



Gary M. Annunziata, D.O., F.A.C.P.
Anh T. Duong, M.D.
Natalie Sloan, FNP-C
Megan Lancaster, FNP-C

INFORMED CONSENT FOR FECAL MICROBITA TRANSPLANTATION (FMT)

Patient Name: _____ DOB: _____

Date of Procedure: _____

I hereby authorize _____ to perform the following procedure: FMT.

FMT is administered to treat chronic (recurrent) of severe *Clostridium difficile* infection (CDI), an inflammatory condition of the large intestine (colon). FMT consists of introducing normal bacteria flora contained in stool collected from a healthy donor into the diseased colon where the flora is missing.

The nature, purpose, risks and benefits of this procedure has been discussed with me. I understand that the donor stool, from OpenBiome, have been screened of exposure to communicable infectious agents through a detailed health questionnaire, and also undergo blood and feces testing for occult infectious pathogens as some infectious diseases may be silent or clinically undetectable. I understand I have the right to review the donor's screening results of the specimen I will be receiving during the procedure.

In choosing to proceed with FMT, I understand that a solution of donor stool will be infused into my colon during colonoscopy. The Colonoscopy procedure used for FMT will be explained and provided in a separate consent.

I have discussed alternative treatments for recurring CDI including antibiotic options, surgery, or no treatment at all. I understand the risk and benefits of alternative treatments. I understand that my condition could improve, stay the same, or worsen with alternative treatment options, including FMT. I understand that persons with severe CDI have a risk of dying regardless of which treatment is used and fecal transplant may not be successful. I understand that at the current time the cumulative experience with FMT is limited and that FMT is therefore considered investigational.

This authorization is given with the understanding that any procedure and recuperation involves some risks and hazards. According to American College of Gastroenterology physician experts, the most common risks of fecal microbiota transplant are transient cramping (1-3 days), bloating, gaseousness, altered bowel habit (constipation more than diarrhea), and low grade fever for no more than 12-24 hours.

Complications may include but are not limited to:

- Transmission of infectious organisms contained in stool (bacteria, viruses, fungi, parasites)
- Transmission of antibiotic-resistant bacteria: These are bacteria that are resistant to one or more antibiotics. These bacteria could be transmitted through FMT and cause a serious infection. The FMT that you will receive is provided by a company called OpenBiome where donors who provide stool for the FMT treatments undergo screening for certain antibiotic-resistant bacteria and clinical risk factors that would make their exposure to antibiotic-resistant bacteria more likely. Individuals who test positive for these bacteria or have these risk factors are excluded from donating.
- Allergic reactions to antigens contained in the donor stool.
- Mechanical complication related to the insertion and presence of the tube, such as potential perforation of the colon or trauma to the rectum.
- Missed polyp, cancer or other lesion as infusing donor stool interferes with visualization of colonic mucosa.

I understand that this is not a complete list of potential complications, and that unforeseen risks that have not been discussed with me may exist. Complications may occur even when the procedure is properly performed. I acknowledge that no guarantee or promise can be made by my physician as to the outcome of my treatment.

Patient's Acknowledgement:

I confirm that the entire content of this form has been explained to me and I understand the contents. I have the opportunity to ask questions and all of my questions have been answered to my satisfaction.

Patient Signature

Date