NCT Number:	NCT04486326
Official Title:	Crofelemer for Functional Diarrhea
Document Type:	ICF
Document Date:	05/08/2023

FOR CCI USE ONLY
Approved by the Beth Israel Deaconess Medical Center Committee on Clinical Investigations:

Consent Approval Date: 05/09/2022

Protocol Number: 2020P000464

BETH ISRAEL DEACONESS MEDICAL CENTER
APPROVED BY THE COMMITTEE ON CLINICAL INVESTIGATIONS
05/08/2023
APPROVAL EXPIRATION DATE

INFORMED CONSENT FORM TO TAKE PART IN A RESEARCH STUDY

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: Crofelemer for functional diarrhea
PRINCIPAL INVESTIGATOR: Anthony Lembo, MD
PROTOCOL NUMBER: 2020P-000464

KEY INFORMATION

The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?
We invite you to take part in a research study because you have functional diarrhea.

What should I know about a research study?
- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- Your participation is completely voluntary.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- Your refusal to participate will not result in any consequences or any loss of benefits that you are otherwise entitled to receive.
- You can ask all the questions you want before you decide.
- If you choose not to take part, or if you leave the study, your decision will in no way harm your relationship with any member of the research team or any other individuals at Beth Israel Deaconess Medical Center.

Why is this research being done?
This study is being done to test the efficacy of crofelemer in treating functional diarrhea.

How long will the research last and what will I need to do?
We expect that you will be in this research study for ten weeks.

You will be asked to have blood drawn, complete symptom questionnaires for the duration of the study, and take crofelemer (or placebo) twice daily.

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: Crofelemer for functional diarrhea
PRINCIPAL INVESTIGATOR'S NAME: ANTHONY LEMBO, MD
PROTOCOL #: **2020P-000464**

BETH ISRAEL DEACONESS MEDICAL CENTER
APPROVED BY THE
COMMITTEE ON CLINICAL INVESTIGATIONS
05/08/2023
APPROVAL EXPIRATION DATE

If you complete the study treatment period of the study, you'll have the opportunity to enter an open-label extension study where you will receive the active study drug (crofelemer) and there is no possibility of receiving a placebo.

More detailed information about the study procedures can be found under ***"DESCRIPTION OF STUDY DETAILS".***

Is there any way being in this study could be harmful to me?
The most common side effect from taking crofelemer is upper respiratory tract infection.

More detailed information about the risks can be found under ***"RISKS AND DISCOMFORTS".***

Will being in this study help me in any way?
We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include reduction in symptoms of functional diarrhea.

What happens if I do not want to be in this research?
Participation in research is completely voluntary. You can decide to participate or not to participate.

Your alternative to participating in this research study is to seek other available treatments for functional diarrhea from your doctor.

DETAILED INFORMATION SECTION

Please read this consent form carefully and ask the investigators or study staff to explain any words or information that you do not clearly understand. Once you read this consent form and understand what your participation in this study will involve, you will be asked to sign this form if you wish to take part. You will be given a signed copy of the form to keep for your records.

DISCLOSURE OF SPECIAL INTERESTS OF BIDMC AND INVESTIGATORS

This study is being conducted by Dr. Anthony Lembo. Napo Pharmaceuticals, Inc. is providing crofelemer at no cost. BIDMC or Dr. Lembo have no additional interests in this research project.

WHOM TO CONTACT IF YOU HAVE QUESTIONS OR PROBLEMS

If you have any questions, concerns or complaints about this research or experience any problems, you should contact Dr. Anthony Lembo at [617] 667-2138.

PURPOSE

The drug involved in this study, crofelemer is investigational. This means that the study drug is still being tested in research studies and is not approved by the Food and Drug Administration [FDA] for the way it is being used in this study. This particular investigational agent, crofelemer, has been approved by the FDA for use in noninfectious diarrhea in adults living with HIV, but we do not yet know if it is useful or safe as a treatment for functional diarrhea not caused by HIV.

The purpose of this study is to evaluate the efficacy of crofelemer in treating functional diarrhea.

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: Crofelemer for functional diarrhea
PRINCIPAL INVESTIGATOR'S NAME: ANTHONY LEMBO, MD
PROTOCOL #: **2020P-000464**

BETH ISRAEL DEACONESS MEDICAL CENTER
APPROVED BY THE
COMMITTEE ON CLINICAL INVESTIGATIONS
05/08/2023
APPROVAL EXPIRATION DATE

STUDY PARTICIPANTS

You have been asked to be in the study because you have functional diarrhea.

Approximately 120 people will take part in this study at Beth Israel Deaconess Medical Center.

DESCRIPTION OF STUDY DETAILS

The study will consist of a 2-week screening phase, a 4-week double-blind study treatment phase, followed by a 4 week open-label extension for both groups.

If you agree to be in this study, you will be in this research study for about 10 weeks and you will take the active study drug (crofelemer) for either 4 weeks or 8 weeks.

After you sign the consent form, the following things will happen:

1. Screening Procedures: Screening procedures are tests and procedures that will be done to determine if you are eligible to take part in the research study. For this research study, the screening procedures include:

   Visit 1 (This visit will last approximately one hour)
   - We will obtain your medical history including what you have used to treat your symptoms.
   - We will obtain your vitals including height, weight, blood pressure, temperature, heart rate.
   - We will draw your blood to test for bile acid malabsorption (BAM) and other potential markers of diarrhea.
   - For the duration of the study, you will complete questionnaires every day about your GI symptoms including medication use, abdominal discomfort, stool consistency and frequency. The questionnaires are done online via a secure website.
   - If you qualify for the study based on your GI symptoms, you will have a second visit about two weeks later.

2. Randomization Procedures: It is not clear at this time which of the study treatments in this study would be better for you. For this reason, the study treatment plan offered to you will be picked by chance [like the flip of a coin]. You will not be able to choose which study treatment you receive. The chances of receiving either of the study treatments are approximately equal. After the randomization, you will be assigned to one of the following groups:

   A) 125mg crofelemer twice daily

   B) placebo twice daily

   Depending upon the group to which you are assigned, you may receive a placebo instead of the study drug. A placebo is an inactive pill that looks like the study drug, but a placebo contains no active medication. Placebos are used to help determine if the results of the study are truly from the study drug. You will not know whether you will be receiving the study drug or the placebo. However, this information can be learned in case of an emergency.

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: Crofelemer for functional diarrhea
PRINCIPAL INVESTIGATOR'S NAME: ANTHONY LEMBO, MD
PROTOCOL #: **2020P-000464**

BETH ISRAEL DEACONESS MEDICAL CENTER
APPROVED BY THE
COMMITTEE ON CLINICAL INVESTIGATIONS
05/08/2023
APPROVAL EXPIRATION DATE

Neither you nor your research doctor will know which drug you are receiving. However this information can be learned in case of an emergency.

3. Research Procedures: If you qualify to take part in this research study, you will undergo these research procedures:

Visit 2 (This visit will last approximately one hour)
- We will ask you if you have had any changes in your medical history
- We will obtain your vitals including weight, blood pressure, temperature, heart rate.
- You will receive study drug for the next four weeks.
- You will continue to complete daily questionnaires of your GI symptoms and use of medication.

Visit 3 (This visit will occur about four weeks after Visit 2 and last approximately one hour)
- We will ask you if you have had any changes in your medical history
- We will obtain your vitals including weight, blood pressure, temperature, heart rate.
- We will draw your blood to test for potential markers of diarrhea.
- You will be asked to return your unused study medication.
- If you choose, you will be given four weeks of crofelemer 125mg twice daily for the next four weeks.
- You will continue to complete daily questionnaires of your GI symptoms and use of medication.

Visit 4 (This visit will occur about four weeks after Visit 3 and last approximately one hour)
- We will ask you if you have had any changes in your medical history
- We will obtain your vitals including weight, blood pressure, temperature, heart rate.
- You will be asked to return your unused study medication.

You will be allowed to continue on your anti-diarrheal mediations for the duration of the study, as long as they remain stable and do not exceed the recommended dosage.

Individual Research Results
Your study doctor will disclose any clinically relevant research results to you, including any significant results of the bile acid malabsorption.

Information and Biological Samples
Your information and biological samples will be used by the researchers involved in this study to conduct the research. The consent form provides information on who will have access to identifiable information and identifiable biological samples during the study. We also want you to know that your information or biological samples may be stripped of any identifiers (for example your name, medical record number or date of birth) and used for future research studies or distributed to another researcher for future research studies without additional informed consent. BIDMC researchers or other third party researchers may use your information and samples in other scientific research, product testing or commercial development. It is unknown whether a product will ultimately be developed from the research described in this consent form or from any such work that may be performed by BIDMC or other third parties receiving your information or biological samples. In signing this

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: Crofelemer for functional diarrhea
PRINCIPAL INVESTIGATOR'S NAME: ANTHONY LEMBO, MD
PROTOCOL #: **2020P-000464**

BETH ISRAEL DEACONESS MEDICAL CENTER
APPROVED BY THE
COMMITTEE ON CLINICAL INVESTIGATIONS
05/08/2023
APPROVAL EXPIRATION DATE

consent form, you are acknowledging and voluntarily consenting to the possibility that your information and biological samples may be used for commercial purposes. For example, your samples and information may be used to develop a new product or medical test to be sold. BIDMC and other researchers may benefit if this happens. There are no plans to pay you if your samples and information are used for this purpose.

If your identifiers are removed, we will not be able to destroy or remove your information or biological samples from distributed information or samples. As part of this research program and as further explained in this form, samples of your tissue and/or information about your medical history may be provided to other researchers and/or outside collaborators.

Storing of Identifiable Information and Samples for Future Use

At the completion of this research, we would like to store any remaining sample(s) and information collected from or about you for this research for possible future use. Your sample will be stored with identifiers, such as your name or medical record number. The remaining samples and information may be stored indefinitely and may be used for future research of diarrhea. The research staff will have a list to know which sample is linked to which participant and this list will be kept confidential in a secure location. If the research investigator distributes your samples to other researchers or institutions, they will be labeled with a research code without identifiers so that you cannot be identified by the other researchers or institutions.

If you have questions about storing samples or information, or would like to request that samples or information be removed from storage, please let us know. It is not always possible to remove samples or information from storage or to retrieve samples or information that have/has already been sent to other investigators.

I agree to allow my samples and information to be stored and used for future research as described above: (please check and initial one to indicate your choice)

_____ YES _____ NO

RISKS AND DISCOMFORTS

Crofelemer is FDA-approved for patients with HIV infection. Those patients are at risk for the following side effects listed in this section. As a result of your participation in this study, you are at risk for side effects listed in this section. You should discuss these with the investigator and with your regular doctor if you choose.

More Common

- upper respiratory tract infection

Less Common

- bronchitis
- gas
- increased bilirubin or ALT (markers of your liver health)
- nausea
- back pain

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: Crofelemer for functional diarrhea
PRINCIPAL INVESTIGATOR'S NAME: ANTHONY LEMBO, MD
PROTOCOL #: **2020P-000464**

BETH ISRAEL DEACONESS MEDICAL CENTER
APPROVED BY THE
COMMITTEE ON CLINICAL INVESTIGATIONS
05/08/2023
APPROVAL EXPIRATION DATE

- joint or muscle pain
- urinary tract infection
- common cold
- hemorrohoids
- anxiety
- abdominal bloating

BLOOD DRAW RISK
The risks and discomforts of blood drawing from a vein include the possibility of pain or bruising at the site of the blood draw, occasional feeling of lightheadedness, and rarely, infection at the site of the blood draw.

RISKS ASSOCIATED WITH SURVEYS/QUESTIONNAIRES
Some of the questions we will ask as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions and you may take a break at any time during the study. You may stop your participation in the study at any time.

PREGNANCY
Because of the effects of this (these) study medication(s) on the developing fetus is (are) not known, you may not participate in this study if you are pregnant. You will be required to take a pregnancy test to verify that you are not pregnant before receiving your first dose of the study medication(s).

For the duration of the study, if you are engaged in sexual activity that could cause you or your partner(s) to become pregnant, you and your partner(s) must agree to use a highly effective method of birth control or abstain from sexual activity that could cause you or your partner(s) to become pregnant.

The methods of highly effective birth control for this study are below:
1. Contraceptive implant, such as Nexplanon or Implanon
2. Levonorgestrel or copper intrauterine device (IUD), such as Mirena, Skyla, ParaGard or Liletta
3. Permanent female sterilization, such as tubal ligation or Essure with confirmed tubal occlusion
4. Male partner(s) has had a vasectomy more than three months before study enrollment
5. Oral contraceptives pill, patch or ring
6. Injectable contraception, such as Depo Provera
7. Consistent use of a barrier method, such as diaphragm with spermicide or condoms

If you believe you have become pregnant while participating in this study, you must inform your study doctor immediately

<u>Loss of confidentiality</u>
There is the potential for loss of confidentiality by participating in this study. Every effort will be made to protect the confidentiality of your identifiable information.

CONFIDENTIALITY
Information learned about you during this research program will be maintained confidentially by the research staff as described in this form.

Information learned from your participation in this study and from your medical record may be reviewed and

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: Crofelemer for functional diarrhea
PRINCIPAL INVESTIGATOR'S NAME: ANTHONY LEMBO, MD
PROTOCOL #: **2020P-000464**

BETH ISRAEL DEACONESS MEDICAL CENTER
APPROVED BY THE
COMMITTEE ON CLINICAL INVESTIGATIONS
05/08/2023
APPROVAL EXPIRATION DATE

photocopied by the Food and Drug Administration (FDA) and/or other federal and state regulatory agencies, accreditation agencies, the Committee on Clinical Investigations, the Human Subjects Protection Office and others involved in research administration of the Beth Israel Deaconess Medical Center. Information resulting from this study and from your medical record may be used for research purposes and may be published; however, you will not be identified by name in such publications.

MEDICAL RECORD

The information collected during this research may become part of your medical record, if the information is relevant to the care you receive at Beth Israel Deaconess Medical Center. Medical records are considered permanent records; therefore, information cannot be deleted from the record. Medical records are available to health care professionals at Beth Israel Deaconess Medical Center and may be reviewed by staff when carrying out their responsibilities, as well as by external parties such as health care insurers and others in certain circumstances. If you are not currently a patient at Beth Israel Deaconess Medical Center and do not have a medical record at Beth Israel Deaconess Medical Center, one may be created for you for your participation in this research. You may also be required to register as a patient of Beth Israel Deaconess Medical Center in order to participate in this research.

POSSIBLE BENEFITS

It is not possible to predict whether you will benefit directly from participation in this study. However, your participation may help others in the future as a result of knowledge gained from the research.

OTHER AVAILABLE OPTIONS

Taking part in this study is voluntary. Instead of being in this study, you have the option to seek other available treatments for functional diarrhea from your doctor.

IF YOU DECIDE NOT TO TAKE PART IN THE STUDY

Participation in this study is voluntary. You have the right to decide not to take part in this study. If you choose to participate, you have the right to leave the study at any time. Your decision to not participate will not result in any penalties or loss of benefits to you. The investigators will tell you about new information that may affect your willingness to stay in this study.

If you decide not to participate in the study or decide to leave the study early, your decision will not affect your relationship with the research team or any other individual at Beth Israel Deaconess Medical Center.

INVESTIGATORS RIGHT TO STOP THE STUDY

The investigators have the right to end your participation in this study if they determine that you no longer qualify to take part, or if it would be dangerous for you to continue, or if you do not follow study procedures as directed by the investigators. Beth Israel Deaconess Medical Center or the funding source may stop the study at any time.

COSTS AND/OR PAYMENTS TO YOU

COSTS COVERED BY STUDY

You will not be charged for any of the tests, procedures, or medications that are part of this research study. You will receive $50 for completion of Visit 1, $50 for completion of Visit 2, and $100 for completion of Visit 3 (up to $200 total). It may take up to 8 weeks for you to receive payment by check.

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: Crofelemer for functional diarrhea
PRINCIPAL INVESTIGATOR'S NAME: ANTHONY LEMBO, MD
PROTOCOL #: **2020P-000464**

BETH ISRAEL DEACONESS MEDICAL CENTER
APPROVED BY THE
COMMITTEE ON CLINICAL INVESTIGATIONS
05/08/2023
APPROVAL EXPIRATION DATE

COST OF RESEARCH RELATED INJURY:
If you are injured as a direct result of your participation in this study you should contact the investigator at the number provided under the section "Whom to Call if You Have Questions" in this form. You will be offered the necessary care to treat your injury. You or your insurance company will be billed for medical care and/or hospitalization related to this injury. You will be responsible for all co-payments and deductibles required under your insurance. BIDMC will consider reimbursement of injury related expenses not covered by your insurance on a case-by-case basis. At this time there is no plan to reimburse you for items such as lost wages or lost time from work. By signing this consent form you have not given up any legal rights.

OTHER IMPORTANT INFORMATION
A description of this clinical trial will be available on www.ClinicalTrials.gov as required by U.S. law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

AUTHORIZATION FOR USE AND DISCLOSURE OF YOUR PROTECTED HEALTH INFORMATION
As part of this study, we will be collecting, using and sharing with others information about you. Please review this section carefully as it contains information about the federal privacy rules and the use and disclosure of your information.

DESCRIPTION OF PROTECTED HEALTH INFORMATION [PHI]
By signing this informed consent document, you are allowing the investigators and other authorized personnel to use and disclose health information about you. This may include information about you that already exists (for example: your medical records and other sources of health information, demographic information, the results of any laboratory tests as well as any new information generated as part of this study. This is your Protected Health Information.

PEOPLE/GROUPS AT BIDMC WHO WILL SHARE AND USE YOUR PROTECTED HEALTH INFORMATION
Your Protected Health Information may be shared with and used by investigators working on this study, including the supporting research team (such as research assistants and coordinators, statisticians, data managers, laboratory personnel, pharmacy personnel, and administrative assistants), and may also be shared with and used by other health care providers at BIDMC who have treated you in the past and have information relevant to the research, or who provide services to you in connection with the research. Your Protected Health Information may also be shared with the members and staff of the Committee on Clinical Investigations of Beth Israel Deaconess Medical Center, which is responsible for reviewing studies for the protection of the research subjects, so that it can carry out its oversight responsibilities with respect to the study.

PEOPLE/GROUPS OUTSIDE OF BIDMC TO WHOM YOUR PROTECTED HEALTH INFORMATION WILL BE DISCLOSED (SHARED) AND WHO MAY USE YOUR PROTECTED HEALTH INFORMATION
We will take care to maintain confidentiality and privacy about you and your Protected Health Information. We may share your Protected Health Information with the following groups so that they may carry out their duties related to this research study:

- Other research collaborators and supporting research team members taking part in this study
- Any external health care providers who provide services to you in connection with this research
- Laboratories not affiliated with BIDMC that are involved in conducting tests related to the research
- Statisticians and other data monitors not affiliated with BIDMC

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: Crofelemer for functional diarrhea
PRINCIPAL INVESTIGATOR'S NAME: ANTHONY LEMBO, MD
PROTOCOL #: **2020P-000464**

BETH ISRAEL DEACONESS MEDICAL CENTER
APPROVED BY THE
COMMITTEE ON CLINICAL INVESTIGATIONS
05/08/2023
APPROVAL EXPIRATION DATE

- The members and staff of any other IRBs (beyond the BIDMC Committee on Clinical Investigations) that oversee the research
- Centralized data collectors
- Your health insurance company
- The Food and Drug Administration [FDA], the Department of Health and Human Services [DHHS], the National Institute of Health [NIH], the Office for Human Research Protections [OHRP], and other federal and state agencies that may have jurisdiction over the research
- Hospital and Clinical Research Accrediting Agencies
- Data and Safety Monitoring boards that oversee this study (if applicable)

Those who receive your Protected Health Information during the course of the research may not be required by the federal privacy regulations to protect it, and they may make further disclosures to others and use your information without being subject to penalties under those laws.

PURPOSE: WHY WE ARE USING AND SHARING YOUR PROTECTED HEALTH INFORMATION

The reason for using and sharing your Protected Health Information is to conduct and oversee the current, secondary, and future research described in this Informed Consent Document. There are many other reasons beyond the research for which BIDMC may use or disclose your Protected Health Information. Not all of these reasons require your express written authorization. For example, we will use and share your Protected Health Information to ensure that the research meets legal, institutional and accreditation requirements and to conduct public health activities. The various ways in which BIDMC may use and disclose your protected health information without your authorization are explained in a document called the Notice of Privacy Practices. If you have not received a copy of BIDMC's Notice of Privacy Practices, please ask us for one and review it before signing this form. In addition to signing this document, you may also be asked to sign a BIDMC General Agreement form acknowledging that you have received the BIDMC Notice of Privacy Practices.

NO EXPIRATION DATE – RIGHT TO WITHDRAW AUTHORIZATION

Your authorization for the use and disclosure of your Protected Health Information in this Study shall never expire. However, you may withdraw your authorization for the use and disclosure of your Protected Health Information at any time provided you notify the Principal Investigator in writing. If you would like to take back your authorization so that your Protected Health Information can no longer be used in this study, please send a letter notifying the Principal Investigator of your withdrawal of your authorization to Dr. Anthony Lembo at 330 Brookline Ave., Boston, MA 02215. Please be aware that the investigators in this study will not be required to destroy or retrieve any of your Protected Health Information that has already been used or disclosed before the Principal Investigator receives your letter, and they are permitted to continue to use and disclose your previously collected information as necessary to complete the research.

REFUSAL TO SIGN

Your clinical treatment may not be conditioned upon whether you sign the Authorization for Research. However, if you choose not to sign this informed consent document and authorization for the use and disclosure of your Protected Health Information, you will not be allowed to take part in the research study.

RIGHT TO ACCESS AND COPY YOUR PHI

If you wish to review or copy your Protected Health Information as it is made part of your medical record, you may do so after the completion or termination of the study by sending a letter to the Principal Investigator

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: Crofelemer for functional diarrhea
PRINCIPAL INVESTIGATOR'S NAME: ANTHONY LEMBO, MD
PROTOCOL #: **2020P-000464**

BETH ISRAEL DEACONESS MEDICAL CENTER
APPROVED BY THE
COMMITTEE ON CLINICAL INVESTIGATIONS
05/08/2023
APPROVAL EXPIRATION DATE

requesting a copy of your Protected Health Information. You may not be allowed to inspect or copy your Protected Health Information until this study is completed or terminated.

ADDITIONAL CONTACT FOR QUESTIONS OR CONCERNS

You may contact the Human Subjects Protection Office at [617] 975-8500 in the event that you would like to obtain information or to offer input about the research study. This office is independent of the investigator or investigator's research staff and can also assist with questions relating to your rights as a participant in research, which may include questions, concerns or complaints about your participation in the study.

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: Crofelemer for functional diarrhea
PRINCIPAL INVESTIGATOR'S NAME: ANTHONY LEMBO, MD
PROTOCOL #: **2020P-000464**

BETH ISRAEL DEACONESS MEDICAL CENTER
APPROVED BY THE
COMMITTEE ON CLINICAL INVESTIGATIONS
05/08/2023
APPROVAL EXPIRATION DATE

THE FOLLOWING PARAGRAPHS CONTAIN SOME STANDARD INFORMATION WHICH GENERALLY APPLIES TO INDIVIDUALS PARTICIPATING IN A RESEARCH STUDY.

CONSENT FORM FOR CLINICAL RESEARCH

I have read the previous page[s] of the consent form and the investigator has explained the details of the study. I understand that I am free to ask additional questions.

If I wish additional information regarding this research and my rights as a research subject, or if I believe I have been harmed by this study, I may contact the Human Subjects Protection Office (HSPO).

I am aware that this is a research project and that unforeseen side effects may occur.

I understand that the Beth Israel Deaconess Medical Center has no formal program for compensating patients for medical injuries arising from this research. Medical treatment will be provided for injuries at the usual charge to me or to my insurer unless payment is otherwise provided for in this consent form.

I understand that participation in this study is voluntary and I may refuse to participate or may discontinue participation at any time without penalty, loss of benefits, or prejudice to the quality of care which I will receive.

I acknowledge that no guarantees have been made to me regarding the results of the treatment involved in this study, and I consent to participate in the study and have been given a copy of this form.

_____ _____

Signature of Subject or Legally Authorized Representative (Parent if the subject is a minor) — Date

_____

Relationship of Legally Authorized Representative to Subject

The subject has been given the opportunity to read this consent form and to ask questions before signing, and has been given a copy.

_____

SIGNATURE OF INVESTIGATOR/Co-Investigator DATE

_____

PRINT INVESTIGATOR'S/Co-Investigator's NAME

A signing co-investigator must be listed on the study's approved Research Staffing Form at the time of consent.

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: Crofelemer for functional diarrhea
PRINCIPAL INVESTIGATOR'S NAME: ANTHONY LEMBO, MD
PROTOCOL #: **2020P-000464**

BETH ISRAEL DEACONESS MEDICAL CENTER
APPROVED BY THE
COMMITTEE ON CLINICAL INVESTIGATIONS
05/08/2023
APPROVAL EXPIRATION DATE

THE FOLLOWING SECTIONS ARE NOT NEEDED FOR ALL STUDIES AND SHOULD BE UTILIZED AS INDICATED:

If the subject is able to speak and understand English but is not able to read or write

I was present during the entire oral presentation of the informed consent and witnessed the subject's agreement to participate in the study.

Signature of Witness: _____

Printed Name of Witness: _____

Date: _____

If the subject is able to understand English but is not physically able to read or write or see

I was present during the entire oral presentation of the informed consent and witnessed the subject's agreement to participate in the study.

Signature of Witness: _____

Printed Name of Witness: _____

Date: _____

If the subject is not English speaking and signed the translated Short Form in lieu of the English consent document.

As someone who understands both English and the language spoken by the subject, I interpreted, in the subject's language, the researcher's presentation of the English consent form. The subject was given the opportunity to ask questions.

Signature of Interpreter: _____

Printed name of Interpreter: _____

Date: _____