

## Consent for Fecal Microbiota Transplantation (FMT)

1. I \_\_\_\_\_ or \_\_\_\_\_ for  
(Patient name) (Legal guardian)

\_\_\_\_\_ authorize the performance of FMT to be administered by  
(Patient name)

Dr. \_\_\_\_\_ and/or his assistants or designees.

2. I understand that FMT may be performed through a nasoduodenal tube inserted via the nose into the first part of the small intestine. FMT is administered to treat chronic (recurrent) or severe *Clostridium difficile* infection (CDI), an inflammatory condition of the large intestine (colon). FMT consists of introducing normal bacterial flora contained in stool collected from a healthy donor into the diseased colon where the flora is missing.

3. The nature, purpose, risks and benefits of this procedure has been discussed with me. I understand that the donor will be screened for a possible history of exposure to a 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 have discussed all alternative treatments for recurrent CDI with my physician, including various antibiotic options, surgery, or no treatment at all, and understand the risk and benefits of the alternative treatments. I understand that my condition could improve, worsen or stay the same with each of the alternative treatment options, including FMT. I understand that individuals who are severely ill with FMT have a high risk of dying from their illness, regardless of what treatment is used. I understand that at the current time the cumulative experience with FMT is limited and that FMT is therefore considered investigational.

In choosing to proceed with FMT I understand that a solution of donor stool will be infused into the beginning of my small intestinal tract via a hollow tube inserted through the nose OR into my colon through a tube with an inflatable balloon at the tip.

4. The risks of FMT procedure has been discussed in detail with me. I understand that complications may arise as a result of FMT. Complications may include but are not limited to:

- Transmission of infectious organisms contained in stool (bacteria, viruses, fungi, parasites)
- Allergic reactions to constituents (antigens) contained in the donor stool
- Mechanical complication related to the insertion and presence of the tube, such as potential perforation of the lining of the esophagus, stomach, or duodenum, or aspiration of stool into the lungs (for the nasoduodenal tube), or trauma to the rectum and perforation of the colon (for the enema).

I understand that the outline above is not a complete list of potential complications, and that unforeseen risks that have not been discussed with me may exist.

5. I understand that the above risks, as well as other complications, may require additional procedures or operations and that these issues have been discussed with me. I give my consent to undergo additional procedures which my physician deems necessary.

6. I am aware that the practice of medicine is not an exact science. I acknowledge that no guarantee or promise can be made by my physician as to the outcome of my treatment.

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

Signature: \_\_\_\_\_ Date \_\_\_\_\_ Time \_\_\_\_\_  
(Patient or legal guardian)

Signature: \_\_\_\_\_ Date \_\_\_\_\_ Time \_\_\_\_\_  
(Stool donor)

**Provider's Acknowledgement:**

I confirm that I have fully explained to the above patient or legal representative the nature and purpose of Fecal Microbiota Transplantation and the possible risks and benefits of FMT and treatment alternatives.

Printed name: \_\_\_\_\_ Signature: \_\_\_\_\_  
(Provider) (Provider)

Date: \_\_\_\_\_ Time: \_\_\_\_\_

**Interpreter's Acknowledgement (when applicable):**

I confirm that consent to proceed with FMT, as explained above, has been given by this patient or legal guardian.

Printed name: \_\_\_\_\_ Signature: \_\_\_\_\_  
(Interpreter) (Interpreter)

Date: \_\_\_\_\_ Time: \_\_\_\_\_