University of Wisconsin-Madison
Consent to Participate in Research
and
Authorization to Use Protected Health Information for Research

Study Title: Fecal Microbiota Transplantation (FMT) for *C. difficile* Infection (CDI) in Solid Organ Transplant Recipients (RECOVER)

Lead Researcher: Nasia Safdar, MD, PhD (608-263-1545)

Where Lead Researcher works: University of Wisconsin School of Medicine and Public Health

Invitation

We invite you to take part in a research study about fecal microbiota transplant (FMT) for the treatment of *Clostridioides difficile* infection (CDI) in transplant recipients. We are inviting you because you are a transplant recipient and have had at least two episodes of *C. diff* infection, and are currently being treated for a CDI.

The purpose of this consent and authorization form is to give you the information you need to decide whether to be in the study. It also explains how health information will be used for this study and for other research in the future and requests your authorization (permission) to use your health information. Ask questions about anything in this form that is not clear. If you want to talk to your family and friends before making your decision, you can. Once we have answered all your questions, you can decide if you want to be in the study. This process is called “informed consent.”

Why are researchers doing this study?

The purpose of this research study is to determine the effect of fecal microbiota transplantation as treatment of recurrent (repeating) *Clostridioides difficile* infection (CDI) in organ transplant recipients. Fecal microbiota transplantation has been found to reduce *C. diff* infection recurrence dramatically in non-transplant patients but has not been studied in organ transplant recipients. The results of this study will also advance our knowledge of the role of fecal microbiota transplantation in organ transplant recipients for other multidrug-resistant organisms.

Fecal microbiota transplant (FMT) is a procedure in which fecal matter, or stool, is collected from a person (stool donor), filtered and frozen with a preservative or another

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solution, freeze dried and placed into a capsule, then administered as encapsulated fecal microbiota. Stool donors are tested before donated stool can be given to another person.

The goal of fecal transplant is to replace good bacteria into the colon that has been killed or suppressed, causing bad bacteria, specifically *Clostridioides difficile*.

The use of encapsulated fecal microbiota is investigational, which means the Food and Drug Administration (FDA) have not yet approved it for use in the United States. Therefore, right now it is only available to subjects taking part in a research study, and for patients who have not received relief with standard treatment.

This study is being done at the University of Wisconsin-Madison (UW-Madison) and other sites around the U.S. A total of about 158 people will participate in this study. About 30 participants will take part in the study here at the UW-Madison.

The National Institute of Allergy and Infectious Diseases (NIAID) provides funding for this study.

What will happen in this study?

If you decide to participate in this research study, the researchers will ask you to complete 7 study visits over approximately 30 weeks.

If you are eligible, you will be assigned to one of two groups, the encapsulated fecal microbiota group or the vancomycin group. You have an equal chance (50/50) of receiving encapsulated fecal microbiota or vancomycin. A method called randomization (selected by chance) will determine which group you will be in.

Below is a description of the two randomized groups:

<u>Group 1: Active encapsulated fecal microbiota/placebo</u>
If you are randomized to this group, you will receive active encapsulated fecal microbiota capsules plus you will take oral placebo capsules (inactive medication) that look identical to active oral vancomycin.

<u>Group 2: Active vancomycin/encapsulated fecal microbiota matching placebo</u>
If you are randomized to this group, you will receive active oral vancomycin capsules plus encapsulated fecal microbiota matching placebo capsules (inactive medication) that are identical to the encapsulated fecal microbiota except they contain only an inactive substance normally used as a filler.

This type of study design is called “double dummy” and it is used to make certain that neither you nor the study team know which active group you are assigned to, and therefore everyone remains unbiased.

Your study doctor can find out which group you are in, in the event of an emergency.

Study Visits and Procedures

The following information related to your health will be collected from your medical record at each study visit: rejection episodes, maintenance immunosuppression, nutritional status, bowel habits, organ function assessment, metabolic parameters (weight, blood sugar, cholesterol, triglycerides), infections, hospitalizations, emergency department visits, gastric acid suppression, antibiotic use, probiotic use, FMT treatments, concomitant medications, and information related to safety outcomes.

Visit 1 (Baseline) will take approximately 1-2 hours and will be completed in person. The following procedures will occur:

- The study staff will explain the study in detail and answer all of your questions. If you agree to participate, you will sign this informed consent document.

- We will record your demographics and contact information.

- We will review your medical history and medications you are currently taking.

- The study doctor will perform a brief physical examination including height, weight, and vital signs (blood pressure, heart rate, respiratory rate, and temperature).

- If you are a female of childbearing potential, we will perform a pregnancy test. You will be informed of the test results. The result from this pregnancy test will not be entered into your medical records. Pregnant women will be excluded from this study.

- If you are a female of childbearing potential in a sexual relationship with a man, you must agree to use an acceptable method of birth control for 4 weeks after completing the study medication. Acceptable methods of birth control include, but are not limited to: barrier, such as a condom, with spermicidal foam or jelly, intrauterine device, hormonal contraception (started at least 30 days prior to study enrollment), and intercourse with men who have had a vasectomy.

- Males must agree to avoid impregnation of women during and for 4 weeks after completing study treatment by using an acceptable method of birth control. Acceptable methods are described above.

- You may have your blood drawn, if necessary, to test for antibodies to Cytomegalovirus (CMV) and Epstein-Barr Virus (EBV). These tests must be positive for you to participate in this study.

- You will be asked to complete several questionnaires.

- You will be asked to provide a stool sample 24 hours before your next visit. You will have the option to ship your stool sample to the study team ahead of time or bring it to your visit. To obtain the sample, you will be given a stool collection kit/hat to collect the stool sample at home. If you are unable to provide a stool sample prior to Visit 2, study staff may collect a perirectal swab.

- You must agree to not take the following medications during the study, unless they are given because of a CDI recurrence: fidaxomicin, metronidazole, nitazoxanide, rifampin, rifaximin, antidiarrheal medications (loperamide, bismuth daysubsalicylate, atropine/diphenoxylate). You should continue to take any transplant-related and other prescribed medications.

- You must agree to not take any non-dietary probiotics (supplements, prescriptions, and non-prescriptions) for the duration of the study. Dietary probiotics, such as yogurt, may be consumed.

- If you are eligible to continue in the study, we will schedule Visit 2. Visit 2 may occur on the same day as Visit 1.

- You will be instructed to stop your prescribed *C. difficile* treatment for at least 48 hours prior to being randomized to study treatment at Visit 2.

Visit 2 (Randomization) will take approximately 1-2 hours and will be completed in person. The following procedures will occur:

- When you arrive at the clinic, we will confirm you stopped taking your prescribed *C. difficile* treatment for at least 48 hours prior to the administration of the study medication.

- We will review any changes to your medications and your health since your last visit.

- If you are a female of childbearing potential, we will perform another pregnancy test. You will be informed of the test results.

- You will have blood drawn for research purposes.

- You will return the stool sample (if not shipped back ahead of visit). If you are unable to provide a stool sample, study staff will collect a perirectal swab.

- Before being given your study medication, you will be asked to swallow one sample capsule containing no medicine to ensure that you are able to swallow capsules without any complications. If there are no complications, you will be given the study medication.

- The study doctor and staff will confirm you are eligible to continue in the study and, if so, you will be randomized to the encapsulated fecal microbiota group or oral vancomycin group.

- You will take the study medication (encapsulated fecal microbiota or matching placebo) at the clinical research unit. You will be asked to take these capsules in clinic in the presence of study staff. You will be asked to remain in clinic for 30 minutes after taking study medication for observation.

- We will provide you with the oral study medication (vancomycin or placebo). You will already have stopped taking your previously prescribed treatment for your *C. difficile* infection and we will have you start taking the oral study medication every 6 hours for a total of 10 days, including the treatment for your *C. difficile* infection that you took before the FMT treatment. Then you will take the study medication every 12 hours for 7 days, followed by 1 time per day for 7 days, and then 1 time every 3 days for 14 days.

- You will be asked to complete a medication diary for the duration of treatment with the study medication, and will be asked to return this dairy at Visit 4.

- You will be asked to provide a stool sample 24 hours before your next visit (which can either be brought to your visit or shipped ahead of time in the shipping materials provided.

- You will be asked to complete a specific stool diary, for the 7 days post FMT, that in addition to recording every bowel movement, you will also be asked to record if you experience any of the following symptoms: fever, vomiting, abdominal pain, bloating, flatulence, diarrhea, and constipation (for the 7 days post FMT). You will be asked to return this completed diary at Visit 3.

- We will give you another stool diary to complete after the 7 days post FMT diary, and instruction on how to use it. You will be asked to complete this daily stool diary for the duration of the study.

FMT Treatment Follow-up Phone Call on Day 1 (to Day 3)

- A study staff member will call you to review any changes to your medications and your health since your last visit.

- They will remind you to complete the stool and medication diaries and remind you to take the study medication as directed.

- You will also be reminded to collect a stool sample within 24 hours of your next visit.

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Visit 3 (Day 31 to Day 38) will take approximately one hour and will be completed in person. The following procedures will occur:

- The study doctor will perform a brief physical examination including height, weight, and vital signs (blood pressure, heart rate, respiratory rate, and temperature).
- We will review any changes to your medications and your health since your last visit.
- You will return the 7 day post FMT stool diary and any additional stool dairies (if applicable) to study staff.
- You will have blood drawn for research and safety purposes.
- We will ask you to complete a brief questionnaire.
- If you have finished taking the study medication, you will return the study medication with any unused capsules and medication diaries to study staff. If you have not finished, you will continue taking the study medication and filling out the medication diary.
- You will be asked to provide a stool sample 24 hours before your next visit and continue filling out the daily stool diary in the same manner as discussed above.

Visit 4 (Week 9) will take approximately one hour. This visit may be completed by phone call or an in-person clinic visit. This is the start of the safety follow-up portion of the study. The following procedures will occur:

- We will review any changes to your medications and your health since your last visit.
- You will return the oral study medication with any unused capsules, a stool sample, and daily stool and medication diaries to study staff. These materials may be shipped if visit is completed via telephone.
- You will be asked to provide a stool sample 24 hours before your next visit and to continue filling out the daily stool diary.

Visits 5 (Week 13) and 6 (Week 17) are identical and will take approximately 30-60 minutes. These visits may be completed by phone call instead of a clinic visit if you are willing to ship your stool sample to the study team. Although an in-person visit is preferred. The following procedures will occur:

- We will review any changes to your medications and your health since your last visit.

- You will return a stool sample (if not shipped back ahead of visit) and completed daily stool diaries to study staff.

- You will be asked to provide a stool sample 24 hours before your next visit and to continue filling out the daily stool diary.

Visit 7 (Week 29) will take approximately one hour. This visit can be completed in person or via telephone, however an in-person visit is preferred. This is the final study visit. The following procedures will occur:

- We will review any changes to your medications and your health since your last visit.

- You will return a stool sample (if not shipped ahead of visit) and completed daily stool diaries to study staff.

- You will have blood drawn for research purposes (if visit is completed in person).

- We will ask you to complete a brief questionnaire.

Unscheduled Visit

If we suspect you have a CDI recurrence after receiving the study medication, we may ask you to complete an additional visit. If a CDI recurrence is confirmed, study procedures may stop and you would receive treatment for your CDI through your regular healthcare team. If you are withdrawn from the study, you will also complete the Early Termination Visit at this time. At the Unscheduled Visit, the following procedures will occur:

- We will review any changes to your medications and your health since your last visit, including additional information about your suspected CDI recurrence.

- You will be asked to collect and return a stool sample and your daily stool diaries to study staff.

Early Termination Visit

You may withdraw from the study or discontinue study treatment at any time. If you decide to end your participation, the research team may ask you to complete one final visit to ensure your safety. At the Early Termination Visit, the following procedures will occur:

- We will review any changes to your medications and your health since your last visit.

- You will be asked to return a stool sample and your daily stool diaries to study staff.

- You will be asked to return any unused study medication and medication diaries.

- You will have a blood test.

- We will ask you to complete a brief questionnaire.

Weekly Phone Calls
A study team member will call you weekly during the follow-up period. We will ask you about any changes to your medications and health since the last contact. We will remind you to continue filling out the daily stool and medication diary and answer any questions you have about the study. With your permission, we can leave a message if you are unavailable when we call.

How will we use your protected health information (PHI)?

Protected health information, also called PHI, is information about your physical or mental health that includes your name or other information that can identify you, like your date of birth or medical record number. To do this study, we will use the following kinds of PHI:

- Results of tests or procedures done as part of the study
- Things you tell the researchers about your health
- Information currently in your medical records as well as information added to your medical records during the course of this study. This information could include your medical history, transplant details, lab test results, and medical imaging. We will get this information from your health care providers.

How long will I be in this study?

If you decide to participate in this research study, your participation will last approximately 30 weeks. The baseline/screening period is 1-6 days. If you are eligible to be randomized the treatment period is 31-34 days. The follow-up period is about 24 weeks.

The researchers may take you out of the study, even if you want to continue, if

- your health changes and the study is no longer in your best interest
- you do not follow the study rules or no longer meet the requirements to be in the study
- the study is stopped by the sponsor or researchers

How is being in this study different from my regular health care?

- Solid organ transplant recipients are usually prescribed vancomycin to treat *Clostridioides difficile* infection and prevent recurrence. In this study, some people will get this standard treatment, and others will get encapsulated fecal microbiota instead.

- If you take part in this study, the main difference between your regular care and the study is there is a chance you may receive encapsulated fecal microbiota instead of vancomycin to treat a *C. difficile* infection.
- This study is not part of your health care.

Do I have to be in the study? What if I say "yes" now and change my mind later?

No, you do not have to be in this study. Taking part in research is voluntary. This means that you decide if you want to be in the study. If you decide now to take part, you can choose to leave the study at any time.

If you decide to be in the study, the researchers will tell you about new information or changes in the study that may affect your willingness to continue in the study.

Let the researchers know if you choose to leave the study. We will ask you to come in for a final study visit to check your health.

If you decide not to take part in the study, or if you choose to leave the study, your choice will not affect any treatment relationship you have with healthcare providers at UW-Madison, UW Health or any affiliated organizations, or any services you receive from them. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

Your authorization for researchers to use your protected health information (PHI) does not have an end date. However:

- You can choose to take back your authorization for researchers to use your health information. You can do this at any time before or during your participation in the research.
- If you take back your authorization, information that was already collected may still be used and shared with others, but the researchers will no longer be able to collect NEW information about you.
- If you take back your authorization, you will not be able to take part in the research study.
- To take back your authorization, you will need to tell the researchers by writing to the Lead Researcher at:

Nasia Safdar, MD, PhD
Medical Foundation Centennial Building
5th Floor
1685 Highland Ave
Madison, WI 53705

What are my other choices if I do not take part in this study?

You do not have to be in this research study to get treatment for your *C. diff* infection. If you decide not take part in the study, you have other choices.

For example:

- You may choose to get the standard care described above for CDI.
- You may choose to take part in a different study, if one is available.

Will being in this study help me in any way?

Being in this study may decrease the rate of recurrence of *C. difficile* infection. If you are in the group that gets encapsulated fecal microbiota, this may work better than the standard treatment for your condition, but we cannot promise this will happen. The study treatment might not work at all, or it may have side effects. If you are in the group that gets standard care (oral vancomycin), we do not expect you to get any additional health benefit from being in the study. Your treatment will be the same as you would get outside of this study.

This study is not a substitute for your regular medical care. You should continue to see your regular medical providers.

What are the risks?

The anticipated risks in this study are mainly related to the encapsulated fecal microbiota and oral vancomycin.

Encapsulated Fecal Microbiota

The most common known risks include:

- Abdominal discomfort (e.g., nausea, bloating, cramping, diarrhea)

Very rare side effects include:

- Gastrointestinal issues: Abdominal pain, appendicitis, peritonitis, IBD flare and diverticulitis
- Allergy/Anaphylaxis: Reaction to antigens in the donor stool.
- Autoimmune issues: Rheumatoid arthritis, Sjogren‘s syndrome, peripheral neuropathy and Idiopathic thrombocytopenic purpura.
- Energy metabolism dysregulation
- Cancer
- Neurological disease and psychiatric disorders

- Infection: Although the fecal material has been screened for bacteria, viruses, fungi and parasites there is a risk of transmission of known and unknown infectious organisms contained in the donor stool. Post-FMT bacteremia (e.g. *E. coli*), sepsis and fatal events may rarely occur.

    - A potential risk is the transmission of antibiotic-resistant bacteria. These are bacteria that are resistant to many antibiotics. These bacteria could be transmitted through FMT. This could lead to the transmission of microbes (germs) that have been known to cause difficult to treat infections resistant to antibiotics that have been known to lead to serious infection or death.

    - It is possible that healthy, asymptomatic stool donors may potentially shed two specific viruses called BK virus and CMV in the stool. To prevent transmission of CMV, we use only donors who have tested negative for CMV as a way to reduce the risk of CMV transmission. For BK, we test the donor urine to evaluate for BK virus shedding in the urine and if that test was positive, we would not use that donor specimen for FMT. It is important to recognize that tests for CMV and BK have limitations and no test can guarantee 100% accuracy. However, the actions described above can reduce the risk to very low.

- A potential risk of FMT is the transmission of SARS-CoV-2, a novel coronavirus that causes the disease COVID-19. Infection with SARS-CoV-2 could be transmitted through stool and could cause serious infection or death. It is possible for healthy, asymptomatic stool donors to potentially be infected with SARS-CoV-2.

    - The donor screening protocol for prepared FMT materials includes the following procedures to reduce the risk of transmission of SARS-CoV-2:

        - All donors have been immunized against COVID-19

        - Daily diary of symptoms, temperature, and potential COVID-19 contacts starting at least 28 days prior to donation and continuing at least through 14 days following donation.

        - Testing for SARS-CoV-2 is done every 14 days starting 14 days before donation and continuing through at least 14 days following donation.

    - Though precautions have been taken to lessen the risk of SARS-CoV-2 transmission via FMT, the scientific community is still learning about SARS-CoV-2 and COVID-19, and there may be additional risks that are unknown at this time.

It is unknown if FMT will impact the risk of organ rejection, organ function, malignancy, hospitalizations, and emergency department visits.

To minimize the risks of receiving a transplant, all donors in this study will be thoroughly screened by the study doctor before they are accepted as donors. After they are accepted they will continue to be screened on an ongoing basis. Importantly, fecal microbiota is very complex biological material. We acknowledge that our tests are not perfect and can miss important information about individual or groups of microbes present in the preparation.

Additionally, it is unknown if FMT will have significant effects on pregnancy outcomes; therefore women of childbearing potential in sexual relationships with men must use an acceptable method of contraception from 30 days prior to enrollment until 4 weeks after completing study treatment. Males must agree to avoid impregnation of women during and for four weeks after completing study treatment through use of an acceptable method of contraception.

Like any capsule or tablet, there is a rare risk of aspiration or inhalation of a substance into the lung, which may be life threatening. Subjects with swallowing troubles are excluded and a safety capsule will be given ahead of time to check if there are any issues.

Oral Vancomycin
This antibiotic is the standard of care treatment for *C. diff* infection. There are still risks associated with this treatment.

Common side effects include the following:
- Nausea and stomach pain
- Low potassium levels in the blood

Less common side effects include:
- Swelling in the arms and legs
- Tiredness
- Fever
- Headache
- Diarrhea
- Gas
- Vomiting
- Urinary tract infection
- Back pain

Rare but serious side effects include:
- Kidney failure
- Decrease in platelets
- Hearing problems

- Blood vessel inflammation
- Increased risk developing antibiotic resistance

Placebo Capsules
The placebo agent used in this study is composed of inactive substance that is normally used as a filler in the formulation of tablets and capsules. Being an inactive substance, the risk of side effects is virtually none. There are no obvious foreseeable risks associated with the placebo capsules.

Stool Sampling
There are no risks associated with stool collection.

Blood Draw
Blood draw complications are rare, but include fainting, dizziness, infection, and bruising or swelling at the puncture site.

Reproductive Risks
The study medication may harm a fetus or breastfeeding baby. If you are pregnant or breastfeeding, you cannot take part in this study. If you are able to become pregnant, you must have a pregnancy test before you begin the study. You should not get pregnant, breastfeed, or father a baby while in this study. All study participants must avoid becoming pregnant or causing a pregnancy for the duration of the study.

Because taking the study drug during pregnancy may cause birth defects, safeguards are required to avoid becoming pregnant or causing a pregnancy. If you or your partner can get pregnant, it is important while on this study for you to either use birth control or not have sex that could result in pregnancy. Check with your study doctor about what kind of birth control methods to use and how long to use them. Some birth control methods might not be approved for use in this study.

Women should not breastfeed while on this study. Check with your doctor about how long you should wait to breastfeed after you stop study treatment.

Breach of Confidentiality
There is a risk that your information could become known to someone not involved in this study. If this happens, it could result in damage to your reputation, which could also affect your relationships with family and friends, affect your employment, or make it harder to get insurance or a job.

It is possible that your study information could become known to someone who is not involved with the study. We have measures in place to protect against this - see the section of this form called "**How will the researchers keep my research information confidential?"**

Questionnaires

The questionnaires you will complete in this study ask about symptoms of emotional distress such as depression. We are using the questionnaires only for research, not to diagnose mental health issues. We will not tell you the results. If you are experiencing emotional distress, you should contact your physician or other health care provider, such as a mental health professional.

Unknown Risks
As the study involves an investigational drug, there may be risks to participation that are currently unknown. Any significant new findings developed during the course of the research, which may relate to your willingness to continue participation, will be provided to you in a timely manner.

Will being in this study cost me anything?

There will be no cost to you for any of the study activities or procedures. If you need treatment for side effects while you are on the study, you or your insurance will need to pay for this treatment. You and/or your health insurer are responsible for paying the costs of the routine standard of care for your existing medical conditions The study will provide the study medications at no cost to you. There will be no costs to you as a result of participating in this study.

Will I be paid or receive anything for being in this study?

We will pay you $200 for Visit 2 and $60 for each visit thereafter (Visits 3-7). Payment will be provided at the end of each visit. If you complete all the study visits, you will receive a total of $500 for being in this study. If you choose to leave or we take you off the study for any reason, you will receive payment(s) for your participation up until you are off the study.

What happens if I am injured or get sick because of this study?

If you are injured or get sick because of this study, medical care is available to you through your local provider or emergency services, as it is to all sick or injured people.

- If it is an emergency, call 911 right away or go to the emergency room.
- For non-emergency medical problems, contact the study team for instructions.
- Call the Lead Researcher, Dr. Safdar, at 608-263-1545 to report your sickness or injury.

Here are some things you need to know if you get sick or are injured because of this research:

- If the sickness or injury requires medical care, the costs for the care will be billed to you or your insurance, just like any other medical costs.

- Your health insurance company may or may not pay for this care.
- No other compensation (such as lost wages or damages) is usually available.
- UW-Madison and UW Health do not have a program to pay you if you get sick or are injured because of this study.
- By signing this consent form and taking part in this study, you are not giving up any legal rights you may have. You keep your legal rights to seek payment for care required because of a sickness or injury resulting from this study.

How will the researchers keep my research information confidential?

We have strict rules to protect your personal information and protected health information (PHI). We will limit who has access to your health information, your name, address, phone number, and other information that can identify you. We will also store this information securely. We may publish and present what we learn from this study, but none of this information will identify you directly without your permission.

However, we cannot promise complete confidentiality. Federal or state laws may permit or require us to show information to university or government officials responsible for monitoring this study. This includes access to your medical records so that study monitors, auditors, the Institutional Review Board and regulatory authorities can verify study procedures and/or data. These groups will maintain your confidentiality. By signing this consent form, you are authorizing this access to your records. We may also have to tell appropriate authorities, such as child protective services or health care providers, if we learn during the study that you or others are at risk of harm (for example, due to child or elder abuse, or suicidal thoughts).

Who at UW-Madison can use my information?

- Members of the research team
- Offices and committees responsible for the oversight of research
- Personnel who schedule or perform medical tests or procedures, handle accounting and billing, or do other tasks related to this study

Who outside the UW-Madison may receive my information?

- U.S. Office for Human Research Protections
- The U.S. Food and Drug Administration (FDA)
- The study sponsor, National Institute of Allergy and Infectious Diseases (NIAID)
- Collaborating researchers outside UW-Madison, including researchers at the Ohio State University, Indiana University, and Mayo Clinic.
- Companies or groups performing services for the research team, such as laboratories outside UW-Madison, data management (Frontier Science and Technology Research Foundation), and encapsulated fecal microbiota distribution.

The study has a Certificate of Confidentiality from the National Institutes of Health. A Certificate of Confidentiality prohibits researchers from disclosing information or biospecimens that may identify you in a legal proceeding or in response to a legal request without your consent. We may publish and present what we learn from this study, but none of this information will identify you directly without your permission.

With appropriate institutional permissions and confidentiality protections, we might use information and biospecimens that we collect during this study for other research or share with other researchers without additional consent from you or your legally authorized representative.

Will information from this study go in my medical record?
Some of the information that we collect about you for this study will be put in your medical record. This includes information about the procedures performed in the hospital such as the study visits and study medication administration.

Authorizing the research team to use your PHI means that we can release it only to the people or groups listed above, and only for the purposes described in this form. However, once your health information is released outside UW-Madison or UW Health it may not be protected by privacy laws and might be shared with others.

Also, if ALL information that can identify you is removed from the health information collected in this study, then it is no longer PHI and this authorization will no longer limit how the remaining information can be used. This means the information could be used or shared for reasons other than the ones described in this form, such as a research study about another kind of disease. It also means that the information could be shared with researchers working at institutions that are not listed above.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

What if I have questions?

If you have questions about this research, please contact the Lead Researcher, Dr. Safdar at 608-263-1545. If you have any questions about your rights as a research subject or have complaints about the research study or study team, contact UW Health Patient Relations at 608-263-8009. The Patient Relations Representatives work with research subjects to address concerns about research participation and assist in resolving problems.

E-mail contact

If you prefer e-mail over phone calls, we are able to communicate with you via e-mail about study visit appointments and reminders for home stool collection and dosing. You do not have to provide your e-mail address to participate in this study. E-mail is generally not a secure way to communicate about your health as there are many ways for unauthorized users to access e-mail. You should avoid sending sensitive, detailed personal information by e-mail. E-mail should not be used to reach someone immediately; if you need urgent assistance please call Dr. Nasia Safdar at (608) 213-4075

____No, I do not want to be contacted via e-mail.

____Yes, you may use e-mail to contact me for this study.

My e-mail address is:_____

Optional Sample and Data Banking

The UW-Madison would like to keep your data and stool samples for an indefinite period of time, meaning we have no plans of ever destroying your data and samples. Keeping data or samples for future research is called “banking.” The banked data and samples will be kept in a secure location for use by researchers. If you agree, your specimen will be labeled with a code that will not identify you in any way. It will however, be linked to certain information, such as your medical history. However, no information that could identify you directly will be provided for purposes of the banking.

These samples and data will be kept indefinitely, meaning there are no plans to destroy them. You can decide if you want your sample to be used for future research or have them destroyed at the end of the study. Your decision can be changed at any time, even after the study ends by notifying the study team. However, if you consent to future use and some of your stool has already been used for research purposes, the information from that research may still be used.

Samples may be shared with other institutions. Each sample will be coded (labeled) only with a barcode and a unique tracking number to protect your confidentiality. Other institutions may conduct research using stored samples and data. Any samples provided to the receiving institution will be coded. In no case will either individual personal identifiers or the key linking coded data to individuals be released to the other institution.

Researchers may develop products from the samples and information you provide for this study. Some of these products may have commercial value. If the research team or others use your samples or information to develop products of commercial value, you will not receive any profits from products created from your samples or information.

Agreement to allow optional stool banking for future use

Please indicate below your willingness to allow UW-Madison to keep your stool samples or future research:

____ Yes, I agree to allow UW-Madison to keep the stool samples collected for this study for potential use in future studies

____ No, I do not agree to allow UW-Madison to keep the stool samples collected for this study for potential use in future studies

Agreement to participate in the research study

By signing this form, you are agreeing that:

- You have read this consent and authorization form.
- You have had a chance to ask questions about the research study, and the researchers have answered your questions.
- You want to be in this study.
- You give authorization for your protected health information to be used and shared as described in this form.

You do not have to sign this form. If you decide not to sign, however, you cannot take part in this research study.

_____

Printed Name of Subject

_____

Signature of Research Subject Date

_____

Signature of Person Obtaining Consent and Authorization Date

****You will receive a copy of this form****

IRB Approval Date: 10/20/2021
University of Wisconsin – Madison