Study Title: The Magnetic Flexible Endoscope (MFE): Inflammatory Bowel Disease (IBD) Trial
Version Date: February 18, 2025
PI: Keith L. Obstein, MD, MPH

The Magnetic Flexible Endoscope (MFE): Inflammatory Bowel Disease (IBD) Trial

Name of participant: _____ Age: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

Key Information:
The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

Purpose:
The purpose of this study is to evaluate the ability of a relatively new device, the Magnetic Flexible Endoscope (MFE), to travel through and visualize the colon. The MFE is driven by magnetic coupling between the endoscope head, containing an internal permanent magnet, and a robotic arm that holds an external permanent magnet. This enables a "front-pull" actuation mechanism that advances the MFE from the front camera head while the ultra-compliant tether passively follows—hence, eliminating the need to push the conventional colonoscopes semi-rigid insertion tube from the shaft in attempt to advance the front camera head (thereby avoiding colon wall stress, risk of perforation, and pain during a procedure). This study builds on successful completion of the first-in-human feasibility study of the MFE that identified no safety issues and had good tolerability in healthy patients who were already scheduled for their routine standard-of-care screening colonoscopy. In this secondary study of the MFE for unsedated colonoscopy, and our experience with patients who choose to undergo unsedated standard of care colonoscopy, we plan to assess safety and tolerability of MFE navigation in the colon from the rectum to the cecum in patients with stable non-active IBD who are due for their IBD/CRC surveillance/screening colonoscopy exams.

Key information about this study:
In this study, we will evaluate the ability of the Magnetic Flexible Endoscope (MFE) to travel through the colon. The MFE is a device made of flexible tubing that contains a camera, light, and magnet at the tip. The tip of the tube is less than the size of a penny. The magnet inside the tip allows the MFE to be moved through the colon by a second magnet attached to a robotic arm that is outside of the body (Figure 1). This enables a "front-pull" actuation mechanism to eliminate the need for pushing a semi-rigid insertion tube for advancement, thus avoiding colon wall stress, risk of perforation, and pain during a procedure. As the MFE device has a smaller size and increased flexibility compared to conventional colonoscopes, we are investigating whether it is similarly safe and effective at visualizing the colon. The MFE has already been used in the colon of five (5) patients where it moved through their colon without any complication and was well tolerated.

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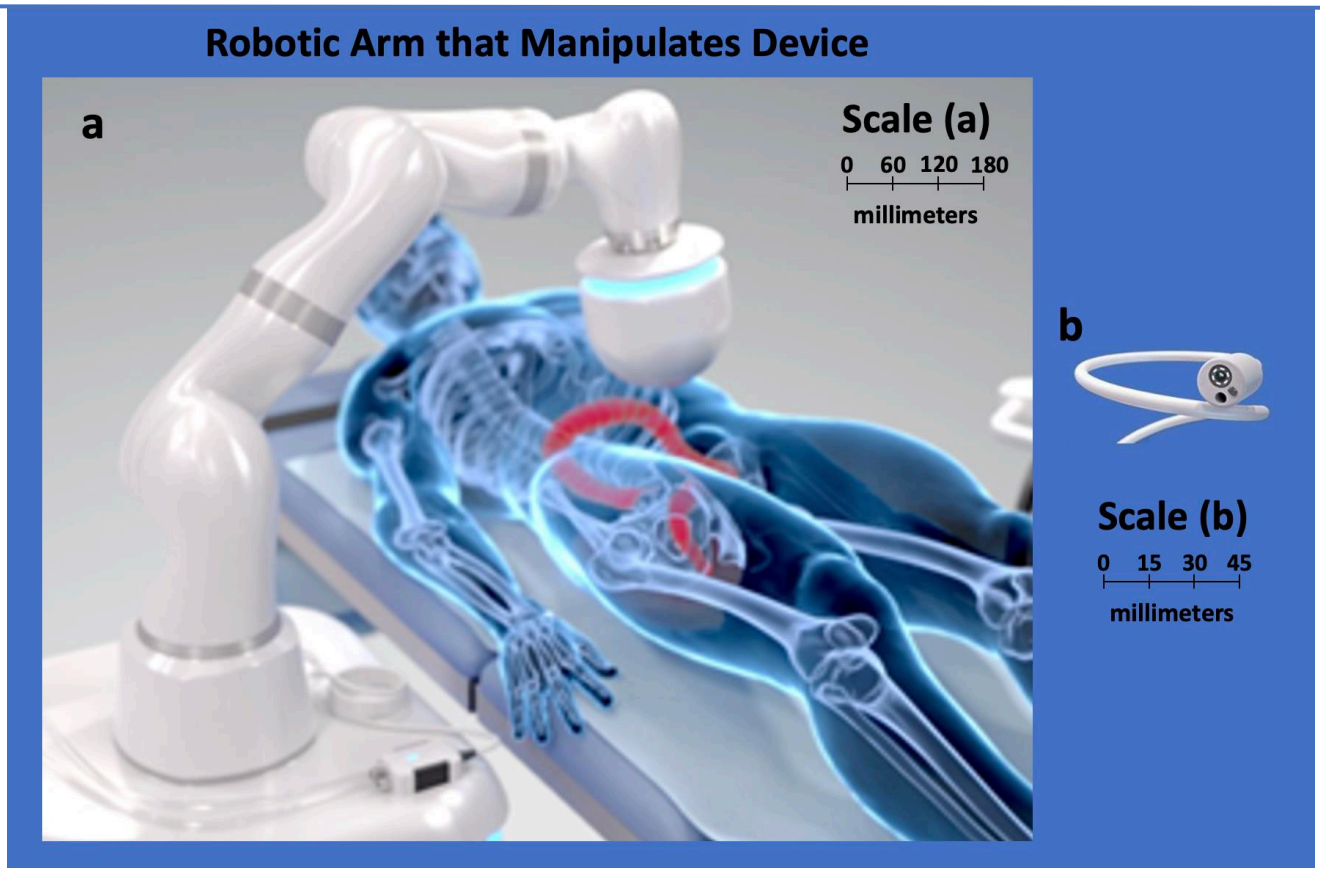

Figure 1: *The MFE platform: (a) robotic arm; (b) flexible tubing with camera, light, and magnet at the tip.*

Your participation in this study will consist of: (1) one study procedure that will occur immediately preceding or following your routine standard of care colonoscopy, (2) one interview that will occur immediately after your study procedure, (3) one single question survey that will occur immediately after your study procedure, and (4) one survey that will be completed immediately after your agreement to participate in the study.

You will recover from your colonoscopy and MFE in the same procedure room in which you had the procedure. There will be no additional time or delay in transporting to a recovery room since you will recover in the procedure room. Once you have met the standard of care metrics for post-procedure sedation recovery from sedation, you will be able to go home directly from the procedure room. There will be no additional charge for your recovery in the procedure room.

With regard to billing, you/your insurance will be billed for your standard of care colonoscopy and the sedation/anesthesia utilized as part of your standard of care colonoscopy. You/your insurance will not be billed for your care that is specific to the time or space occupied while the MFE is in use. There will be no anesthesia time or medication billed to you for the MFE portion of your participation in this research study.

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If you have any kind of metal implant, including cardiac or gastric pacemakers, or if your Body Mass Index (BMI) is greater than 30 kg/m^2, you cannot be enrolled in the study.

We plan to enroll six (6) participants.

Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

You are being asked to take part in this research study because you are a patient of the Vanderbilt University Medical Center Digestive Disease Center undergoing a colonoscopy as a part of your routine care.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study. Your medical record will contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information.

Side effects and risks that you can expect if you take part in this study:
Magnetic flexible endoscope (MFE): The potential risk of using the MFE include bleeding, infection, discomfort, and perforation. As the MFE is designed to be extremely flexible, preventing buckling or looping of the instrument, the forces generated are less than 91.7% of those necessary to cause colon perforation. Therefore, the risk of perforation is extremely low. Still, should a perforation occur, additional treatment or surgery would be required as per standard of care. The MFE is a single use, sterile, and individually packaged device, therefore the risk of infection is extremely rare. If infection does occur, treatment as per the standard of care would be implemented. As no additional sedation is administered during the study portion, there may be a potential risk of discomfort and/or of waking-up while the MFE is traveling through your colon. Five patients have already experienced the MFE moving through their colon without sedation and all tolerated the MFE device well without discomfort.

Magnet: A set of magnets will be used in order to move the MFE through your colon. These magnets are low strength. If you have any magnetic implants in your body, including cardiac or gastric pacemakers, you will be unable to participate in this study. All other magnetic material (i.e. jewelry, mobile phone) or items that could be affected by a magnet (i.e. credit card, bank card) will need to be removed prior to initiation of the procedure. Therefore, the risk from exposure to a magnetic field that is used in this technology is extremely low.

Kuka medical robot: The robot is a fully compliant medically certified robot (CB Test Certificate; IEC 60601-01 and IEC 62304) that is approved to safely work and interact directly with humans. While there is a small potential for collision with the robot arm, if this occurs, the arm immediately stops and is able to be pushed away consistent with the human-robot collaboration safety certification.

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Awakening from sedation: As no sedation will be administered for the MFE part of the procedure, you will awaken from your standard of care, monitored anesthesia care (MAC), sedation while the MFE procedure is taking place. As you awaken you may feel disoriented to time, place, and situation. The GI endoscopy team consisting of your procedure nurse, proceduralist, and endoscopy technologist, who are in the procedure room, will help to orient you.

Breach of confidentiality: There is a potential risk of breach of confidentiality associated with participation in any research study. Every measure will be taken to ensure that specific participant information is kept confidential throughout the conduct of this study.

Risks that are not known:
The MFE system itself is investigational, meaning non-FDA approved, and therefore there may be potential risks that are unknown at this time, these are likely to be minimal, if any at all, given the testing and validation work performed on the MFE platform that has taken place before this study. These include laboratory tests and animal studies designed to verify the system's performance, validate its safety profile, and evaluate its diagnostic capabilities.

Laboratory tests focused on assessing key areas including electrical safety, electromagnetic compatibility (EMC), biological compatibility, mechanical robustness, and force analysis. Electrical and EMC testing was conducted, using the electrical standard IEC/EN 60601-1 as a guide, to allow us to demonstrate that the MFE system operates safely alongside other technologies with electrical integrity and without electromagnetic interference. All MFE device materials that contact human tissue were chosen and evaluated using guiding principles of ISO/EN 10993-1, 10993-18, and 10993-19 to ensure the materials' biological compatibility. Mechanical robustness testing was completed to ensure that the MFE device can withstand the forces involved in a colonoscopy, while maintaining precision and durability of the robotic arm, camera, and illumination. Force analysis testing found that the maximum force exerted by the MFE system on the intestinal mucosa is less than 91.7% of the force that is necessary to cause perforation of the human colon.

Animal studies were conducted in the colon of live swine, an ideal pre-clinical model that closely resembles the human colon in terms of elasticity, friction, and other mechanical properties. Additionally, swine colon tissue is more delicate than human colon tissue, making swine tissue an excellent choice for testing the safety of the MFE system in a controlled environment. The animal studies demonstrated that the MFE system could be used effectively in the colon without causing tissue perforation or bleeding. The robotic device's precise control and navigation capabilities ensured that the MFE colonoscopy could be performed successfully without complication or adverse event.

The MFE was developed and evaluated through pre-clinical feasibility work carried out over the past decade. This evaluation included careful safe-by-design optimization of the size, shape and arrangement of the magnets, magnetic manipulation technique, colon navigation strategy, and robotic motion control (including core software application). This project started with a foundation of pre-clinical feasibility work, including strong evidence supporting the success of the design process—as no safety events were encountered over the decade of bench and animal studies.

Evidence to further support the safe-by-design MFE platform, beyond preclinical and animal trials, include the first-in-human clinical trial completed at Vanderbilt University Medical Center where the MFE device was navigated in the colon of 5 healthy patients who were scheduled for their routine standard-of-care screening colonoscopy. All 5 patients were alert and awake for the MFE navigation of their colon with all 5 patients tolerating MFE navigation well without discomfort, pain, or other complaints. Additionally, there were no safety events or tissue trauma, and the system was robust with no system hardware or software failures.

Good effects that might result from this study:
We hypothesize the MFE colonoscopy might benefit science and humankind as a result from this study through reducing risks, improving convenience, and enhancing the patient experience compared to conventional colonoscopy. In conventional colonoscopy, procedural sedation is the highest risk of the procedure—and its use is directly related to the mechanical properties of conventional colonoscopes that distort the colon wall. By utilizing magnetic coupling, the MFE enables a "front-pull" actuation mechanism, avoiding colon wall stress, and therefore reducing the risk of perforation, trauma, and pain to allow for an unsedated procedure.

Risk reduction through use of the MFE can be attributed to the lower perforation risk, avoidance of sedation and sedation-related risk, and avoidance of cross-contamination risk as the MFE is single use. Patients undergoing an unsedated MFE procedure, may experience improved convenience of their colonoscopy procedure (i.e. would be able to immediately resume activities, have no need to inconvenience another individual such as the required accompanying chaperone or driver to sedated procedures, and perhaps have their MFE procedure completed at their primary care providers office or closer center to their work or home). Additionally, as the patient is awake during the procedure, their experience may be aided due to real-time feedback and discussion of findings that would enhance physician-patient communication, avoidance of amnestic effects from sedation, facilitate improved patient comfort during the procedure as the patient would be able to inform the physician of their feelings, and reduce work-related injuries of endoscopy team members, as well as improving patient safety, as patients would be able to move themselves on the stretcher for the procedure (instead of team members needing to move a sedated patient on a stretcher into procedural positions).

Procedures to be followed:
Study Visit:
Your study visit will occur at the same time as your standard of care visit (conventional colonoscopy). When you arrive to your study visit, you will be randomly assigned to receive your conventional colonoscopy first followed by the MFE or the MFE first followed by conventional colonoscopy.

If assigned to receive conventional colonoscopy first, followed by the MFE, your study visit will be completed as follows:
After your conventional colonoscopy, and only if your colon appears normal, your sedation will be stopped as per standard practice, and you will recover from sedation in the endoscopy room.

While you are recovering from sedation, the medical doctor who is part of the study team, will guide the MFE from your rectum toward the cecum of your colon (the beginning to the end). The MFE will not be used for any interventions (i.e. biopsies, polypectomy—removal of polyps). The study is only to see how the MFE travels in the colon and your experience with having the MFE travel in your colon.

If assigned to receive the MFE first, followed by conventional colonoscopy, your study visit will be completed as follows:
The medical doctor, who is part of the study team, will guide the MFE from your rectum to the cecum of your colon (the beginning to the end). The MFE will not be used for any interventions (i.e. biopsies, polypectomy—removal of polyps). The study is only to see how the MFE travels in the colon and your experience with having the MFE travel in your colon. Once the MFE reaches the cecum of your colon or if 40 minutes have passed since the MFE entered your colon, the MFE will be withdrawn from your colon and the study portion of your endoscopy will be stopped. The sedation for your conventional colonoscopy will then be started as per standard practice, administered by the Vanderbilt University Medical Center Out-of-OR Anesthesia team, and your conventional colonoscopy exam will be completed as per standard of care.

The MFE is a single use device that is sterilized and individually packaged. The tip of the device is less than the size of a penny and contains a camera, light, and magnet. The tube is made of a soft, flexible medical grade material [Figure 2]. The magnet in the tip of the device allows it to be moved through your colon by interacting (attracting and repelling) with another magnet that is attached to the Kuka Medical Robot. This robot is for use with humans and in other medical procedures such as surgeries and ultrasounds [Figure 3].

The MFE will be manually placed in the colon per rectum (the same method of placement for the conventional colonoscope), and the robot will be positioned above your abdomen. Once the MFE is in position, the robot will gently pull the device through your colon to the cecum (the last part of your colon) using the magnets. The robot will be operated by the medical doctor who is part of the study team during the procedure. Once the cecum has been reached, the MFE will then be withdrawn from your colon and the study will be stopped. This will take no more than 40 minutes to complete. If 40 minutes is reached before the MFE is able to reach your cecum, the MFE will be withdrawn from your colon and the study will be stopped.

Please note that by participating in this research study, you will spend more time in the endoscopy procedure room—as you will have the standard of care colonoscopy, the MFE procedure, and your after-sedation recovery in the procedure room. You will not have your after-sedation recovery in the recovery room and once you meet the Vanderbilt post-anesthesia standard of care discharge criteria, you will be able to be discharged directly from the procedure room. By being in this study, you may be awakening from the anesthesia used for your standard of care colonoscopy while the MFE procedure is occurring; while if you were not in this study, you would be awakening from the anesthesia used for your standard of care colonoscopy in our endoscopy recovery room. The extra time spent in the procedure room for the research portion of the day (MFE procedure) and for your recovery from anesthesia in the procedure room will be at no additional charge. You/your insurance will not be billed

for your care that is specific to the time or space occupied while the MFE is in use. There will be no anesthesia time or medication billed to you for the MFE portion of your participation in this research study.

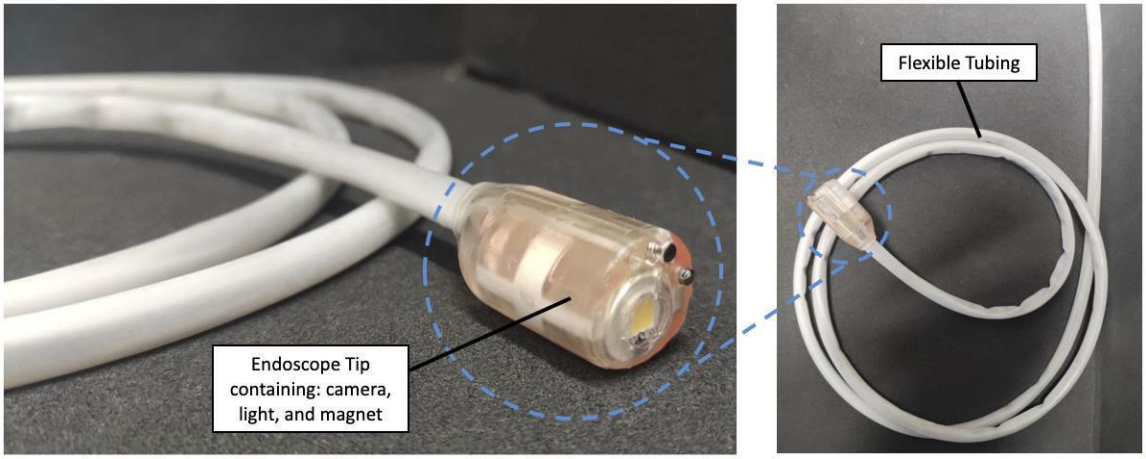

Figure 2: *The MFE Endoscope made of flexible tubing that contains a camera, light, and magnet at the tip.*

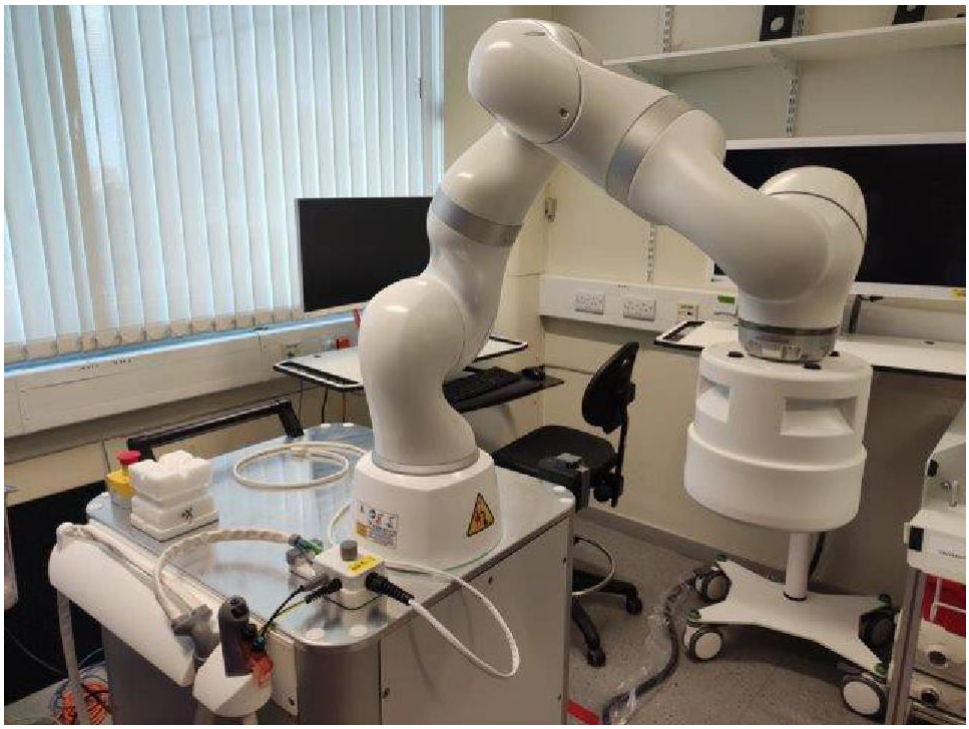

Figure 3: *The KUKA medical robot within the MFE platform.*

Questionnaire and Interview:
After agreeing to be in the study and before your conventional colonoscopy or MFE study, you will be asked to complete a questionnaire on your overall health status. After completion of your study

procedure, (1) you will be asked to complete a single question survey (scale score) and (2) a member of the study team will perform a structured interview to ask about your comfort and experience during the procedure. This will be performed in a private consultation room in the endoscopy suite.

Medical Record Review:
During the study, we will gather information about you and your health from your medical record.

Payments for your time spent taking part in this study or expenses:
Participants will receive a $100 Amazon gift card after participating in this study. You are not allowed to accept any money for taking part in this study if you are not eligible to receive money from a U.S. person or company or the U.S. government because of U.S. national security and/or foreign policy laws. You can still take part in the study; however, you will not be paid if you are a resident of a country restricted by the U.S. government's comprehensive territorial sanctions or if you are listed on the U.S. Treasury Department's Office of Foreign Assets Control's Specially Designated Nationals (SDN) list of prohibited individuals. You do not have to say why you choose not to be paid.

Costs to you if you take part in this study:

If you agree to take part in this research study, you and/or your insurance will not have to pay for the tests and treatments that are being done only for research.

However, you are still responsible for paying for the usual care you would normally receive for the treatment of your illness. This includes treatments and tests you would need even if you were not in this study. These costs will be billed to you and/or your insurance.

You have the right to ask what it may cost you to take part in this study. If you would like assistance, financial counseling is available through the Vanderbilt Financial Assistance Program. The study staff can help you contact this program. You have the right to contact your insurance company to discuss the costs of your routine care (non-research) further before choosing to be in the study. You may choose not to be in this study if your insurance does not pay for your routine care (non-research) costs and your doctor will discuss other treatment plans with you.

Payment in case you are injured because of this research study:
If it is determined by Vanderbilt and the Investigator [with Sponsor input] that an injury occurred, then you and/or your insurance may be billed for the cost of medical care provided at Vanderbilt to treat the injury. You will be responsible for any copayments or deductibles associated with the treatment of that injury.

There are no plans for Vanderbilt [or the Sponsor] to pay for the costs of any additional care. There are no plans for Vanderbilt [or the Sponsor] to give you money for the injury.

Who to call for any questions or in case you are injured:
If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact Dr. Keith Obstein or his study team at (615) 322-4643. If

you cannot reach the research staff, please contact the Manager of the GI Research Enterprise, Michael McGill, at (615) 322-4643.

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the VUMC Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Reasons why the study doctor may take you out of this study:
You will be withdrawn from the study if the study doctor decides it is best for you. If you are withdrawn from the study, you will be told the reason.

What will happen if you decide to stop being in this study?

If you decide to stop being part of the study, you should tell your study doctor. Deciding not to be part of the study will not change your regular medical care in any way.

Clinical Trials Registry:
A description of this clinical trial will be available on 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.

Confidentiality:
There is a potential risk of breach of confidentiality associated with participation in any research study. Every measure will be taken to ensure that specific participant information is kept confidential throughout the conduct of this study.

Electronic data will be stored in REDCap and will only be accessible by key study personnel. REDCap is a secure database. The information in the database can only be accessed with a specific username and password.

Study related documents will be stored in locked filing cabinets in the study doctor's office. This office is only accessible with a key by the study team.

The study team will meet regularly to monitor the progress of the study and review any study and/or participant issues. The study doctor will oversee all aspects of the study conduct and is available to all participants at any time by calling the number listed above.

This study may have support from the National Institutes of Health. If so, your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

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Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

Privacy:

Any samples and information about you may be made available to others to use for research. To protect your privacy, we will not release your name. You will not receive any benefit as a result of the tests done on your samples. These tests may help us or other researchers learn more about the causes, risks, treatments, or how to prevent this and other health problems.

Study Results:
Study results will not be individually shared with participants. A copy of any peer-reviewed publications that result from this research will be made available to participants upon their verbal or written request.

Authorization to Use/Disclose Protected Health Information
What information is being collected, used, or shared?
To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Vanderbilt University Medical Center and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STI treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?
The people who may request, receive or use your private health information include the researchers and their staff. Additionally, we may share your information with other people at Vanderbilt, for example if needed for your clinical care or study oversight. By signing this form, you give permission to the research team to share your information with others outside of Vanderbilt University Medical Center. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team. We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?
You do not have to sign this Authorization, but if you do not, you may not join the study.

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Do you have to sign this Authorization?
You do not have to sign this Authorization, but if you do no, you may not join the study.

How long will your information be used or shared?
Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?
You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

_____ _____
Date Signature of patient/volunteer

Consent obtained by:

_____ _____
Date Signature

_____
Printed Name and Title

Time: _____