

# INFORMED CONSENT FOR FECAL MICROBIOTA TRANSPLANTATION

PATIENT NAME: \_\_\_\_\_

I hereby authorize Dr. \_\_\_\_\_, and/or such associates, assistants, consultants, residents and fellows, as may be selected by my doctor, to perform the following procedure on me: Fecal Microbiota Transplantation (FMT).

I understand that during Fecal Microbiota Transplantation stool from a donor will be administered to me in a solution through either the lower gastrointestinal tract (using either a colonoscope or enema) or through the upper gastrointestinal tract (using a nasogastric tube). My doctor has evaluated the different ways to perform FMT, and I understand that a solution of donor stool will be administered to me as follows:

- infused into the colon via colonoscopy or sigmoidoscopy, or
- inserted via Naso-gastric tube (NGT) placement, or
- inserted through an enema preparation.

## RISKS OF PROCEDURE

The doctor named above has discussed with me the procedure for Fecal Microbiota Transplantation (FMT), including the anticipated benefits for FMT in the treatment of chronic or recurrent *C. difficile* infection, the material risks, the alternative therapies, and potential problems during recuperation and the likelihood of achieving my goals. My doctor has also reviewed with me criteria that would allow me to undergo this procedure and criteria that would exclude me from this procedure.

\_\_\_\_\_(Patient Initials) My doctor has discussed with me the investigational nature of FMT to treat *C. difficile*. I understand that FMT is *investigational*, which means that while there is published data that the use of FMT may help manage *C. difficile* infections that have not responded to standard therapies, the effectiveness and safety of FMT has not been fully evaluated in controlled clinical trials and FMT has not been approved by the FDA.

I understand that any procedure and recuperation involves some risks and hazards. 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. Other potential risks include:

- transmission of infectious organisms (bacterial, viral, fungal, parasitic) contained in the donor stool;
- missed polyp, cancer or other lesion (If FMT is performed by colonoscopy or sigmoidoscopy) as infusing donor stool interferes with visualization of colonic mucosa;
- allergic reaction to antigens in donor stool;
- enhanced colitis activity in patients with underlying inflammatory bowel disease;
- theoretical increased risk of developing disease which may be related to donor gut bacteria (obesity/metabolic syndrome, autoimmune conditions, allergic/atopic disorders, neurologic disorders, malignancy).
- abdominal pain
- other unreported infections or complications.

I understand that this is NOT a complete list of the risks of FMT and that unforeseen and unknown risks exist which have not been discussed with me. Complications may occur even when a procedure is properly performed. I understand that patients critically ill with severe *C. difficile* have a high risk of dying from this condition regardless of what treatment is used and I understand that fecal transplant may not be successful.

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## RISKS FROM DONOR STOOL

\_\_\_\_\_(Patient Initials) I have been made aware of certain risks and consequences that are associated with Fecal Microbiota Transplantation, some of which may be associated with the donor sample. I understand that I will receive FMT using stool from an un-named donor in a preparation provided to my doctor by OpenBiome, a company that provides fecal material preparations for clinical use in hospitals. I understand that OpenBiome, and not my doctor or the hospital, is solely responsible for screening and testing the donor stool for infectious diseases that might be transmitted to me during FMT. I understand that even with careful screening there may be infectious agents or non-infectious diseases or other pathogens in the donor stool that are not detected and which might be transmitted to me.

## RECUPERATION

Recuperation from FMT is generally complete within a few hours following the procedure if done on an outpatient basis. Most individuals can return to typical activities and diet at that time. Increasing abdominal pain, bleeding, fever or other signs of illness could be signs of complications and should be reported promptly to your physician. You will be provided with written instructions on discharge telling you how to contact us in the event of a problem after the procedure.

## PATIENT CONSENT

I understand that no guarantees have been made to me regarding the results of this procedure and that it may or may not improve my condition. I have had sufficient opportunity to discuss my condition and treatment with my physicians and/or their associates, and all of my questions have been answered to my satisfaction. I believe that I have been given sufficient information and have adequate knowledge upon which to make an informed decision about undergoing the proposed procedure. I have read and fully understand this form and I voluntarily authorize and consent to the procedure.

DO NOT SIGN UNLESS YOU HAVE READ AND THOROUGHLY UNDERSTAND THIS FORM

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Printed Name of Patient /Legal Representative (if applicable)	Signature	Date Signed
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Relationship of Legal Representative to Patient (if applicable)

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Printed Name of Interpreter (if applicable)	Signature of Interpreter	ID #
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Printed Name of Physician Performing Procedure	Signature of Physician Performing Procedure	Date Signed
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