Missouri Baptist
MEDICAL CENTER
BJC HealthCare

CONSENT FOR PROCEDURE (F.M.T.)

Patient Identification Label

I authorize _____ to perform the following procedure(s):

FECAL MICROBIOTA TRANSPLANT (F. M.T.)

1) I understand that I may need urgent procedures that are unanticipated. I consent to the performance of any additional procedures determined during my original procedure to be in my interests and if delayed might cause additional harm.

2) I understand that other qualified practitioners may be chosen to do or help with these procedures. All qualified practitioners will only perform the tasks that are within their scope of practice and for which they have been granted clinical privileges.

3) I understand my diagnosis/condition to be: **CLOSTRIDIUM DIFFICILE INFECTION (C. Diff).**

4) It has been explained to me that the transfer of stool (fecal) products may be beneficial in the judgment of my attending physician.

5) **I understand the procedure will be performed by putting 1-2 cups of liquefied and filtered stool into my colon during a colonoscopy. This stool will come from a donor, chosen by me, who has been checked for:**

   Hepatitis A, Hepatitis B, Hepatitis C, Human Immunodeficiency Virus or HIV (the cause of AIDS), Syphilis, Clostridium difficile, parasites and other intestinal diseases. This testing greatly reduces, but does not eliminate, the possibility that I might acquire one or more of these transmissible diseases. The donor has verified that he/she has no history of high risk sexual behavior, use of illicit drugs, tattoos or piercings or incarceration in the last 6 months, known communicable disease, inflammatory bowel disease, gastrointestinal cancer, and chemotherapy or antibiotics in the last 3 months. I understand that although the individual who donates the stool has been screened for the diseases listed above, there is still the remote chance I could be infected with one of these diseases or another unknown disease. The risks involved have been explained to me. These risks include contracting transmissible diseases (see above), as well as possible allergic and immune responses. Autoimmune diseases (Sjogren's and other lupus-like diseases) have been reported after this procedure.

6) I understand that I designated an individual of my choice to donate their stool for transfer. The stool from the donor has previously been tested and screened prior to today. I understand that the special donations are not completely free of risks and they may not satisfy all of my requirements.

7) No assurances or guarantees have been made to me about the outcome of the fecal transplant or the fitness or quality of the stool I am to be given.

8) I have been told that this is a new treatment that has limited evidence based information in the literature. This treatment I am agreeing to have is considered investigational and experimental. Significant risks from the transplant itself are believed to be rare although there is the remote possibility of under reported infectious or autoimmune complications. These would include but are not limited to hepatitis, allergic reactions, fever, diarrhea, abdominal pain, or other under reported infections or complications.

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CONSENT FOR PROCEDURE (F.M.T.)

9) I understand that these risks exist despite the fact that the stool has been carefully tested. I understand the alternatives to the proposed procedure to be prolonged antibiotic treatment. I understand the risks related to the alternative.

10) If this transplant is not effective, it can be repeated. I understand I would be responsible for finding this donor and the cost of testing this donor stool. There is a chance that FMT may not eliminate my C. Difficile infection and it may continue to progress or require antibiotics or other therapy including surgery.

11) I understand that photographs and/or electronic recordings may occur during my procedure and may be used for internal performance improvement or education purposes.

12) I understand that any tissues or parts removed during my procedure may be maybe disposed of by the hospital or used for any lawful purpose including education and research.

13) I agree to return calls from my gastroenterologist and Missouri Baptist Hospital after the procedure at one month, 3 months, and one year and in the event I am hospitalized elsewhere within 3 months, to provide my gastroenterologist with a copy of my discharge summary and stool studies.

14) I have read the above information and understand it. I have had an opportunity to discuss this information with my physician and ask questions. All of my questions have been answered.

I consent to a colonoscopy and to the administration of donor stool (F. M. T.) into my colon to try to help alleviate my current Clostridium difficile infection. I agree to receive the care, treatment, or services listed on this consent. I understand this transfer of donor stool may not alleviate my symptoms.

Patient Signature	Date	Time	Witness to Signature

If the patient does not sign, indicate relationship to patient:

Patient Signature/Representative	Date	Time	Relationship to Patient

I have explained the procedures stated on this form, including the possible risks, complications, alternative treatments (including no treatment) and anticipated results to the patient and/or his/her representative. The patient and/or the representative has communicated to me that they understand the contents of this form.

Signature of Physician	Date	Time

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MBMC 13-3343-1027

Missouri Baptist
MEDICAL CENTER
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Patient Identification Label

FECAL DONOR CONSENT FORM

I, _____, hereby consent to be considered as a stool donor for fecal transplant. I understand that I will be tested for contagious diseases that may be present in my stool or in my blood. I understand that these tests are being performed to determine if I am a suitable stool donor candidate. I also understand that some of these diseases, if found, will be reported to the St. Louis County Health Department. These tests are not covered by any insurance plan. I am aware that positive test results may need to be reported to state and national agencies.

The Red Cross will test for the following diseases if you donate blood. A special form will be faxed to get the results to the doctor to see if you are a safe donor. Stool studies are performed at the hospital. You may prefer to have all your tests performed at the hospital instead of going to the Red Cross. The following diseases will be tested for all donors.

- Hepatitis A, B and C
- HIV EIA (AIDS virus)
- Syphilis

If you are positive for any of these tests, it will be reported to the Health Department.

At the hospital, your stool will be tested for Clostridium difficile, Giardia, parasites, Shigella, Salmonella and Campylobacter. If your stool test is positive for Shigella, Salmonella or Campylobacter, it will be reported to the Health Department. All results are part of a medical records with the doctor's office that ordered the tests and thus might be subject to inspection by your insurance company if you disclose that these tests were performed.

I have read the information above and I consent to have my blood and stool tested for the above listed diseases as well as any other diseases my physician deems necessary to determine if I am a suitable stool donor. I understand some or my entire test results may be shared with the St. Louis Health Department and my insurance company.

Signature: _____ Date: _____ Time: _____

Printed Name: _____ _____
Witness to Signature

DO NOT WRITE BELOW THIS LINE

MBMC 13-3343-1026

Missouri Baptist
MEDICAL CENTER
BJC HealthCare

FECAL TRANSPLANT DONOR QUESTIONNAIRE

Patient Identification Label

Name: _____ Date: _____

Contact Information: _____ Date of Birth: _____

☐Y ☐N	Have you ever been diagnosed with hepatitis A?
☐Y ☐N	Have you ever been diagnosed with Hepatitis B?
☐Y ☐N	Have you ever been diagnosed with Hepatitis C?
☐Y ☐N	Have you ever been diagnosed with an intestine infection called C. difficile?
☐Y ☐N	Have you ever been diagnosed with Giardia or another parasite?
☐Y ☐N	Have you received antibiotics within the past 90 days for any reason?
☐Y ☐N	Have you had any tattoos or body piercing within the past 180 days?
☐Y ☐N	Have you been in jail for any reason in the past 180 days?
☐Y ☐N	Have you ever been diagnosed with or treated for syphilis or gonorrhea?
☐Y ☐N	Have you ever been diagnosed with HIV/AIDS or other immune system problem?
☐Y ☐N	Have you had unprotected sex with someone of the same gender, even once?
☐Y ☐N	Have you ever received money, drugs or other payment for sex?
☐Y ☐N	Do you have diabetes?
☐Y ☐N	Have you ever been diagnosed with any inflammatory bowel disease such as Crohn's or Ulcerative colitis?
☐Y ☐N	Have you ever been diagnosed with any type of cancer?
☐Y ☐N	Have you taken prednisone or other immune suppressing medication (including chemotherapy) in the past 90 days?
☐Y ☐N	Have you ever had an infection called H. pylori (a stomach infection)?
☐Y ☐N	Do you have chronic (longstanding) diarrhea or constipation?
☐Y ☐N	Have you been diagnosed by a doctor with chronic fatigue syndrome?
☐Y ☐N	Have you been diagnosed by a doctor with irritable bowel syndrome?
☐Y ☐N	Have you been diagnosed by a doctor with an autoimmune disease?
☐Y ☐N	Have you been diagnosed by a doctor with metabolic syndrome or significant obesity?
☐Y ☐N	Have you traveled outside of the United States or Canada in the past 5 years?
☐Y ☐N	Have you ever traveled to Africa or Central America?
☐Y ☐N	Have you ever traveled to Japan?

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Patient Identification Label

FECAL TRANSPLANT
DONOR QUESTIONNAIRE

Name: _____

☐Y ☐N	Have you ever received a blood transfusion in the United Kingdom (England) or France?
☐Y ☐N	Have you ever had a positive test for HIV/AIDS virus?
☐Y ☐N	Have you ever used clotting factor concentrates (for hemophilia or other blood disorders)?
☐Y ☐N	Have you ever been told by a doctor that you have malaria, Babesiosis or Chagas disease?
☐Y ☐N	Have you ever been told by a doctor that you have a bleeding disorder (such as hemophilia or von Willebrand's disease) or blood disease (leukemia, multiple myeloma, polycythemia)? These are very rare diseases that are diagnosed by a physician.
☐Y ☐N	Have you ever had sexual contact with anyone who was born in or lived in Africa?
☐Y ☐N	Have any of your relatives had Jacob Creutzfeldt disease (a rare brain disorder)?
☐Y ☐N	Have you ever received a dura mater (brain covering) graft? This is a very rare surgery.
☐Y ☐N	Have you ever used needles to take drugs or any substance not prescribed by a doctor?

If you answered Yes to any of the questions above, please explain. Give dates and treatment.

Signature: _____ Date: _____

DO NOT WRITE BELOW THIS LINE

MBMC 13-3343-1025