Affix Patient Label	
Patient Name:	Date of Birth:

Informed Consent: Human Fecal Microbiota Transplant

This information is given to you so that you can make an informed decision about having a **Human Fecal Microbiota Transplant**.

Reason and Purpose of the Procedure:

Fecal Microbiota Transplant is done to treat Clostridium difficile colitis infection. The first treatment for this disease is an antibiotic. When antibiotic treatment fails, we can try other things like fecal transplant. The C. difficile in the intestine is replaced with normal bacteria. Normal bacteria can be donated by another person. The donor must be healthy. The donor's bacteria are put into my intestine through a tube that is placed in the nose and goes into the intestine. It can also be placed during a colonoscopy.

Benefits of this procedure:

You might receive the following benefits. Your doctor cannot promise you will receive any of these benefits. Only you can decide if the benefits are worth the risk.

- Studies show that this treatment cures the disease in over 90% of patients.
- Colitis will usually improve within a day after treatment.

Risks of procedure:

No procedure is completely risk free. Some risks are well known. There may be risks not included in the list that your doctor cannot expect.

General risks of fecal transplantation:

- The fecal transplant may not work. It may need to be repeated.
- Infection. This may require antibiotics.
- Allergic Reaction. This may require medications to control symptoms.

Risks Specific to You:

____

____

____

____

Alternative Treatments:

Other choices:

- Your doctor can discuss other treatments for your symptoms.

If you choose not to have this treatment:

- You may need more antibiotics.

General Information:

During this procedure, the doctor may need to perform more or different procedures than I agreed to.

During the procedure the doctor may need to do more tests or treatment.

Tissues or organs taken from the body may be tested. They may be kept for research or teaching. I agree the hospital may discard these in a proper way.

Students, technical sales people and other staff may be present during the procedure. My doctor will supervise them.

Pictures and videos may be done during the procedure. These may be added to my medical record. These may be published for teaching purposes. My identity will be protected.

BRONSON

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By signing this form, I agree:

- I have read this form or had it explained to me in words I can understand.
- I understand its contents.
- I have had time to speak with the doctor. My questions have been answered.
- I want to have this procedure: **Human Fecal Microbiota Transplant** ____

  ____
- I understand that my doctor may ask a partner to do the procedure.
- I understand that other doctors, including medical residents or other staff may help with procedure. The tasks will be based on their skill level. My doctor will supervise them.

Provider: This patient may require a type and screen or type and cross prior to surgery. If so, please obtain consent for blood/products.

Patient Signature: ____ Date: __________ Time: ___________

Relationship: ☐ **Patient** ☐ **Closest relative (relationship)** ___________________________ ☐ **Guardian**

Interpreter's Statement: I have interpreted the doctor's explanation of the consent form to the patient, a parent, closest relative or legal guardian.

Interpreter's Signature: ______________________________ ID #: __________ Date: __________ Time: ___________

For Provider Use ONLY:

I have explained the nature, purpose, risks, benefits, possible consequences of non-treatment, alternative options, and possibility of complications and side effects of the intended intervention, I have answered questions, and patient has agreed to procedure.

Provider signature: ____ Date: ___________ Time: ___________

Teach Back:

I have explained the nature, purpose, risks, benefits, possible consequences of non-treatment, alternative options, and possibility of complications and side effects of the intended intervention, I have answered questions, and patient has agreed to procedure.

Patient shows understanding by stating in his or her own words:

_____ Reason(s) for the treatment/procedure: ____

_____ Area(s) of the body that will be affected: ____

_____ Benefit(s) of the procedure: ____

_____ Risk(s) of the procedure: ____

_____ Alternative(s) to the procedure: ____

OR

_____ Patient elects not to proceed: ______________________________ Date: ___________ Time: ___________
(Patient signature)

Validated/Witness: ____ Date: ___________ Time: ___________