

INFORMED CONSENT FOR FECAL MICROBIOTA TRANSPLANTATION

PATIENT NAME: _____

DIAGNOSIS/CONDITION: _____

DATE OF PROCEDURE: _____

I hereby authorize _____ to perform the following procedure: Fecal Microbiota Transplantation (FMT).

RISKS OF PROPOSED OPERATION/PROCEDURE

Dr. _____ has discussed with me the investigational procedure for Fecal Microbiota Transplantation (FMT). He/She has reviewed with me: 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. He/She has also reviewed with me criteria that would allow me to undergo this procedure and criteria that would exclude me from this procedure. He/She has also reviewed with me the investigational nature of using FMT products to treat *C. difficile*.

The procedure for conducting the Fecal Microbiota Transplant can be performed in different ways, each of which has been evaluated by my physician for my particular medical status. I understand that a solution of donor stool is either:

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

The procedure (colonoscopy, sigmoidoscopy, naso-gastric tube (NGT) placement, or enema) used for the fecal microbiota transplant will be explained and provided in a separate consent.

This authorization is given with the understanding that any procedure and recuperation involves some risks and hazards. According to American College of Gastroenterologists 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. Other potential risks include:

- transmission of infectious organisms (bacterial, viral, fungal, parasitic) contained in the 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, and that unforeseen risks do exist which may not have been discussed with me. Complications may occur even when a procedure is properly performed. Patients critically ill with severe *C. difficile* have a high risk of dying from this condition regardless of what treatment is used and fecal transplant may not be successful.

DONOR RISKS

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 have chosen my donor to be _____ whose stool has been screened as below. The donor has responded to screening questions as part of the eligibility requirements to be a stool donor.
- I choose an un-named donor whose stool has been screened as outlined below. The donor has responded to screening questions as part of the eligibility requirements to be a stool donor.

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Donors are screened and undergo testing for many common communicable diseases to ensure that the procedure is done as safely as possible, but it is not possible to test donors for all possible organisms and some infections may be undetectable. The donor has verified that he/she has no history of:

- high risk sexual behavior,
- use of illicit drugs,
- tattoos or piercings in the last 6 months,
- incarceration,
- known communicable disease,
- metabolic syndrome (overweight, high blood pressure, fatty liver and/or diabetes).

The donor/donor sample was screened for:

- Human Immunodeficiency virus (HIV) 1/2, hepatitis A IgM, hepatitis B (HBsAg), hepatitis C antibody, syphilis
- Human T- lymphotropic virus (HTLV) I/II if from an endemic region or deemed high risk by the provider.
- Stool tested for: detection of ova, parasites, Giardia, C. difficile toxin, rotavirus, and vancomycin resistant Enterococcus (VRE), methicillin resistant S. aureus (MRSA), Salmonella, Shigella, E.coli O157 H7, Yersinia, Listeria monocytogenes, Vibrio cholera, Vibrio parahemolyticus, Helicobacter pylori and Campylobacter. Donor sample may also be tested for norovirus and adenovirus if the donor is considered at increased risk of carriage by the provider.
- History of any type of active cancer or autoimmune disease.
- History of risk factors for acquisition of HIV, syphilis, Hepatitis B, Hepatitis C, prion infection or any neurological disease
- History of gastrointestinal comorbidities, e.g., inflammatory bowel disease, irritable bowel syndrome, chronic constipation or diarrhea
- Receipt of blood transfusion from a country other than US/Canada in preceding 6 months
- Antibiotic use or any systemic immunosuppressive agents in the 3 months prior to stool donation
- Receipt of any type of live vaccine within 3 months prior to stool donation
- Ingestion of nut or shell fish 3 days preceding donation if the recipient has known allergies to these food.
- Chemotherapy in the last 3 months

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.

ASSISTANTS

I understand that some aspects or important tasks of this procedure may be performed by healthcare providers other than the primary physician/provider (i.e., residents, medical students, physician assistants, advanced practice registered nurses, etc.). I understand that the care provided by these assistants will be within the scope of their practice or privileges granted and will be performed in accordance with the state law and the hospital's policies and, in the case of residents or medical students, based on their skill set and under the supervision of their responsible surgeon.

PATIENT CONSENT

I understand that no guarantees have been made to me regarding the results of this operation/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 adequate knowledge upon which to make an informed decision about undergoing the proposed operation/procedure. I have read and fully understand this form and I voluntarily authorize and consent to this operation/procedure.

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

Patient Name (Please Print)

Patient Signature

Date Signed

**INFORMED CONSENT FOR FECAL MICROBIOTA
TRANSPLANTATION**

Printed Name of Legal Representative Signature of Legal Representative Date Signed
(if applicable)

Relationship of Legal Representative to Patient

Printed Name of Interpreter Signature of Interpreter ID #
(if applicable)

Printed Name of Physician Performing Procedure Signature of Physician Performing Procedure Date Signed