You will not be informed of these results and the results do not affect eligibility for your study participation. The samples may be stored for up to 10 years.

Follow-Up Period (REDCap secure online survey via email, Text Message,Phone Call, or bedside visit):
We will follow up with you for 24 weeks after your last study visit is complete to see if you have any side effects or complications. We will do this by sending you a secure online survey via encrypted email, sending a text message,calling you on the telephone, or visiting you at the bedside once a month times 6 months.

We will attempt to contact you three times for each follow-up visit. We may also access your medical records to obtain similar information. Keeping in touch with you and checking your condition helps us understand the safety of MT.

Who owns your study data 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 still be used for this study.

What are the possible risks and discomforts?

There may be side effects from the study agent or procedures that are not known at this time. There are risks to taking part in any research study. One risk is that you may get a study agent/intervention that does not help treat your condition or may make your condition worse. Another risk is that there may be side effects.

All treatments can have side effects, which can range from mild and reversible to severe, long lasting and possibly life-threatening. There is a great deal of variability among side effects of different treatments and between individuals. In a research study, all of the risks or side effects may not be known before you start the study. **You need to tell your doctor or a member of the study team immediately if you experience any side effects.**

Everyone in the research study will be watched carefully for side effects. You will be monitored during the administration of the study agent to keep track of how you are feeling. If you experience side effects, they may go away if you take a break or after you stop receiving the study agent. Some side effects can be mild; but others can be long lasting and may never go away. Some may be life-threatening or fatal.

Since the effect of the study agent taken with other medications may not be known, it is important that you tell the research doctor about all prescription and non-prescription drugs, herbal preparations and nutritional supplements that you are taking or planning to take. There may also be some medications (such as probiotics and antibiotics) that you should avoid while on this research study and your research doctor will review this information with you.

During the research study, you will be notified of newly discovered side effects or significant findings, which may affect your health or willingness to participate. You may be asked to sign a new consent form that shows that you have been informed of new information relating to this research study.

As noted earlier in this section, there may be side effects or complications from the study procedures that have not been reported and are not known at this time. The risks that you should consider before making a decision to participate or not to participate are listed below. If any of these risks are not clear, please ask your study doctor for a clearer explanation.

- ***Risks Associated with the Investigational/Study Agent:***
  These are the risks associated with receiving MT.

  Very common:
  - Diarrhea
  - Abdominal Pain

  Common:
  - Nausea
  - Constipation
  - Flatulence (gas)
  - Abdominal distension

- Urinary tract infection

Rare:

- Pyrexia (Fever ≥ 37.8° C (100.0°F))
- Fatigue
- Chills
- Vomiting
- Hypotension
- Anorectal irritation
- Rectal bleeding

Other:

- Belching
- Colitis
- Puncture of intestine
- Disease transmission from the donor to recipient

- ***Risks Associated with Study Intervention/Procedure:***

These are the risks associated with the rectal retention enema procedure itself.

Rare but serious (Estimated less than 1% chance that this will happen):

- Bleeding
- Perforation or tears
- Severe abdominal pain
- Cardiovascular events, such as a heart attack, low blood pressure, or the heart skipping beats or beating too slow
- Death related to the procedure is an extremely rare event

- ***Risks Associated with Stool Samples:***

Uncommon:

- Discomfort, inconvenience

- ***Risks Associated with Perirectal Swabs:***

Occasional:

- Discomfort

Uncommon:

- Bleeding

- ***Reproductive Risks:***

The study agent and intervention used in this research study may affect an egg, sperm, embryo, or fetus. However, these risks are currently unknown.

While participating in this research study, if you are of reproductive potential, you should not:

- Father a baby with your own sperm

- Donate eggs or sperm
- Become pregnant in any way, including in-vitro fertilization (sometimes called "I-V-F")
- Nurse a baby

How will you prevent pregnancy?
As noted in the screening section of this consent form, you will provide information about the status of your reproductive potential on a form. You will get a copy of this form.

- **If you are not of reproductive potential:** you will indicate how you know this (e.g., surgery, age, hormonal testing, or abstinence).
- **If you are of reproductive potential:** you will agree to the use of contraceptives during heterosexual intercourse. We can provide you with counseling about preventing pregnancy.

For Reproductive Women: What happens if I become pregnant while on the study?
Pregnant women will be removed from the study. Immediately tell your study doctor if you become pregnant.

For Reproductive Men: What happens if you father a child while on the study?
Immediately tell your study doctor if you find out that you are going to be the father of a child. If this happens, it may be critical to share information regarding your participation in this research study with that person. The study sponsor may want to collect data on your partner's pregnancy. However, in order for us to share information about the pregnancy with the study sponsor is by obtaining her written informed consent and authorization. This would be done using a separate consent form.

- ***Risks Associated with Disrupting Your Gut Microbiota:***
  We are studying the bacterial diversity of the gut to understand if microbiome therapeutics can help people with disrupted gut microbiotas. It is important that you take certain steps to not alter the flora of your gut while on this study. This includes avoiding taking probiotics or inserting foreign objects into your rectum while participating on the study. This standardization will make the research study stronger because researchers will not have to worry if the microbiome therapeutic did or did not work because something else was introduced into your rectum.

  While on the study (except during the follow-up period), we ask that you avoid the following:
  - Colonoscopy
  - Enemas (rectal and vaginal)
  - Douching (rectal and vaginal)
  - Receptive anal sex
  - Other activities and treatments that require any foreign objects or substances to enter your rectum

- ***Non-Physical Risks:***
  Because of side effects or the time required for tests while you are on this research study, it may impact your schedule.

It is possible that the researchers will learn something new during the study about the risks of being in it or ways that some parts of the study are conducted. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

Will you benefit from the study?

Taking part in this research study may or may not benefit you directly. Based on scientific literature, we believe that MT might effectively reduce colonization with antibiotic resistant bacteria. Whether the MT will prevent the development of an infection due to a MDRO in your body is uncertain and something we are also asking in this study. The overgrowth of MDRO in your body may improve while you are in this study but it may not, and it may even get worse. This study may help researchers learn information that may help people in the future.

Will you be paid for your time and effort?

For each qualifying study visit/cycle, you will be compensated for **$50.00 United States Dollars (USD).** If you complete all study visits in two cycles, you may get a maximum of $**200.00 USD**.

Qualifying Study Visit	Reimbursement (USD)
Day 0 completed:	$50.00
Day 7 completed:	$25.00
Day 14 completed:	$25.00
Day 21 completed:	$25.00
Day 28 completed:	$25.00
Follow-up calls completed:	$50.00
Total maximum compensation:	**$200.00**

[A] Denotes study activities if MDRO positive on Day 7 and receiving second MT dose on Day 1

You may 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.

Is there anything you will not be compensated for?

We may use your samples and information to develop a new product or medical test to be sold. The sponsor and hospital may benefit if this happens. There are no plans to pay you if your samples are used for this purpose.

What are your other options?

Taking part in this research study is voluntary. Instead of being in this research study, you have other options which may include the following:

- Receive no therapy specific to your condition because there are no approved treatments for gut MDRO colonization.
- Take part in another research study.

If you decide not to enter this study, there is care available to you outside of this research study. You should follow up with your doctor and be monitored in case you develop an infection related to being colonized with *C. difficile,* CRE, VRE, ESBL, CRPA in your gut. If this happens, you may need to go on antibiotics. The study doctor will discuss these with you.

The FDA has not approved MT for MDRO colonization after infection, but there may be other research studies offering other MTs.

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, such as MT. 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. Please talk to the research doctor about all of your options before you decide whether you will take part in this research study.

How will your private information be protected?

Emory University will keep any research records that it creates private to the extent that this is required to do so by law. We will take measures to protect the privacy and security of all your personal information, but we cannot guarantee complete confidentiality of study data. 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.

Medical information created by this research study may become part of your hospital medical record and may be forwarded to your primary doctor. Information that does not become part of your medical record will be stored in your study file. It may also become part of an Emory University research database. The results of this research study may be published. You will not be identified in publications without your permission.

Certificate of Confidentiality

There is a Certificate of Confidentiality from the Centers for Disease Control and Prevention (CDC) 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 (data that has been stripped of all information that can identify you), including your de-identified genetic information, 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.

Your data and specimens from this study may be useful for other research being done by investigators at Emory or elsewhere. To help further science, we may provide your deidentified data and/or specimens to other researchers. If we do, we will not include any information that could identify you. If your data or specimens are labeled with your study ID, we will not allow the other investigators to link that ID to your identifiable information.

As they become available, do you want us to contact you and ask whether you want to receive your results? If so, let the study team know, and they will contact you as the results become available.

Medical Record

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

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

Emory Healthcare may create study information about you that can help with your care. For example, the results of study tests or procedures. These study results will be put in your Emory Healthcare medical record. Anyone who has access to your medical records 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. State and federal laws may not protect the research information from disclosure.

Which results will not be placed in my Medical Record?

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: sequencing and metagenetic analyses from perirectal swab sampling and cultures of your skin.

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

In Case of Injury

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

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

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

Costs

There will be no costs to you for participating in this study, other than basic expenses like transportation. You will not be charged for any of the research activities. If the study procedures result in any medical complications that would not fall under "injury" as discussed above, the cost of treatment for those complications may be charged to you or your insurance.

Withdrawal from the Study

You have the right to leave a study at any time and/or withdraw your permission for the research doctors and participating Emory entities to use or share your protected health information without penalty.

We will not be able to withdraw all the information that already has been used or shared with others to carry out related activities such as oversight, or that is needed to ensure quality of the study. To withdraw your permission, you must do so in writing by contacting the Sponsor-Investigator, [redacted], by emailing him at [redacted] or mailing him at the address :

[redacted]
Health Sciences Research Building
[redacted]

You have the right to request access to your protected health information that is used or shared during this research and that is related to your treatment or payment for your treatment, but you may access this information only after the study is completed. To request this information, please contact the Sponsor-Investigator, [redacted].

For your safety, however, you should consider the study doctor's advice about how to go off the study treatment. If you leave the study before the final planned study visit, the researchers may ask you to have some of the final steps done.

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 this study.

PHI that Will be Used/Disclosed:

The PHI that we will use or disclose for this 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 disclose your PHI for the conduct and oversight of the research study. We will use and disclose your PHI to provide you with study related treatment and for payment for such treatment. We will also use and disclose your PHI to conduct normal business operations. We may disclose your PHI to 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 disclose your PHI as described in this document. You do not have to sign this form. If you do not sign this form, you may still receive non-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 Principal Investigator and research staff will disclose your PHI to other people and groups to help conduct the study or to provide oversight for the study.
- The U.S. Centers for Disease Control and Prevention (CDC) is the funder of this study and [redacted] is the Sponsor-Investigator for 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 research team and the Sponsor may use and disclose your PHI, including disclosure to insurance carriers to administer payment for subject injury.

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; Food and Drug Administration
- Public health agencies (including the CDC)
- Research monitors and reviewerAccreditation agencies

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

Expiration of Your Authorization

Your HIPAA authorization will not expire when this study ends, because samples collected in this study and your PHI will be kept indefinitely.

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 [redacted] by email at:

[redacted]

At that point, we will not collect any more of your PHI. We may use or disclose the PHI already collected so we 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 PHI to people who are not covered by the Privacy Rules, then your PHI won't be protected by the Privacy Rules. People who do not have to follow the Privacy Rules can use or disclose your PHI to 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 to other people or organizations for purposes besides this study.

Contact Information
Contact [redacted] at [redacted]

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

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 **https://tinyurl.com/ycewgkke.**

TO BE FILLED OUT BY PARTICIPANT or LAR ONLY

Please **print** your name, **sign**, and **date** below if you agree to be in this research 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 form to keep.

Name of Participant

Signature of Participant (18 or older and able to consent) **Date** **Time**

Name of Legally Authorized Representative (LAR)

Signature of Legally Authorized Representative **Date** **Time**

Authority of Legally Authorized Representative or Relationship to Participant

TO BE FILLED OUT BY STUDY TEAM ONLY

Name of Person Conducting Informed Consent Discussion

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