UNIVERSITY OF PENNSYLVANIA
RESEARCH SUBJECT
COMBINED INFORMED CONSENT FORM AND HIPAA AUTHORIZATION

Protocol Title:	Fecal Microbial Transplantation (FMT) for the Treatment of Fecal Incontinence in Women
Principal Investigator:	Uduak Andy, MD [redacted]
Emergency Contact:	24 - Hour Urogynecology Nurse or Fellow on Call [redacted]

Summary

You are being invited to participate in a research study. Your participation is voluntary, and you should only participate if you completely understand what the study requires and what the risks of participation are. You should ask the study team any questions you have related to participating before agreeing to join the study. If you have any questions about your rights as a human research participant at any time before, during or after participation, please contact the Institutional Review Board (IRB) at (215) 898-2614 for assistance.

The research study is being conducted to determine if Fecal Microbial Transplantation (FMT) is a potential treatment for fecal incontinence in women. Fecal microbiota transplant, also known as stool transplant, is the process of taking fecal bacteria from a healthy individual and administering it to a recipient.

If you agree to participate, you will receive a Fecal Microbial Transplantation. You are agreeing to have us collect some background information on you, your health history and stool samples. You may be asked to fill out questionnaires and diaries during your participation in the study.

Your participation in the study would begin today and continue through six months after you receive FMT.

There are risks associated with FMT such as gastrointestinal (stomach) symptoms, abdominal pain, and unforeseen risk as this is the first time FMT is being used for this specific syndrome. We do not know if you will benefit from this study; however, your participation will help us advance knowledge regarding the use of FMT for fecal incontinence.

Please note that there are other factors to consider before agreeing to participate such as additional procedures, use of your personal information, costs, and other possible risks not discussed here. If you are interested in participating, a member of the study team will review the full information with you. You are free to decline or stop participation at any time during or after the initial consenting process.

Why am I being asked to volunteer?

You are being invited to participate in a research study because you have fecal incontinence also commonly referred to as accidental bowel leakage (ABL) and other therapies have not aided in treating your symptoms. Your participation is voluntary which means you can choose whether or not you want to participate. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. The research team is going to talk to you about the research study, and they will give you this consent form to read. You may also decide to discuss it with your family, friends, or family doctor. You may find some of the medical language difficult to understand. Please ask the investigator and/or the research team about anything you do not understand. If you decide to participate, you will be asked to sign this form. Your doctor may be an investigator in this research study. As an investigator, your doctor is interested both in your clinical welfare and in the conduct of this study. Before entering this study or at any time during the research, you may want to ask for a second opinion about your care from another doctor who is not an investigator in this study. You do not have to participate in any research study offered by your doctor.

What is the purpose of this research study?

The purpose of this study is to determine if Fecal Microbial Transplantation (FMT) leads to clinical improvement of accidental bowel leakage in women.

How long will I be in the study? How many other people will be in the study?

You will be involved in the study from today until 6 months after your FMT procedures (approximately 8 months total). The study is expected to take 24 months to enroll 15 subjects and analyze data. All subjects will be enrolled from the University of Pennsylvania Health System.

What am I being asked to do?

You are being asked to participate in a study that will measure if FMT leads to clinical improvement for accidental bowel leakage and may provide an alternative treatment option.

You are being asked to provide us with some general background information, including information regarding your health history. Additionally, you will be asked to complete

questionnaires and diaries regarding your fecal incontinence severity before and after the FMT procedures.

The FMT procedure will involve the placement of a GI tube (a thin tube which will go in your nose to stomach), X-ray imaging to ensure the tube is in the proper place, and finally administration of the fecal microbial transplant through the GI tube. Afterwards, the tube will be removed, and you will be assessed for adverse events. This will all take place in the Urogynecology clinic. The entire procedure will last approximately 3hours. The study doctor will further detail the procedure and will be the individual performing all steps of FMT.

Up to 7 days following the procedure the study team will follow up with you via a telephone call to ensure you are not experiencing any negative systems. You will also come into office at 4 weeks and then have the option of coming for an in-person or virtual study visit at 12 weeks. Stool samples will be collected at treatment and 4-week follow up as well as at the 12-week follow up visit if subject comes for in-person visit. Lastly, the study team will again call you approximately 180 days after treatment to ensure you are not experiencing any side effects.

What are the possible risks or discomforts?

In general, fecal transplantation is very well tolerated. However, the following are known risks of FMT when used for indications other than FMT:

- gastrointestinal (stomach) symptoms including fever, aspiration, belching, bloating, nausea or vomiting;
- gastroesophageal reflux, abdominal cramps, abdominal pain, diarrhea, or constipation;
- the risks included with GI tube placement include discomfort, possible wrong placement which would necessitate the procedure being repeated;
- the theoretical risks associated with the introduction of bacterial species include infection and death, however, all donors providing stool for transplantation are screened for blood- and stool-borne infections, including HIV and stool infections. These screening measures significantly, reduce the risk of an infectious disease being transmitted from the stool donor to you.

This research involves an x-ray. Therefore, you will receive a small additional radiation dose. This additional radiation dose is not necessary for your medical care and will occur only as a result of your participation in the study. At doses much higher than you will receive, radiation is known to increase the risk of developing cancer after many years. At the doses you will receive, it is very likely that you will see no effects at all.

FMT products may contain food allergens, and you should notify the study team if you have any severe food allergies. Questionnaires and diary collection may contain items which you feel uncomfortable providing answers to. You do not need to answer any questions that make you feel uneasy.

As FMT has not yet been studied for FI there may also be other unknown side effects that could harm you during or after your treatment. We cannot predict what these side effects may be, which is why it is so important for you to report any side effects you experience to your doctor(s). There is always the possibility that you will have a reaction that, if not treated properly, could be life threatening.

All donors are also screened for infection with the novel coronavirus, SARS-CoV-2, which causes the disease called COVID-19. This screening uses swabs of the nose to detect current infection. Additionally, donors who provide stool for PMT products manufactured after March 15, 2022, are questioned about potential exposure to the monekypox virus. Donors are also asked regularly about any symptoms that could be caused by these viruses. Stool from donors who have confirmed or suspected infection with these viruses will not be used for the PMT products. However, it is possible for healthy donors without any symptoms to have these viruses. While regular screening and testing will help reduce the likelihood of passing this infection, the tests are not perfectly accurate, and so there is still a risk of transmission of this virus.

UPENN takes numerous steps to ensure that your personal health information is kept private. However, participation in research could involve some loss of privacy. We will do our absolute best to make sure that information about you is kept confidential, but we cannot guarantee total privacy. Your healthcare providers will know that you are participating in this study. Your name or other identifying information will not be used in any published reports about this study. At all times, we will do everything we can to make all data less recognizable.

What if new information becomes available about the study?
During the course of this study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

What are the possible benefits of the study?

By participating in the study, you may receive a reduction in you FI severity. This, however, is not a guaranteed benefit.

The results of this study may benefit future patients and treatment options for FI.

What other choices do I have if I do not participate?
You may choose to join the study or you may choose not to join the study. Your participation is voluntary. There is no penalty if you choose not to join the research study. You will lose no benefits or advantages that are now coming to you, or would come to you in the future. If you are currently receiving services and you choose not to volunteer in the research study, your services will continue at the discretion of your doctor.

Will I be paid for being in this study?
Your participation in this study will not cost you anything. You will receive a specially designed debit card for clinical research, called a ClinCard. Your payments will be approved and loaded onto your debit card after your completion of your research visit. (Payment can take up to one day to load onto the card). If you do not complete the study for any reason, you will not be paid. No additional financial compensation will be provided.

Participation includes 4 separate visits over the course of the study. The payment will be $50 for the first visit; $125 for the second visit, $50 for the third visit and $75 for the fourth visit; for a total of $300.

Please note: In order to be compensated for your participation in this study, you must provide your Social Security Number. Additionally, please note that the University of Pennsylvania is required to report to the IRS any cumulative payments for participation in research studies that exceed a total of $600 in a calendar year.

Will I have to pay for anything?
You will not have to pay for anything associated with study visits or the FMT procedures. All other appointments with the Urogynecology team will still be billed to you / your insurance.

Will I receive the results of research testing?
Stool and blood tests done for this study are only for research and have no clear meaning for health care. Research test results will not be returned to you nor placed in your medical records because they would not be relevant to your health care.

What happens if I am injured from being in the study?
We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

There are no plans for the University of Pennsylvania to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

If you think you have been injured as a result of taking part in this research study, tell the person in charge of the research study as soon as possible. The researcher's name is listed on the first page of this document.

When is the Study over? Can I leave the Study before it ends?

The study is expected to end after all participants have been recruited and all information has been collected. This study is expected to take 24 months. This study may also be stopped at any time by your physician, the study Sponsor, or the Department of Obstetrics and Gynecology without your consent because:

- The Primary Investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.
- The study Principal Investigator, or the Department of Obstetrics and Gynecology has decided to stop the study.

If you decide to participate, you are free to leave the study at any time. Withdrawal will not interfere with your future care.

How will my personal information be protected during the study?

We will do our best to make sure that the personal information obtained during the course of this research study will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. The Institutional Review Board (IRB) at the University of Pennsylvania will have access to your records.

You will be assigned a unique ID number. The link between your name and ID number along with your personal information will be held in a research database on a password protected computer in a locked office in the Department of Urogynecology. Only the principal investigator and select study staff will have access to these files.

Will information about this study be available to the public?

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 Web site will include a summary of the results. You can search this Web site at any time.

What may happen to my information / samples collected on this study?

The following identifiers will be retained with your information: name, date of birth, and phone number. This will allow us to contact you during the study period. In the research database, your information will be coded. Coded means that all you are assigned a unique random identifier (ID number). The link to your name and this identifier will be contained in a separate file and destroyed when the study has completed all analysis.

While this link exists it is possible to re-identify you. When the study has completed all analysis, all information will be de-identified. This means that the link will no longer exist and cannot be associated back to you. The information and samples may be stored and shared for future research in this de-identified fashion. It will not be possible for future researchers to identify you as we will not share any identifiable information about you with future researchers. The future use of your samples or study information may be done without again seeking your consent in the future, as permitted by law. The future use of your information only applies to the information collected on this study.

There is a risk of breach of confidentiality (unintentional release of your information). We will do our best to make sure that this doesn't happen. However, we cannot guarantee total privacy.

Whole Genome Sequencing will not occur in this study or any future analysis on de-identified samples. While it is highly unanticipated and not the goal of this pilot study biospecimens may lead to commercial profit. If this were to occur you will not be informed or share in this commercial profit.

What may happen to my information / samples collected in future studies?

As indicated above some samples will be stored in a de-identified manner for future research. The possibilities of this research at this time is indefinite. You will not be made aware of this research or results of the research as we will not be able to link the samples back to you.

Electronic Medical Records and Research Results

What is an Electronic Medical Record and/or a Clinical Trial Management System?

An Electronic Medical Record (EMR) is an electronic version of the record of your care within a health system. An EMR is simply a computerized version of a paper medical record.

A clinical trial management system (CTMS) is used to register your information as a participant in a study and to allow for your research data to be entered/stored for the purposes of data analysis and any other required activity for the purpose of the conduct of the research.

If you are receiving care or have received care within the University of Pennsylvania Health System (UPHS) (outpatient or inpatient) and are participating in a University of Pennsylvania research study, information related to your participation in the research (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing EMR maintained by UPHS. Information related to your participation in clinical research will also be contained in the CTMS.

If you have never received care within UPHS and are participating in a University of Pennsylvania research study that uses UPHS services, an EMR will be created for you for the purpose of maintaining any information produced from your participation in this research study. The creation of this EMR is required for your participation in this study. In order to create your EMR, the study team will need to obtain basic information about you that would be similar to the information you would provide the first time you visit a hospital or medical facility (i.e. your name, the name of your primary doctor, the type of insurance you have). Information related to your participation in the study (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in this EMR.

Once placed in your EMR or in the CTMS, your information may be accessible to appropriate UPHS workforce members that are not part of the research team. Information within your EMR may also be shared with others who are determined by UPHS to be appropriate to have access to your EMR (e.g. Health Insurance Company, disability provider, etc.).

What information about me may be collected, used or shared with others?
Name and date of birth
Street address-city; county; precinct; zip codes and equivalent geo codes
All elements of date / ages of 89
Telephone and Fax number
Email address
Social Security Number (To be paid)
Current or past medications or therapies
Consumptive habits (drugs or alcohol)
Personal and Family Medical History
Medical Record Number
Results from a physical examination, tests or procedures as described

Why is my information being used?
Your information is used by the research team to contact you during the study. Your information and results of tests and procedures are used to:

- do the research
- oversee the research
- to see if the research was done right
- to evaluate and manage research functions.

Who may use and share information about me?
The following individuals may use or share your information for this research study:

- The investigator for the study and the study team
- Other authorized personnel at Penn, including offices that support research operations
- Other research personnel with access to the databases for research and/or study coordination and as otherwise approved by the IRB.

Who, outside of the School of Medicine, might receive my information?
Oversight organizations

- The U. S. Office of Human Research Protections (OHRP)
- The Food and Drug Administration
- The study data and safety monitoring board

Once your personal health information is disclosed to others outside the School of Medicine, it may no longer be covered by federal privacy protection regulations.

The Principal Investigator or study staff will inform you if there are any additions to the list above during your active participation in the trial. Any additions will be subject to University of Pennsylvania procedures developed to protect your privacy.

How long may the School of Medicine use or disclose my personal health information?
Your authorization for use of your personal health information for this specific study does not expire.

Your information may be held in a research database. However, the School of Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization
- The University of Pennsylvania's Institutional Review Board grants permission
- As permitted by law

Can I change my mind about giving permission for use of my information?
Yes. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the investigator for the study. If you withdraw your permission, you will not be able to stay in this study.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

You will be given a copy of this Research Subject HIPAA Authorization describing your confidentiality and privacy rights for this study.

By signing this document, you are permitting the School of Medicine to use and disclose personal health information collected about you for research purposes as described above.

Who can I call with questions, complaints or if I'm concerned about my rights as a research subject?

If you have questions, concerns, or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on page one of this form. If a member

of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Office of Regulatory Affairs with any question, concerns, or complaints at the University of Pennsylvania by calling [redacted]

When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania to disclose that personal health information to outside organizations or people involved with the operations of this study.

A copy of this consent form will be given to you.

Name of Subject (Please Print)	Signature of Subject	Date
Name of Person Obtaining Consent (Please Print)	Signature	Date