Characterization Of the Intestinal Microbiome Evolution After Kidney Transplant Donation or Receipt

NCT03043339

Date: October 10, 2022

IRB00092450

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

Official Protocol Title: **C**haracterization **O**f the Intestinal **M**icrobiome **E**volution after Kidney **T**ransplant **D**onation or **R**eceipt

Short Protocol Title: COMET-DR

ClinicalTrials.gov ID: NCT03043339
Website: https://clinicaltrials.gov/ct2/show/NCT03043339

Sponsor-Investigator: [redacted] MD, MSc, Associate Professor
Department of Pathology and Laboratory Medicine, Division of Infectious Diseases
[redacted]
Phone: [redacted]

Study-Supporter: Centers for Disease Control and Prevention (CDC)
Source: Intergovernmental Personnel Agreement (IPA)

A. 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 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

We are asking you to take part in this research because we believe that you are:

1. An adult
2. Planning to undergo renal transplantation surgery by either:
    a. Donating your kidney (If this is you, we will refer to you as a "**transplant donor**.")
    b. Receiving a kidney from a living or deceased donor (If this is you, we will refer to you as a "**transplant recipient**.")

This research study is looking at the mix of organisms in the gut. The mix of organisms in your gut is called a **microbiome**. We want to try to determine how your microbiome changes in people who undergo kidney transplantation surgery. Your microbiome can help keep you healthy, but it can also make you sick if it does not work properly. The study will focus on learning about things that may change the microbiome before and after kidney transplantation surgery.

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 research study will be available on https://clinicaltrials.gov/ct2/show/NCT03043339. 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.

For purposes of this research, you will be referred to as a "participant" or "subject". It is expected that about 200 people will take part in this research study.

The Centers for Disease Control and Prevention (CDC) is supporting this study by providing funding for Emory employees to conduct the study under Intergovernmental Personnel Agreements (IPA). We anticipate that this study will take a total of 12 months or longer to complete.

If you decide to participate: please sign and date at the end of this form. We can 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.

If you decide NOT to participate: the research doctors will discuss other options with you.

B. What is the purpose of this study?

The purpose of this pilot research study is to understand how kidney transplantation surgery affects our gut. We do not have a lot of information about this type of surgery affects the microbiome. We want to learn more about these changes and how they affect the health of patients like you.

We will ask you about things you do that may affect your microbiome. These include changes in diet, illnesses, activities, and antibiotics.

We hope that what we learn will help prevent and treat multidrug resistant organisms in future patients.

Patients who have kidney transplants can have infections that are resistant to many antibiotics, often because they have been treated with many antibiotics due to having a higher risk of infections after kidney transplant.

C. What will I be asked to do?

You will be in this research study for approximately 6 months.

Screening might take 1-2 weeks before your surgery and the majority of the other study assessments will occur until 30 days after your surgery. These assessments will include dietary questionnaires and specimen collections (e.g., anal swab sampling, toilet paper collection, and/or stool collection).

You will be in the Follow-Up Period for 24 weeks after your surgery. The Follow-Up Period is only a medical chart review, so if your records are within Emory, we will be able to access the required information during this period. All of the required study assessments are considered research-related and are only being offered as part of this research study.

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 procedures are found to be unsafe or ineffective,
- There is any problem with following study treatments and procedures,
- A decision is made to close the study,
- Or for other unforeseen reasons that make it necessary to stop your participation in the research study.

Most of your assessments will either be performed in the hospital or in the transplant clinic. However, if you are not hospitalized or not scheduled for a clinic visit at the time of an assessment, we will ask you to collect your samples from home and return them to your study team. We will provide you with instructions on how to do this.

In addition to screening (which we can complete today), there are 3 additional study visits that require you to be on campus (at Emory):

1. **Post-Operative Day +2** (approximately 2 days after surgery; will occur while you are in the hospital)
2. **Post-Operative Day +15** (same day as your standard-of-care appointment with your transplant team, which is approximately 15 days after surgery)
3. **Post-Operative Day +30** (approximately 30 days after your surgery)
    a. If you are a donor, you can complete this visit at home by mailing in your specimens (we will provide you with a shipping waybill) and completing the web questionnaires at home.
    b. If you are a transplant recipient, we anticipate that this will occur during an already scheduled, standard-of-care appointment with your transplant team.

Once you are finished with your Post-Operative Day +30 Visit, you will remain in follow-up for 24 weeks. This will only involve review of your Emory medical records. If you leave Emory, we may contact you during this period to obtain your medical records.

In addition to the main study described above, you have the opportunity to opt-in for an additional, optional sub-study. This sub-study is not required to be part of the main study.

- **Optional Sub-Study (banking of samples for future research):** The purpose of this optional, sub-study is to allow researchers to have access to the leftover stool samples from the main study. Researchers at the CDC and Emory University are interested in learning about the bacterial, fungal, and viral components of our gut microbiota. If you provide consent to the optional sub-study, you will be authorizing the CDC and Emory University to store your leftover stool samples for up to 10 years. If you change your mind, you can always contact the study team to withdraw your consent for this optional, sub-study.

For more information regarding what is required at each visit, please continue to **Section F** of this document.

D. What is involved with the anal swab sampling?

We would like you to collect anal swabs at different times during the study so that we can monitor how your gut microbiome may have changed after transplant surgery. These will be collected by study staff and involves inserting a small cotton swab a short distance into your anus and rotating it in a circular motion to collect cells on the tip of the swab. Once collected, the sample will be transferred to the CDC for analyses. You will not be informed of these results.

If you are a transplant donor, you will be asked to self-collect one swab on Post-Operative Day +30 Visit. However, if you are not comfortable collecting an anal swab on your own, tell your study team. We can arrange to have you come into clinic so the study staff can perform the sampling for you.

E. What is involved in the stool collection?

For the stool specimen collection, we will provide you with a collection kit and the following instructions:

1. Put gloves on your hands.
2. Place the plastic toilet hat on your toilet bowl.
3. Defecate into the toilet hat (plastic container/receptacle).
4. Secure the toilet hat lid (as if you were putting a lid on a jar).
5. Put the toilet hat in the provided plastic bag.
6. Using the provided permanent marker, record the date and time of collection.
7. Flush the toilet and discard your gloves into the garbage.
8. Wash your hands thoroughly with soap.
9. Bring the toilet hat to your study team.

F. What is involved in the toilet paper swatch collection?

For the toilet paper collection, we will provide you with a collection kit and the following instructions:

1. Put gloves on your hands
2. Defecate into the toilet bowl as you normally do (preferred); if you are unable to have a bowel movement when your sample is due, proceed with next steps without defecating.
3. Wipe as you normally would.
4. Put the used toilet paper inside of the biohazard bag.
5. Flush the toilet and discard your gloves into the garbage.
6. Wash your hands thoroughly with soap.
7. Bring the sample bag to your study team.

You will also be provided with detailed collection and shipping instructions from your study team.

G. 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.

Visit #	1			2	(Only if your hospitalization is delayed)		3	4	Follow-Up
Study Timepoint	**Screening (Pre-Operative)**			**Post-Operative Day +2**	**Pre-Discharge Day -2**		**Post-Operative Day +15**	**Post-Operative Day +30**	**Post-Operative Week 24**
Is the study visit also a standard-of-care transplant appointment?	Yes – Surgery Consult	Yes – Surgery Pre-Op		No – Additional study visit	No – Additional study visit		Yes – Post-Op Day 15	Yes* – Post-Op Day 30	N/A – Not a visit
Meet study team and obtain copy of the informed consent form to review at home	X								You will remain in follow-up for 24 weeks for chart review. You may be contacted if your records are not at Emory.
Informed Consent		X							
Specimen Collection		X		X	O		X	X	
Verbal Screening Form (VSF)		X							
Online Short Diet Assessment (SDA)		X		X	O		X	X	
Online NHANES Dietary Screener Questionnaire (DSQ)				X					

SURGERY — DISCHARGED

- *Transplant donors will not come to clinic for Post-Operative Day +30 and instead will self-collect and mail in samples.
- The shaded in boxes with O indicate the visit assessments that are only required if your hospitalization is delayed.

Visit 1: Screening Period

This will occur at your pre-operative visit prior to your transplant surgery. After signing this consent form, the study team will review your medical record to find out if you can be in the research study. If you are eligible for the study, the following assessments will occur:

☐ Chart review: The study team will review your electronic medical record including information about your past medical and surgical history, medications and a review of your laboratory studies. If your records are stored within another facility (outside of Emory), we will reach out to the facilities to obtain this information.

☐ Specimen collection: For the specimen collection, you will be asked to provide a stool sample as well as a swab sample. For the swab, you may choose to provide an anal swab or toilet paper swatch sample.

- **Stool sample:** You will be asked to provide us with a small amount of stool. You will be provided with a toilet hat and collection kit that will include instructions on how to safely collect the stool.
  - *Microbiome analysis*: Your stool sample will be sent to the Centers for Disease Control and Prevention (CDC) for microbiome analysis. Various tests will be performed to help researchers at the CDC how transplant surgery affects microbiota diversity and resistant genes. You will not be informed of these results.

- *Microbiome Art*: As part of the microbiome analysis (noted above), researchers at the CDC will be studying antibiotic resistance genes from your stool samples. This information will be compiled by the CDC and created into microbiome art. It is important to know that our understanding of the microbiome and antibiotic resistance is changing quickly, and in many cases, we will not know for sure what the results mean for your future health. This art will be shared with you at a later time. For more information, please ask your study team. If for any reason you do not wish to receive this art, please let your study team know.

- *Optional stool sample banking*: In this study, you may participate in an optional sub-study, where your leftover stool samples will remain in storage for up to 10 years at the Centers for Disease Control and Prevention (CDC) and Emory University. You will not be informed of these results and the results do not affect your eligibility. You do not have to participate in this sub-study to be part of the main study.

- **Swab sampling:** You will have cells collected from your anus by the study team. This anal swab sampling involves inserting a cotton swab a short distance into your anus and rotating it in a circular motion to collect cells on the tip of the swab. Alternatively, you can provide a toilet paper swatch.

- **Genomic sequencing**: The cells collected from your anus will be sent for genomic sequencing to look at all of the types of bacteria found in your stool. You will not be informed of these results and the results do not affect your eligibility.

☐ Self-Administered Questionnaires: You will receive access to an electronic tablet or computer to complete the forms. The questionnaires will be completed using a HIPAA-compliant web service, called REDCap. If you would like, you can also complete these questionnaires at home at a time that is more convenient for you.

- **Verbal Screening Form (VSF)**: This is to gather basic information about your health (e.g., prescriptions, medical conditions, prior procedures, and dialysis information) as well as information that might not be readily found in your Emory health record (e.g., age of household contacts, pet exposure, and location of the majority of your health records whether at Emory or an outside facility). It should take 15-30 minutes to complete.
  - **If you have an email address, we can email you the link to complete this questionnaire online via Emory REDCap. We will have a tablet/computer for you to use if you would like.**

- **Short Diet Assessment (SDA)**: This 5-item questionnaire will ask questions regarding your diet (e.g., meats, fruits, vegetables, probiotic, and grain intake) in the last 3 days. It should take approximately 15 minutes to complete.
  - **If you have an email address, we can email you the link to complete this questionnaire online via Emory REDCap. We will have a tablet/computer for you to use if you would like.**

If you meet the eligibility criteria, you may begin the study and you will be given a study calendar with information about what to expect during and between study visits.

Visit 2: Post-Operative Day +2

This visit will occur while you are hospitalized, two days after your transplant surgery.

☐ Specimen collection:

- **Swab sampling:** You will have cells collected from your anus by the study team. This anal swab sampling involves inserting a cotton swab a short distance into your anus and rotating it in a circular motion to

collect cells on the tip of the swab. Alternatively, you can provide a toilet paper swatch.

- **Genomic sequencing**: The cells collected from your anus will be sent for genomic sequencing to look at all of the types of bacteria found in your stool. You will not be informed of these results.

☐ Self-Administered Questionnaires: You will receive access to an electronic tablet or computer to complete the forms. The questionnaires will be completed using a HIPAA-compliant web service, called REDCap. If you would like, you can also complete these questionnaires at home at a time that is more convenient for you.

- **Short Diet Assessment (SDA)**: This 5-item questionnaire will ask questions regarding your diet (e.g., meats, fruits, vegetables, probiotic, and grain intake) in the last 3 days. It should take approximately 15 minutes to complete.
  - **If you have an email address, we can email you the link to complete this questionnaire online via Emory REDCap. We will have a tablet/computer for you to use if you would like.**

- **National Health and Nutrition Examination Survey (NHANES) 2009-2010 Dietary Screener Questionnaire (DSQ):** This 30-item questionnaire will ask you about your diet in the past month regarding recent intake of various foods (e.g., cereal, milk, soda pop, fruit juice, sugar, honey, fruits, salad, potatoes, beans, rice, vegetables, salsa, cheese, pizza, meat, bread, chocolate, desserts, and popcorn). It should take you approximately 20-30 minutes to complete.
  - **If you have an email address, we can email you the link to complete this questionnaire online either via Emory REDCap or through the DSQ Web portal. We will have a tablet/computer for you to use if you would like.**

Visit: Pre-Discharge Day -2

This visit will only occur in the hospital if your planned transplant admission is extended from the planned duration of stay. If you do not provide additional, optional consent and your hospitalization is not delayed, then you will not complete this visit.

☐ Specimen collection:

- **Swab sampling:** You will have cells collected from your anus by the study team. This anal swab sampling involves inserting a cotton swab a short distance into your anus and rotating it in a circular motion to collect cells on the tip of the swab. Alternatively, you can provide a toilet paper swatch.

- **Genomic sequencing**: The cells collected from your anus will be sent for genomic sequencing to look at all of the types of bacteria found in your stool. You will not be informed of these results.

☐ Self-Administered Questionnaires: You will receive access to an electronic tablet or computer to complete the forms. The questionnaires will be completed using a HIPAA-compliant web service, called REDCap. If you would like, you can also complete these questionnaires at home at a time that is more convenient for you.

- **Short Diet Assessment (SDA)**: This 5-item questionnaire will ask questions regarding your diet (e.g., meats, fruits, vegetables, probiotic, and grain intake) in the last 3 days. It should take approximately 15 minutes to complete.
  - **If you have an email address, we can email you the link to complete this questionnaire online via Emory REDCap. We will have a tablet/computer for you to use if you would like.**

Visit 3: Post-Operative Day +15

This will occur in the transplant clinic at the same time as your scheduled, standard-of-care, post-operative visit, which is approximately 15 days after surgery.

☐ Specimen collection:

- **Swab sampling:** You will have cells collected from your anus by the study team. This anal swab sampling involves inserting a cotton swab a short distance into your anus and rotating it in a circular motion to collect cells on the tip of the swab. Alternatively, you can provide a toilet paper swatch

- **Genomic sequencing**: The cells collected from your anus will be sent for genomic sequencing to look at all of the types of bacteria found in your stool. You will not be informed of these results.

☐ Self-Administered Questionnaires: You will receive access to an electronic tablet or computer to complete the forms. The questionnaires will be completed using a HIPAA-compliant web service, called REDCap. If you would like, you can also complete these questionnaires at home at a time that is more convenient for you.

- **Short Diet Assessment (SDA)**: This 5-item questionnaire will ask questions regarding your diet (e.g., meats, fruits, vegetables, probiotic, and grain intake) in the last 3 days. It should take approximately 15 minutes to complete.
  - **If you have an email address, we can email you the link to complete this questionnaire online via Emory REDCap. We will have a tablet/computer for you to use if you would like.**

Visit 4: Post-Operative Day +30

Please note that the location of this visit depends on which cohort you are in (transplant recipient or donor). See below guidance:

- If you are a **transplant RECIPIENT**, this visit will occur in the transplant clinic at the same time as your scheduled, standard-of-care post-operative visit, which is approximately 30 days after your surgery.

- If you are a **transplant DONOR**, this visit will occur at home and you will be provided with information on how to collect and mail in your stool and anal swab samples. If you have access to Internet at home, you will complete your questionnaires online – otherwise, the study team can contact you to complete this questionnaires either via phone or have you mail in a paper questionnaire with your samples.

☐ Specimens: For the specimen collection, you will be asked to provide a stool sample as well as a swab sample. For the swab, you may choose to provide an anal swab or toilet paper swatch sample.

- **Stool Specimen Collection:** You will be asked to provide us with a small amount of stool. You will be provided with a toilet hat and collection kit that will include instructions on how to safely collect the stool.

  - *Microbiome analysis*: Your stool sample will be sent to the Centers for Disease Control and Prevention (CDC) for microbiome analysis. Various tests will be performed to help researchers at the CDC how transplant surgery affects microbiota diversity and resistant genes. You will not be informed of these results.

  - *Microbiome Art*: As part of the microbiome analysis (noted above), researchers at the CDC will be studying antibiotic resistance genes from your stool samples. This information will be compiled by the CDC and created into microbiome art. It is important to know that our understanding of the microbiome and antibiotic resistance is changing quickly, and in many cases, we will not know for sure what the results mean for your future health. This art will be shared with you at a later time.

For more information, please ask your study team. If for any reason you do not wish to receive this art, please let your study team know.

- *Optional stool sample banking*: In this study, you may participate in an optional sub-study, where your leftover stool samples will remain in storage for up to 10 years at the Centers for Disease Control and Prevention (CDC) and Emory University. You will not be informed of these results and the results do not affect your eligibility. You do not have to participate in this sub-study to be part of the main study.

- **Swab Sampling:** You will have cells collected from your anus by the study team (if you are a transplant recipient) or will be self-collected (if you are a transplant donor). This anal swab sampling involves inserting a cotton swab a short distance into your anus and rotating it in a circular motion to collect cells on the tip of the swab. Alternatively, you can provide a toilet paper swatch.

- **Genomic sequencing**: The cells collected from your anus will be sent for genomic sequencing to look at all of the types of bacteria found in your stool. You will not be informed of these results.

☐ Self-Administered Questionnaires: You will receive access to an electronic tablet or computer to complete the forms. The questionnaires will be completed using a HIPAA-compliant web service, called REDCap. If you would like, you can also complete these questionnaires at home at a time that is more convenient for you.

- **Short Diet Assessment (SDA)**: This 5-item questionnaire will ask questions regarding your diet (e.g., meats, fruits, vegetables, probiotic, and grain intake) in the last 3 days. It should take approximately 15 minutes to complete.
  - **If you have an email address, we can email you the link to complete this questionnaire online via Emory REDCap. We will have a tablet/computer for you to use if you would like.**

H. 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.

I. What are the possible risks and discomforts?

There are risks to taking part in any research study. Risks associated with this study are expected to be minimal and associated primarily with anal swab sampling. If any of these risks are not clear, please ask your study doctor for a clearer explanation. The risks associated with participating in this study are listed below:

There are **no risks** associated with:

- **Stool Donation*:*** There are no risks associated with donating your stool.
- **Toilet Paper Swatch Sampling:** There are no risks associated with donating your used toilet paper swatch.

The **most common risks and discomforts** expected in this study are:

- **Discomfort in Anal Swab Sampling:** We will do everything we can to make the anal swab sampling process as comfortable as possible, but it may still be uncomfortable having a foreign object in your anus.

- **Confidentiality**: The main risk of being in the study is that information collected may be accidentally revealed to someone not connected with the study. However, whenever possible, you will be referred to by a study identification number rather than your name. All of the study materials are locked and protected, so

it is unlikely anyone outside of the study would ever see your information.

- **Discomfort in Providing Personal Information**: We are asking you to share with us some personal and confidential information, and you may feel uncomfortable talking about some of the topics and providing a stool specimen. You do not have to answer any question, provide stool specimens, or take part in the interviews if you don't want to do so. You do not have to give us any reason for not responding to any question.

Some **uncommon but possible** risk include:

- **Bleeding from anal swab sampling:** We will do everything we can to make the anal swab sampling process as comfortable as possible, but it is possible to experience bleeding from the procedure.

- **Perforation or tears of the anus/rectum from anal swab sampling:** We will do everything we can to make the anal swab sampling process as comfortable as possible, but it is possible to experience tearing or perforation from the procedure.

A **rare but possible** risk includes:

- **Psychological Distress**: We plan to provide you with microbiome art. This art will include information regarding antibiotic resistant genes found in your gut microbiome before and after surgery. It is important to know that our understanding of the microbiome and antibiotic resistance is changing quickly, and in many cases, we will not know for sure what the results mean for your future health.

Additionally, there may be side effects from the study procedures that are not known at this time. It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, we 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.

J. Will I benefit directly from the study?

Taking part in this research study may or may not benefit you directly. The intent of this study is to learn more about how the gut microbiome changes after renal transplant surgery. This study may help researchers learn information that may help people in the future.

Your own microbiome will be reported to you for your informational purposes only. We do not know of any uses for this information. Your participation will help us learn more about the how the microbiome changes when patients undergo renal transplantation surgery. This information may help us prevent and treat surgery-related intestinal conditions in the future.

K. Will I be compensated for my time, effort, and participation on the study?

You may be reimbursed for your time, effort, and participant for completing each qualifying study visit. Study staff will review the reimbursement plan and any requirements for reimbursement with you. If you do not finish the study, we will compensate you for the visits you have completed.

- **How much will I be compensated?**
  For completing the assessments for each of the below qualifying study visits, you will be compensated with Microbiome Art and a gift card valued at **$25.00 United States Dollars (USD).** If you complete all study visits, you may get a maximum of **$100.00 USD** in gift cards and Pre- and Post-Surgery Microbiome Art as compensation for your time, effort, and study participation.

Qualifying Study Visit	Completion of the Qualifying Study Assessments	Reimbursement	
		Gift Card Amount (in USD)	**Microbiome Art**
Visit 1: Screening	Stool, Anal Swab, and Questionnaires	$25.00	N/A
Visit 2: Post-Operative Day +2	Anal Swab and Questionnaires	$25.00	N/A
Visit 3: Post-Operative Day +15	Anal Swab and Questionnaires	$25.00	N/A
Visit 4: Post-Operative Day +30	Stool, Anal Swab, and Questionnaires	$25.00	Pre- and Post-Surgery Results
Total maximum compensation:		**$100.00**	**Pre- and Post-Surgery Microbiome Art**

In order to be reimbursed, 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 that I 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. Additionally, you will not be compensated for participating in the optional sub-study to bank leftover stool.

L. What is Microbiome Art?

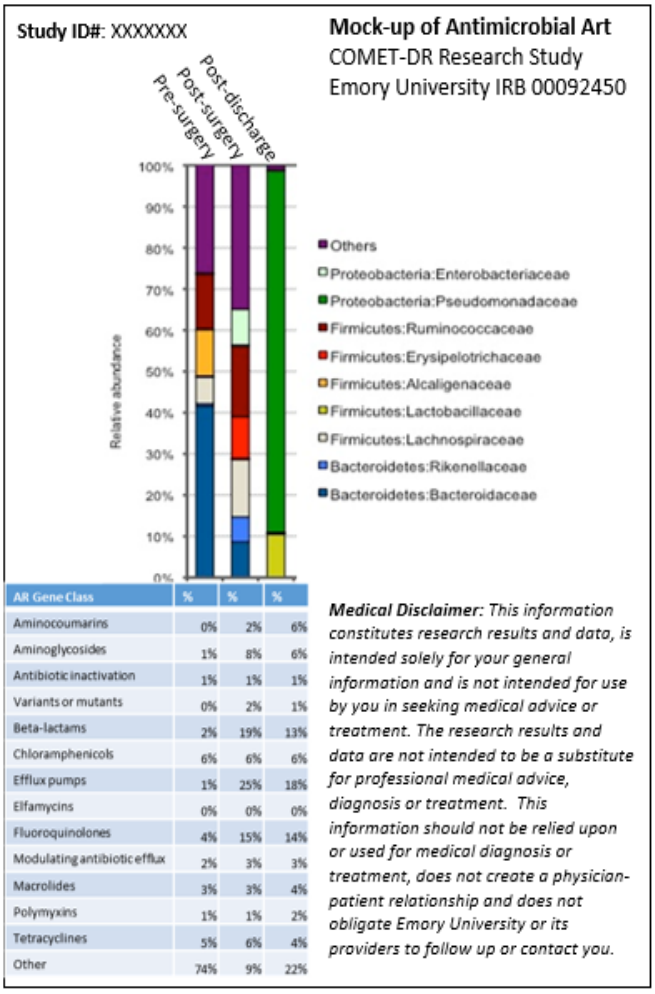
The Microbiome Art is an analysis report will be generated by the Centers for Disease Control and Prevention (CDC) using data that a CDC laboratory obtains from analyzing your stool specimens. Data from your stool samples will be created into art so that you can see the microbiome changes from the Pre-Operative and Post-Operative timepoints.

We anticipate providing you with this art around the time of the Study Completion date or later, which may be in two or more years. Please note that the content, design, and information will be different than the prototype. The CDC team who will be generating this art may need to add or remove some elements before releasing it to you. This will not be known until the data from every subject's stool is collected and analyzed.

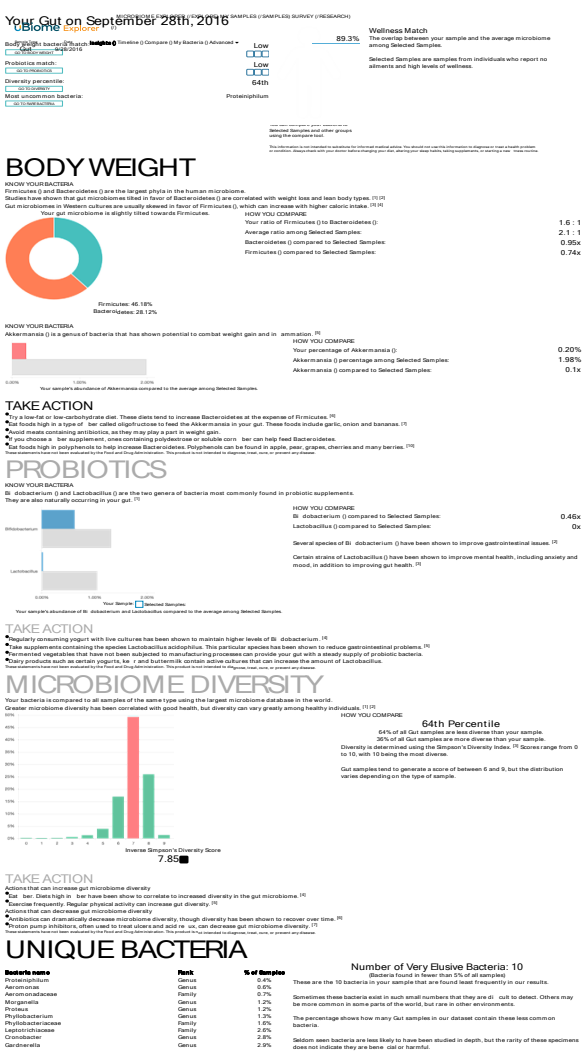
Please review the following medical disclaimer, which will be included on the art itself:

> *"**Medical Disclaimer**: This information constitutes research results and data, is intended solely for your general information and is not intended for use by you in seeking medical advice or treatment. The research results and data are not intended to be a substitute for professional medical advice, diagnosis or treatment. This information should not be relied upon or used for medical diagnosis or treatment, does not create a physician-patient relationship and does not obligate Emory University or its providers to follow up or contact you."*

The following figure is a prototype or "mock-up" of the Microbiome Art:



AR Gene Class	%	%	%
Aminocoumarins	0%	2%	6%
Aminoglycosides	1%	8%	6%
Antibiotic inactivation	1%	1%	1%
Variants or mutants	0%	2%	1%
Beta-lactams	2%	19%	13%
Chloramphenicols	6%	6%	6%
Efflux pumps	1%	25%	18%
Elfamycins	0%	0%	0%
Fluoroquinolones	4%	15%	14%
Modulating antibiotic efflux	2%	3%	3%
Macrolides	3%	3%	4%
Polymyxins	1%	1%	2%
Tetracyclines	5%	6%	4%
Other	74%	9%	22%



M. What are my other options?

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

- Do no participate in any research study
- Take part in another research study

You may wish to research other study options at websites like ClinicalTrials.gov and ResearchMatch.org.

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

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.

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.

Certain offices and people other than the researchers may look at study records, for example, offices at Emory as well as offices at the Centers for Disease Control and Prevention (CDC) that are part of the Human Research Participant Protection Program and those that are involved in study administration. These include the IRB, Compliance Offices, and the Office for Clinical Research. Government agencies may also look at your study records.

O. Storing and Sharing Information

Specimen sequencing will be performed in the Centers for Disease Control and Prevention (CDC) laboratories and uBiome laboratory. Stool specimens and anal swabs will be transferred from Emory University to CDC laboratories under a Material Transfer Agreement. The original source documentation will be housed at Emory in a secure location and destroyed per institutional guidelines. De-identified copies of records will be transferred securely to CDC for entry into a secure database. Stool and anal swab results will be combined with the questionnaire and clinical data, which will be analyzed by CDC epidemiologists and laboratory personnel, as well as laboratory personnel at uBiome, where the anal swabs will be analyzed. uBiome is a microbial genomics company that will only receive de-identified clinical metadata and anal swabs for analysis. Only the researchers at Emory University will know which specimens and results are linked to you.

Your samples, genomic data and health information will be stored and shared via publication with other researchers. The samples and information may be made available to other researchers in the field to develop new scientific methods, or the study of where different groups of people may have come from.

P. Medical/Research 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:

  - Specimen collections (stool sample or anal swab)
  - Sequencing and genomic analyses from anal swab sampling

- Questionnaire responses

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.

Q. Incidental Findings

It is possible that we will discover something of clinical importance that is related to your microbiome but that is unrelated to the purpose of this study. If we believe that the information is of urgent medical importance, we will share this information with you. However, you should not assume that if you are not contacted, that you do not have any microbiome variants that might be related to a particular condition.

Additionally, the meaning of the microbiome results are uncertain. It is important to know that our understanding of the gut microbiome and microbiome in general is changing quickly. Thus, we will not know for sure what the results mean for your future health.

R. Costs

There are no costs, research or standard of care related, associated with the study. Therefore, you will not be charged for any of the research activities, including:

- Interview / questionnaire administration or data analysis
- Stool specimen collection and anal swab sampling, testing, or analysis

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, the cost of treatment for those complications may be charged to you or your insurance.

You will not be charged for any of the following research activities:

- **Physical examination** if this is above and beyond your usual visit schedule. However, if you were already scheduled for a physical examination for regular medical care when you are due for your study visit, the study sponsor will not pay for this visit because it is considered part of your regular medical care.
- **Anal swab sampling and testing**

S. 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.

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 Principal Investigator, Dr. [redacted].

T. Privacy of Protected Health Information

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 and if you choose to participate in the optional sub-study.

Main Study

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

- Existing medical information about you including your:
  - Medical and surgical history
  - Present/past medications
  - Results of exams
  - Results of procedures and tests
- New health information created from study-related assessments including:
  - Procedures
  - Visits
  - Questionnaires
  - Laboratory and culture test results

Purposes for Which Your PHI Will be Used/Disclosed:
The main reasons include the following:

- To conduct and oversight of the research study;
- To ensure the research meets legal, institutional, and accreditation requirements;
- To conduct public health activities (including reporting of adverse events or situations where you or others may be at risk or harm); and
- To provide the study sponsor with information arising from an adverse event for the purpose of this or other related research
- Other reasons may include
  - For study-related treatment, payment, or health care operations/normal business operations. For example, some medical information produced by this research study may become part of your hospital medical record because the information may be necessary for your medical care
  - To 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. We will also comply with legal requests or orders that require us to disclose your PHI. These include subpoenas or court orders.

Authorization to Use PHI is Required to Participate:
By signing this form, you give us permission to use and share your PHI as described in this document. You do not have to sign this form to authorize the use and disclosure of your PHI. If you do not sign this form, then you may not participate in the research study or receive research-related treatment. 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 Sponsor-Investigator and the research staff will use and disclose your PHI to conduct the study and give you study related treatment.
- Emory may use and disclose your PHI to get payment for study related treatment and to run normal business operations.
- The Sponsor-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.
- [redacted] is also 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 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.
    - Research monitors and reviewer.
    - Accreditation agencies.
- Sometimes a Sponsor-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 Study/Storage of Data/Specimens for Future Research:

PHI That Will be Used/Disclosed for Optional Study:
The PHI that we will use and/or disclose (share) for the optional research sub-study includes the same PHI as what has been listed above for the main study.

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

Authorization for This Use of PHI is Required to Participate in Optional 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 study, then you may not participate in the optional research 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 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 research study/storage of PHI for future research. In addition, the following people and groups may also use and disclose your PHI for the Optional Study:

- Future researchers

Expiration of Your Authorization
There is no scheduled date at which your protected health information that is being used or shared for this research will be destroyed, because research is an ongoing process. However, we expect that 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 [redacted], MD, MSc at: [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 main 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.

U. Contact Information

Contact Dr. [redacted] at [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 agent/intervention, or
- if you have questions, concerns or complaints about the research

Contact the Emory Institutional Review Board at [redacted] or [redacted] or [redacted]:

- 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.

V. Consent and Authorization

You are being asked to participate in an **optional sub-study.** You do not have to participate in a sub-study to be part of the main study. Your participation in the optional sub-study is voluntary, and you will not be penalized or lose any benefits if you refuse to participate or decide to stop. Please take your time to make your decision and discuss it with others and your primary care physician. Please initial below if you opt to participate in and authorize use and disclosure of your PHI in the optional study previously described.

A. **Optional, Banking of Leftover Stool for Future Research Use: At Screening and Post-Op Day +30**, researchers will use your leftover stool samples for future, exploratory analyses to study the bacterial, fungal, and/or viral microbiome. These samples will not be stored unless you provide informed consent to this optional part of the study. The samples will remain in storage for up to 10 years at the CDC and Emory University.

Stool Sub-Study - Check one: ☐ Yes **or** ☐ No **Initials**: _____

B. **Microbiome Art:** As part of the compensation for your time and effort please initial if you would like to receive these results once available:

Microbiome Art - Check one: ☐ Yes **or** ☐ No **Initials**: _____

TO BE FILLED OUT BY PARTICIPANT ONLY:

Please **print** your name, **sign**, and **date** below if you agree to be in the main 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.

_____
Printed Name of Participant

_____ _____ _____:_____ ☐AM ☐PM
Signature of Participant **Date** **Time** (please check)

TO BE FILLED OUT BY STUDY TEAM ONLY:

☐ A copy of this signed consent form will be given to the participant

_____
Printed Name of Person Obtaining Consent

_____ _____ _____:_____ ☐AM ☐PM
Signature of Person Obtaining Consent **Date** **Time** (please check)