SUBJECT INFORMATION SHEET AND INFORMED CONSENT FORM AND HIPAA AUTHORIZATION

Study title: ECOSPOR III: A Phase 3 Multicenter, RandomizeEd, Double Blind, -Placebo COntrolled, -Parallel Group- Study to Evaluate the Safety, Tolerability, and Efficacy of SER-109 vs. Placebo to Reduce Recurrence of *ClOstRidium difficile* Infection (CDI) in Adults Who Have Received Antibacterial Drug Treatment for Recurrent CDI (RCDI)

Study protocol number: SERES-012

Study drug: SER-109

Sponsor of the study: Seres Therapeutics, Inc.

Study Doctor Name: **Satinder Gill MD**

Research Site Address(es):

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Introduction

You are being asked to take part in a clinical research study of an investigational drug (a drug that has not been approved as safe and effective by the U.S. Food and Drug Administration (FDA) or other regulatory agencies). To help you decide if you want to take part, you should understand the study and what it will involve for you. To make an informed decision– you should know the purpose of the study, the procedures, how long it will take, the potential benefits and risks of the study, and the discomforts and the precautions taken. This process is called 'informed consent'. Please take the time to read the following information carefully and feel free to share and discuss it with others. Please ask your study doctor if there is anything that is not clear or if you would like more information.

It cannot be promised that the study will help you but in the future the information we get from this study may help improve the future treatment of people with the same condition.

If you decide that you want to take part, you will be asked to sign the informed consent form. You will be given a copy of the signed and dated form to keep, and the original will stay at the study center.

This document uses words such as treatment, drug, medication, and patient. Please remember this is a research study and the use of these terms does not mean the use of the drug has been found to be safe or effective for your condition.

What is the purpose of the study?

The drug to be tested in this study is SER-109. Throughout this document 'Study Drug' or 'Study Treatment' can refer to SER-109 or a placebo, a capsule containing no active drug.

A clinical trial is an investigation in humans of a medical treatment that is designed to discover or verify whether the treatment is effective and safe.

The purpose of this study is to see how safe and effective SER-109 is compared to a placebo, a capsule containing no active drug, in keeping *Clostridium difficile* infection (CDI) from coming back in people who have recovered from three or more episodes of CDI. The medical literature suggests that as many as 60% (6 out of 10 patients) will have another episode of CDI if they have already had three or more episodes.

Clostridium difficile, also called "*C. diff*," is a type of bacteria that is present in the environment, and in a small percentage of healthy people. It can be present in low amounts as part of the bacteria in the intestine or colon. Patients with a history of antibiotic use may develop CDI. Antibiotics can reduce the amount of normal healthy bacteria found in the large intestine or colon, which allows for the growth of *C. diff* bacteria leading to CDI. *C. diff* bacteria makes a toxin, or poison, which causes diarrhea that can be very mild and last a few days, or may be severe causing frequent diarrhea, abdominal pain, and may even require life-saving surgery. After recovering from CDI, it

is not uncommon for the infection to come back in days, weeks, months or years later in some people. This is called recurrent CDI and is a significant medical condition for many people.

This is a Phase 3 study. A Phase 3 study is designed to demonstrate whether or not a product offers a treatment benefit to a specific population. Sometimes known as pivotal studies, these studies involve a larger number of subjects. Phase 3 studies provide most of the safety data, that is, collect more information on side effects of the drug (i.e. drug safety). In previous studies, it is possible that less common side effects might have gone undetected. Because these studies are larger and longer in duration, the results are more likely to show long-term or rare side effects. Patients who have experienced 3 or more episodes of CDI and who have responded to antibiotic treatment for the most recent episode of CDI will be enrolled in this study.

This study is sponsored by Seres Therapeutics, Inc. who will be referred to as the 'Sponsor' in this document. The study doctor/institution is being paid by the Sponsor to conduct this study.

What medication is being tested?
This study involves research about SER-109. SER-109 is a preparation of bacterial spores purified from stool donations obtained from healthy, screened donors and put into capsules. The capsules are taken orally (i.e., by mouth). A bacterial spore is an inactive form of the normal bacteria that lives in a healthy intestine. After ingestion, these spores will develop into bacteria in the gut. SER-109 is a new experimental drug treatment being studied to see if it can help get patients' intestinal bacteria back to a healthy state after recurrent CDI, and potentially keep CDI from returning.

Previous studies in subjects with recurrent CDI suggest that SER-109 is safe and well-tolerated, although it is associated with an increase in gastrointestinal adverse effects, particularly diarrhea, compared to placebo (25% vs 14%). More information is needed as to whether SER-109 may be effective for preventing recurrent CDI.

Why have I been invited?
You are being asked to volunteer to take part in this research study because you have had CDI at least three times in the past 9 months.

How many people will take part in this study?
Up to 320 subjects in approximately 100 study centers in the United States and Canada will take part in this study.

What will happen to me during the study?
If you agree to take part in this study, you will be asked to sign this informed consent form before any study-related procedures are performed.

If you are entered and you complete the entire study, your participation in the study will last about 27 weeks and will include up to 6 study visits at the clinic, and regularly scheduled telephone calls. If your CDI comes back during the first eight weeks of the

study, you may have the opportunity to participate in another, non-blinded extension study in which you would receive SER-109 and be followed for about 27 additional weeks. You would be eligible to enroll once you have been followed for 8 weeks following your receiving study medicine in this trial and completed the 8 week study visit. You would sign a separate informed consent form for this extension study.

If you decide to participate, you will be assigned by chance (like the flipping of a coin), to receive one of two study treatments: SER-109 or a placebo. You will have a 1 out of 2 chance, or a 50% chance of receiving SER-109. If you are assigned to receive SER-109, you will receive single daily doses of 3×10^7 spore colony forming units (SCFU) in 4 capsules administered orally (by mouth) each day for 3 consecutive days. An SCFU refers to the number of bacterial spores in a dose. If you are assigned to receive placebo, you will receive matching placebo containing no active drug in 4 capsules administered by mouth each day for 3 consecutive days.

You will be instructed to take all study drug doses in the morning after an overnight fast of 8 or more hours (nothing by mouth except for small amounts of water). You will need to remain fasting for up to 60 minutes after you take the study drug. You must come to the clinic or have a home visit on Day 2 and Day 3 to witness you taking the study drug.

This study is double-blinded, which means that neither you nor your study doctor or the study staff will know which study drug you are receiving. However, the study drug you receive will be made known in the case of an emergency.

If you enter the study, the following procedures and tests will be done:

Screening Period
The screening period begins with your first study visit and lasts up to 24 days before your Study Treatment (Day 1) Visit. During this time you will be taking a prescribed antibiotic (vancomycin or fidaxomicin) to control your current episode of CDI. The following procedures will be performed during your screening visit at the clinic:

- You will have a physical examination, including measurement of height and body weight.
- You will be asked questions about your past and present medical history.
- You will be asked about any medications that you are taking; what they are for and how long you have been taking them.
- You will be asked questions about your CDI history. We will get your medical records of your diagnosed episode of CDI including date, test results, medications that you were prescribed, including start and stop dates. We will also ask you about your response to treatment.
- Your vital signs will be taken, including blood pressure, heart rate, respiratory rate, and temperature.
- You will have blood drawn (up to approximately 2 tablespoons) from a vein in your arm to check the function of your kidneys and liver.

- If you are a woman who is able to get pregnant, your blood will be checked to make sure that you are not pregnant.
- You will be asked to provide a urine sample to check for bladder infections.
- You will be given a small amount of a laxative called magnesium citrate to take home with you or a prescription for GoLytely ® (polyethylene glycol 3350 and electrolytes oral solution). You will be instructed on how to take this medication 1 day prior to your Study Treatment Day 1 visit, in order to remove residual antibiotic from the gut.
- You will be given a reminder card for your Day 1 visit.
- You will be provided a stool collection kit and given instructions for collecting a stool sample prior to taking your magnesium citrate on Day -1.
- You will be given a paper diary to record on a daily basis the number of bowel movements you experience. You will be given instructions on how and when to complete the paper diary.

Study Day -4 to Day -2 Telephone Call

- You will be contacted by the study site to ask how you are feeling and to see if you have taken any new medications since your last contact.
- You will be asked about any new episodes of diarrhea.
- You will be reminded to stop your antibiotic treatment (vancomycin or fidaxomicin) on Day -2.
- You will be reminded to collect a stool specimen prior to taking your magnesium citrate or GoLytely on Day -1.

Study Day -1 Telephone Call and Stool Sample Collection

- You will be contacted by the study site to ask how you are feeling and to see if you have taken any new medications since your last contact.
- You will be asked whether you stopped taking antibiotics and have taken your last dose of antibiotic on any day from Day -4 to Day -2.
- You will be asked about any new episodes of diarrhea.
- You will be reminded to collect a stool specimen prior to taking your magnesium citrate or GoLytely.
- You will be reminded to bring your stool sample that was collected at home to your visit on Day 1.
- You will be reminded on the instructions for taking magnesium citrate or GoLytely to remove residual antibiotic from the gut.
- You will begin your 8-hour fasting period (nothing to eat or drink except water) to prepare to take the study drug on Day 1.

Study Treatment Visit (Day 1)

You will come to the clinic (study site) for the Day 1 visit. You will give the study site personnel your stool sample that was collected at home on Day -1.

Prior to taking the study drug, you will be evaluated again to make sure that you still qualify to participate in the study. You will be asked about any new episodes of diarrhea. You will be asked about how you have been feeling and if you have taken any new medications since your last contact. We will confirm that you took your last dose of antibiotic on any day from Day -4 to Day -2. We will also confirm that you consumed the magnesium citrate or GoLytely on Day -1 and that you have not eaten any food or drank anything other than water for 8 or more hours.

The following procedures will be performed **prior** to being given the study drug:

- You will undergo a physical examination, including measurement of body weight.
- Your vital signs will be taken, including blood pressure, heart rate, respiratory rate, and temperature.
- You will have blood drawn (up to approximately 2 tablespoons) from a vein in your arm to check the function of your kidneys and liver.
- You will be asked to provide a urine sample to check for a bladder infection.
- You will have blood drawn (up to about 2 tablespoons) and about 10 grams of your stool will be used for future biomedical research. This is optional and is explained in the Future Biomedical Research section of this document.
- If you are a woman who is able to become pregnant, your urine will be checked to make sure that you are not pregnant.
- The study team will administer two questionnaires. One questionnaire asks questions related to general health and well-being and the other questionnaire asks questions related to your *C. diff* infection.

Following these procedures, you will be given 4 capsules of study drug to swallow with at least 8 ounces of water.

The following procedures will be performed after you receive the study drug:

- You will remain at the study site for at least 60 minutes after you take the study drug for observation. You may not eat anything during this hour, but you may have something to drink.
- Your vital signs will be taken approximately 30 minutes after you take the study drug, including blood pressure, heart rate, respiratory rate, and temperature.
- You will be asked how you are feeling.
- You will be provided stool collection kits and instructions for collecting samples at Weeks 1, 2, 8, and 24 or your final visit.
- If you choose to arrange home visits on Days 2 and 3, you will be given a 2-day supply of study drug with instructions for storage.
- You will be asked to keep track of any episodes of diarrhea (e.g., diarrhea log). You will return the paper diary you were provided at the Screening visit and be given an electronic handheld device to record daily whether you have had any diarrheal episodes and, if so how many. The study team will provide you with instructions on how to record this information.

- You will be given a reminder card for your next appointment. You will be given specific instructions for reporting any symptoms or concerns and in particular, notifying the study staff of any new episodes of diarrhea. Note that you may have some diarrhea early-on after receiving study drug.

Day 2
You will come to the study site or arrange for an at-home visit. Should you choose to have a home visit, the health care provider is required to come to your home to witness you taking your study medicine on Day 2 and Day 3.

During this visit:

- You will take your 2nd dose of study drug before breakfast. A person from the site or the person performing your home visit will witness you taking the study medicine.
- You will be asked how you are feeling and to see if you have taken any new medications since your last contact with the study site. If you choose to have a home visit on Days 2 and 3, the study staff will follow up with a phone call to ask these questions.
- You will be asked about any new episodes of diarrhea.
    - You will be reminded that you may have some diarrhea early-on after receiving study drug.
    - You will be reminded to complete the diarrhea log.

Day 3
You will come to the study site or arrange for an at-home visit. During this visit:

- You will take your 3rd dose of study drug before breakfast. A person from the site or the person performing your home visit will witness you taking the study medicine.
- You will be asked how you are feeling and to see if you have taken any new medications since your last contact with the study site. If you choose to have a home visit on Days 2 and 3, the study staff will follow up with a phone call to ask these questions.
- You will be asked about any new episodes of diarrhea.
    - You will be reminded that you may have some diarrhea early-on after receiving study drug.
- You will be reminded to complete the diarrhea log.
- You will be provided a diary card to collect specific symptoms for Days 4-10.
- You will be asked to measure your body temperature daily on Days 4-10

Week 1
You will need to provide a stool sample. You can either bring the sample to the study site and give it to the study site personnel or if you are unable to bring it to the clinic, it is possible that arrangements may be made to have a courier deliver it to the clinic. You will be contacted by the study site and asked how you are feeling and to see if you have taken any new medications since your last contact with the study site. You will be asked about any new episodes of diarrhea and you will be reminded to complete the diarrhea log. You will be administered a questionnaire asking questions about your *C. diff* episode.

Week 2
You will come to the study site or arrange for an at-home visit. During this visit:

- You will be asked how you are feeling and to see if you have taken any new medications since your last contact with the study site.
- You will be asked about any new episodes of diarrhea.
- If you have given consent to store your blood for future research, you will have blood drawn (up to about 2 tablespoons) from a vein in your arm. Please refer to the Future Biomedical Research section of this document.
- You will be reminded to complete the diarrhea log.
- You will give the study site personnel or visiting nurse your stool sample that was collected at home.
- You will be provided a stool collection kit and given instructions for collecting a stool sample
- You will return your diary card from Days 4-10

Weekly Telephone Calls (Weeks 3-7)
You will be contacted by the study site weekly from Week 3 to Week 7 to ask how you are feeling and to see if you have taken any new medications since your last contact with the study site. You will be asked about any new episodes of diarrhea and reminded to complete the diarrhea log. At the Week 7 telephone call, you will be reminded to bring your 8 week stool sample to the clinic at the Week 8 visit.

Efficacy Assessment Visit – Week 8
You will come to the clinic for the Week 8 visit. You will be asked how you are feeling and if you have taken any new medications since your last contact with the study site. You will be asked about any new episodes of diarrhea and to complete the diarrhea log. You will give the study site personnel your stool sample that was collected at home. Assessments performed during the Week 8 visit may be used for the Screening labs should you wish to enroll into the SERES-013 Study.

The following procedures will be performed:

- You will undergo a brief physical examination, including weight.
- Your vital signs will be taken, including blood pressure, heart rate, respiratory rate, and temperature.

- You will have blood drawn (up to approximately 2 tablespoons) from a vein in your arm to check the function of your kidneys and liver.
- If you have given consent to store your blood for future research, you will have blood drawn (up to about 2 tablespoons) from a vein in your arm. Please refer to the Future Biomedical Research section of this document.
- If you are a woman who is able to get pregnant, your urine will be checked to make sure that you are not pregnant.
- Two questionnaires will be administered. One questionnaire asks questions related to general health and well-being and the other questionnaire asks questions related to your *C. diff* infection.
- You will be given specific instructions for reporting any symptoms or concerns and in particular, notifying the study staff of any new episodes of diarrhea.
- You will be provided a stool collection kit and given instructions for collecting a stool sample.
- You will be asked to bring all study drug and study drug containers to this visit.

Monthly Telephone Calls (Weeks 12, 16, 20 and 24)
You will be contacted by the study site on Weeks 12, 16, 20 and 24 to ask how you are feeling and to see if you have taken any new medications since your last contact with the study site. You will be asked about any new episodes of diarrhea and reminded to complete the diarrhea log. You will also be asked to bring your stool sample to the clinic at Week 24. If you are unable to bring it to the clinic, it is possible that arrangements may be made to have a courier deliver it to the clinic. At the Week 24 telephone call, a questionnaire will be administered asking about your general health and well-being.

Unscheduled Visits for New CDI Episodes or Early Termination (ET)
You will be asked how you are feeling and if you have taken any new medications since your last contact with the study site. You will be asked about any new episodes of diarrhea and reminded to complete the diarrhea log. You will give the study site personnel your stool sample that was collected at home.

The following procedures will be performed:

- You will undergo a brief physical examination, including weight.
- Your vital signs will be taken, including blood pressure, heart rate, respiratory rate, and temperature.
- You will have blood drawn (up to approximately 2 tablespoons) from a vein in your arm to check the function of your kidneys and liver.
- If you have given consent to store your blood for future research, you will have blood drawn (up to about 2 tablespoons) from a vein in your arm. Please refer to the Future Biomedical Research section of this document.
- You will be asked to provide a urine sample to check the function of your kidneys.
- If you are a woman who is able to become pregnant, your urine will be checked to make sure that you are not pregnant.

- A questionnaire will be administered asking about your general health and well-being. In addition, if the visit is scheduled prior to Week 8, a questionnaire will also be administered asking about your *C.diff* episode.
- You may be provided stool collection kits and reminded about instructions for collecting samples to bring with you at your future study visits as applicable.
- If applicable, you will be given a reminder card for your next appointment. You will be given specific instructions for reporting any symptoms or concerns and in particular, notifying the study staff of any new episodes of diarrhea.
- If you have a confirmed CDI recurrence prior to the Week 8 visit and you are eligible and wish to enroll in the open label extension study (SERES-013), you must continue in this study (SERES-012) until the Week 8 visit.

FUTURE BIOMEDICAL RESEARCH

You have been asked to give permission for your blood and stool to be used in future biomedical research because you are taking part in the main part of the SERES-012 clinical study. All information from the main study consent form and HIPAA still applies.

Before you decide whether or not to give permission, you should read through the information in this section and ask questions if anything is unclear. If you decide to give permission for your blood and stool to be used in future biomedical research, you will answer “yes” or “no” below.

What is future biomedical research?

New biomedical research discoveries are being made all the time. There may be new discoveries of biological molecules or organisms, including bacteria, that we may want to examine in blood or stool in the future. There may also be new or better ways to examine the presence of biological molecules or organisms in blood or stool in the future. There may be new indicators of *Clostridium difficile* infection (CDI) that we do not know currently. These discoveries may help us better understand CDI and the human microbiome (a collection of small organisms, including bacteria that are present in different areas of the body) or be able to identify subjects who are more likely to benefit from a specific treatment. We cannot anticipate all of the new techniques or discoveries that will be available for future biomedical research related to CDI or to the human microbiome.

Biological molecules and biomarkers

Biological molecules are naturally-occurring substances in the body. Examples of biological molecules are proteins, parts of proteins, or deoxyribonucleic acid (DNA, a molecule that contains the instructions for other cells in your body) and ribonucleic acid (RNA, which tells the cells in your body which proteins to produce). A biological molecule found in blood, body fluids such as stool, or other tissues that is a sign of health or disease is called a biomarker. Testing for the presence or amount of certain biomarkers may help diagnose a certain disease, determine the severity of the disease, or evaluate how well and how effectively a medicine may treat the disease. Biomarkers may also determine if certain people are more likely than others to benefit from treatment with a specific medicine. Some biomarkers for CDI have already been identified, but new discoveries are being made and new biomarkers may be identified in the future.

The human microbiome
The human microbiome is a collection of small organisms, including bacteria, that are present in different areas of the body, such as the intestines or gut. Presence of certain bacteria can indicate health or disease. There may be changes in the microbiome that can lead to changes in health or worsening or improvement of a disease. There is still a lot that we don't know about the human microbiome. It is possible that the type or amount of bacteria present in a person may be a factor in keeping a person in a healthy or disease state. It is also possible that new technologies in human microbiome research in the future may be able to tell us about certain things a person has been exposed to (such as lead, certain foods or medications) or even locations a person has visited in the past.

What will Seres Therapeutics do with my blood and stool?
Seres Therapeutics will retain your blood and stool for future research and potential commercial use by Seres Therapeutics or third parties acting on its behalf. There are no plans to pay you or any of your heirs for any future commercial ventures or products developed as a result of research using your biological samples. Your blood and stool will be stored securely and confidentially. Your samples may be stored for up to 10 years.

Seres Therapeutics or third parties working on behalf of Seres Therapeutics, not the study doctor, may conduct future biomedical research. Your samples may be shared with Seres Therapeutics research collaborators. For more information on future biomedical research, please talk to your study doctor.

Will you do any genetic tests?
We may do human genetic testing or we may evaluate bacterial DNA in your blood and stool samples. We may also measure your samples for the presence or absence and concentration of other biological molecules.

Do I need to have additional tests or procedures?
If you agree to allow future testing on your blood and stool, you will have additional blood collected during the main part of the study. The study team will collect and use a small portion of stool from the samples you are already collecting for this study.

Up to about 8 tablespoons of your blood will be collected for future biomedical research. Approximately 10 grams of your stool collected from the main part of the study will be used for future biomedical research.

How will my personal information be kept confidential?
Your blood and stool will be collected and protected as explained under the confidentiality section of the Main Informed Consent Form.

Your personal data, including your sex, age, race, disease history, general health, response to the study drug, and dose levels of study drug may be relevant to the future biomedical research. This information, along with other personal data, may be used by

the researchers who are studying your blood and stool. You will not be identified by name, only by a number and your partial date of birth. The results of this study may be published. However; your personal data (data that would identify you) will not be disclosed in any publication without your further and explicit consent for that purpose.

Can I still participate in the main part of the study if I don't give permission for Seres Therapeutics to use my blood and stool for future biomedical research?
You may still take part in the main part of the study, and your medical care will not be affected, if you don't give permission to Seres Therapeutics to use your samples for future biomedical research or if you decide not to allow your samples to be collected for future biomedical research. Additionally, there will not be any penalty or loss of benefits to which you are otherwise entitled if you decide not to take part or if you stop allowing the collection of your samples early.

What are the alternatives?
You do not have to allow the collection of your samples to participate in the Main part of the study. Your alternative is not to participate.

Are there any costs?
You do not have to pay for study visits, and tests that have to be done for the collection of your samples.

Will I be paid to take part in this sub-study?
Payment information is listed in the consent for the main part of the study.

Can I withdraw permission for my blood and stool to be used for future biomedical research?
You can withdraw your permission at any time by contacting your study doctor. Any data collected on blood and stool samples before you withdraw permission will remain the property of Seres Therapeutics.

Are there risks and possible discomforts to allowing my blood and stool to be used for future biomedical research?
It's possible that other people could find out you were in the study or see your study information. We will take every step to keep this from happening.

Are there any benefits to allowing my blood and stool to be used for future biomedical research?
It is unlikely that you will benefit directly from allowing your samples to be used for future biomedical research. However, it may help people with CDI or other diseases in the future.

I agree to provide blood samples and a portion of a stool sample already collected for future biomedical research. Please initial below to indicate your choice.

_____Yes _____No

What will I have to do?
When you are in a clinical research study, you are expected to come to all of your study visits and to follow the instructions given to you by the study doctor and study staff. You must also let your study doctor know of any changes in your health while you are in this study. You should check with the study doctor before starting to take any new medications or remedies. You must not take part in any other research studies while you are taking part in this study. If you or your partner becomes pregnant, you must notify your study doctor immediately. If you choose to stop your participation in the study for any reason, you must notify your study doctor immediately so that a plan can be made for your continued medical care. You will be expected to return to the clinic for your final study visit as described above.

Please do not give blood for non-study purposes, unless medically required, while you are taking part in this study.

The following drugs/therapies are prohibited for the duration of the study:

- Probiotics
- Loperamide
- Diphenoxylate/atropine
- Cholestyramine
- Opiate treatment unless on a stable dose (Note: Short term opiate use is permitted (e.g., for a dental extraction).
- Chemotherapy, radiotherapy, or biologic treatment for active malignancy

What will happen to any samples I give?
Your blood and urine samples will be used for routine analysis. Your stool samples will be screened for the presence or absence of certain bacteria or other molecules. If you decide to take part in this study, but later withdraw for any reason, study data, blood, urine, and stool samples collected before your withdrawal may still be used or disclosed as necessary to maintain the integrity or reliability of the current research or as otherwise permitted by law or this informed consent form.

Will I have to pay to take part in the study?
There will be no cost to you for taking part in this study. You will be provided with all study drugs, examinations and medical care related to the study at no cost to you.

You will not be charged for the study drug or for any of the procedures connected with your participation in the study including use of a courier to transport your stool specimens. Expenses related to standard medical care for your CDI are your responsibility (or the responsibility of your insurance provider). Study medication will not be provided to you other than according to the protocol during your study participation.

Will I be paid to take part in the study?
If you take part in this study, you will not be paid or rewarded in any way but you may be reimbursed up to $84.00 per completed study visit for travel expenses.

Do I have to take part?
Taking part in this study is voluntary – you may choose not to take part or you can change your mind and withdraw (drop out) later. You do not have to take part to be treated for your condition. If you decide to withdraw from the study or choose not to take part your future medical care will not be affected in any way and there will not be any penalty or loss of benefits to which you are otherwise entitled. If you would like to withdraw from the study, please tell the study doctor as soon as possible.

What alternative treatments are available?
Your study doctor will discuss with you any other treatments or investigational drugs that may be available, and will also discuss their risks and benefits. You do not need to participate in this study to be treated for your condition. You can take vancomycin or fidaxomicin without being in this study. There may be other procedures, such as a fecal transplant, or other research studies that could be of benefit to you.

What are the possible disadvantages or risks of taking part?
Any research has some risks, which may include things that could make you feel unwell, uncomfortable, or harm you. It is possible that the symptoms of your condition will not improve during the study or may even worsen. You might have negative side effects related to the study drug while taking part in the study. Treatment with this study drug may also involve risks to your future health that we currently don't know about. Everyone taking part in the study will be watched for any negative side effects; however, the study team does not know all of the side effects that the study drug may have on you. These side effects may be mild or serious. In some cases, these side effects might be long lasting, or permanent, and may even be life-threatening. The research study team may give your medicines to help reduce negative side effects.

What could be the side effects of the study drug?

SER-109
As with any investigational treatment, it is not possible to predict all of the unwanted side effects.

To date, a total of 142 subjects have received 1 or 2 doses of SER-109. The available safety data from 3 studies, including one ongoing and one completed open-label study as well as a completed placebo-controlled study, suggests that SER-109 is safe and well-tolerated, although is associated with an increase in gastrointestinal adverse effects, particularly diarrhea, compared to placebo (25% vs 14%).

Across studies with SER-109 as of November 10, 2016, 87% of the patients (123/142) who had received 1 or 2 doses of SER-109 had experienced at least one adverse event. Most adverse events were mild to moderate and the most common (incidence at least 5% in either study) events were gastrointestinal issues. Overall, 24% (34/142) of patients had experienced an adverse event reported as probably or likely due to SER-109. As of November 10, 2016, 15% of patients who had received SER-109 (21/142) had experienced at least one serious adverse event. Of note, 10% of patients who

received placebo (3 of 29) also experienced at least one serious adverse event. No serious adverse events were reported to be due to SER-109. There have been two deaths, both of which were unrelated to SER-109 and one occurred after the subject left the study.

A summary of serious adverse events in addition to the most common and drug-related adverse events is listed below.

Commonly Reported (Incidence at least 5%) Adverse Events in Studies with SER-109	**Adverse Events Reported as Probably or Likely Due to SER-109**	**Serious Adverse Events (SAEs) Reported in Subjects Who have Received SER-109**
Diarrhea Stomach pain Flatulence (gas) Nausea Constipation Back pain Vomiting Urinary tract infection Fever Common cold Fatigue Bloated stomach Rectal bleeding Bacterial skin infection Headache Pain Irritable bowel syndrome Dizziness Feeling of general discomfort	Diarrhea Nausea Stomach pain Flatulence (gas) Constipation Bloated stomach Fatigue Frequent bowel movements Increased liver enzyme Fever Fast resting heart rate Chills Dizziness Vomiting Excessive sweating Gastroesophageal reflux disease Diverticulitis Feeling of general discomfort Irritable bowel syndrome Altered sense of taste Muscle pain Muscle spasm Pain	*One patient experienced the following SAEs:* Fluid overload Chronic obstructive pulmonary disease Acute respiratory failure Bacterial skin infection Shortness of breath Congestive heart failure Headache Black “tarry” stool Back pain Suicidal thoughts Hypoxia (lack of oxygen) Nausea Vomiting Dizziness Skin ulcer Diarrhea Cough Blocked dialysis shunt *One patient experienced the following SAEs:* Stroke Congestive heart failure Aspiration pneumonia Low blood platelet count Irregular heartbeat Decreased ability of heart to pump blood Abnormal physical weakness

Commonly Reported (Incidence at least 5%) Adverse Events in Studies with SER-109	**Adverse Events Reported as Probably or Likely Due to SER-109**	**Serious Adverse Events (SAEs) Reported in Subjects Who have Received SER-109**
		Fever Bacterial skin infection Shingles Pneumonia Oral thrush (infection in the mouth) Sepsis (blood poisoning) Delirium (confused thinking) Type 2 diabetes Hypoxia (low oxygen) Mental status changes Heart attack Low blood pressure *Other SAEs reported include:* Elevated blood potassium Staphylococcal skin infection *Clostridium difficile* colitis Chest pain Jaw pain Venous thrombosis (blood clot in a vein) Enlarged pelvic mass Chronic cardiac failure Hematuria (red blood cells in urine) Drug Overdose Abdominal pain Gastrointestinal bleeding Lung cancer Fainting Lumbar spine fracture Worsening kidney function

SER-109 is also being studied as SER-287 (the same investigational product as SER-109) in patients with mild to moderate ulcerative colitis (Seres study: SERES-101), another intestinal disease with low amounts of normal healthy intestinal bacteria.

As of October 26, 2016, a total of 21 patients have been enrolled in this study and have received multiple doses of either SER-287 or placebo. Eight of these patients (38%) have experienced a total of 26 adverse events. Three patients have experienced adverse events that have been reported to be probably or likely due to study drug

although we do not know whether these patients are receiving SER-287 or placebo. No serious adverse events have been reported. A summary of the most common and drug-related adverse events is listed below.

Adverse Events in Study SERES-101 Reported as Probably or Likely Due to SER-287 or Placebo	**Other Adverse Events in Study SERES-101 Reported Not Due to SER-287 or Placebo**	**Serious Adverse Events (SAEs) Reported in Study SERES-101**
Stomach cramps Constipation Diarrhea Flatulence (gas) Fecal incontinence (accidental bowel leakage)	Constipation Stomach pain Stomach cramps Rectal discharge Positive leucocyte (positive urine test for infection) Positive nitrite (positive urine test for infection) Insomnia/trouble sleeping Swimmer's ear Upper respiratory infection Pneumonia Sinus infection Cough Cough with congestion Pelvic pain Chest pain Low back pain Low back spasm	None

There may also be a risk of an allergic reaction to SER-109. Additionally, although stool donors are carefully screened to ensure they are healthy, and SER-109 is processed in a way that reduces the risk of disease transmission, there is some risk that SER-109 treatment may transmit disease to you from the donor.

If you suffer any of these side effects (or any others not listed) or you think you are experiencing a side effect, during this study, please tell your study doctor immediately.

Any side effects or other health issues occurring during the study will be followed up by the study doctor.

Placebo Risk

Some research subjects in this study will receive a placebo. There is no active medication in the placebo capsules so no added risks related to placebo treatment are expected. Taking a placebo may be similar to not taking any medication. If you are one of the people who receive a placebo, your recurrent CDI may stay the same or get worse, or your recurrent CDI may suddenly get better just as it may have done without additional treatment.

Risks related to antibiotic treatment
You may be required to take vancomycin or fidaxomicin as part of this study. Vancomycin and fidaxomicin are poorly absorbed after oral administration, so side effects are not common, however, the following have been seen in clinical trials using these drugs:

- Nausea (11%)
- Vomiting (6-7%)
- Abdominal pain (4-6%)
- Gastrointestinal hemorrhage (2-4%)
- Anemia (2%)
- Neutropenia (1-2%)- lowered number of white blood cells which could increase the risk of infection

Risks related to study procedures
Most medical tests have risks. Many of the tests that you will have in this study would be done even if you were not in the study in order to help your doctor decide on a treatment for your recurrent CDI. However, the study may require that more blood is collected than if you were not in the study.

During blood draws, you may have discomfort and/or bruising at the place on your arm where the skin is punctured by the needle. Rarely, blood clots may form and infections may occur. If you feel faint or do not feel well after having your blood drawn, you should lie down right away to avoid falling down. You should let your study doctor or staff know if you have any of these problems.

Magnesium citrate and GoLytely are laxatives used to clean stool from the intestines. In addition to diarrhea, they may cause mild abdominal discomfort, cramps, gas and/or nausea and vomiting.

Risks related to GoLytely
GoLytely risks include nausea, bloating, stomach cramps, vomiting, and anal irritation. Serious but rare side effects include stomach or intestinal bleeding, chest pain, fainting, fast or irregular heartbeat, sudden shortness of breath, severe or persistent stomach or abdominal pain, bloody stools, rectal bleeding, and seizure. Serious allergic reaction is rare but you should tell your doctor if you notice rash/itching/swelling of the face or tongue, severe dizziness, or trouble breathing.

Risks related to Magnesium citrate
Magnesium citrate risks include gas, diarrhea, nausea, vomiting, stomach cramps, high levels of magnesium in your blood, and an imbalance of your electrolytes (chemicals in your blood).

Pregnancy Related Risks/Use of Birth Control

Female Subjects

Currently we are not fully aware of the effects of SER-109 on unborn babies, or pregnant or breastfeeding women. If you are pregnant, or may become pregnant, treatment with SER-109 may lead to new, previously unknown, side effects that we currently don't know about and this may involve risks to you or your unborn baby. Because of this, if you are pregnant or planning to become pregnant, you may not participate in this study. If you are able to become pregnant, a urine pregnancy test will be done at your screening visit, as well as before you take your study medication on Day 1, at the Week 8 visit, or your final visit or any recurrence visit, if applicable. You should discuss this with your partner(s) and you and your partner(s) must agree to practice at least one highly effective method of birth control to avoid becoming pregnant while you are in the study. Your doctor will discuss the methods of birth control that are considered adequate. If you suspect that you are pregnant you should tell the study doctor immediately. If you become pregnant while you are in the study, you will be withdrawn and your pregnancy will be followed through to the pregnancy outcome.

Your study doctor will determine what follow-up visits are necessary during your pregnancy.

Male Subjects

It is not known if SER-109 affects sperm and there is no information on the long-term effects of SER-109 on fertility. You should avoid getting your partner(s) pregnant while participating in this study. You and your partner(s) must agree to practice at least one highly effective method of birth control while you are in the study. Inform your study doctor if your partner becomes pregnant. The study doctor will discuss the methods of birth control that are considered adequate. In the event that your partner does become pregnant, with her permission, her pregnancy will be followed through to the pregnancy outcome.

Birth Control Methods

To participate in the study, you must not be of childbearing potential, or must practice at least one acceptable method of birth control. For women, childbearing potential is defined as postmenopausal for at least 1 year or surgically sterile, meaning your ovaries and/or uterus have been removed (bilateral oophorectomy and/or hysterectomy). For men, sterile means that you have had a vasectomy with proof of no sperm after the procedure.

Any women of childbearing potential (able to get pregnant) must be practicing at least one highly effective method of birth control including the barrier method (condom, sponge with spermicide), birth control pill, birth control implant, birth control depot injection, a vasectomized partner; or abstinence (not having sex) for the duration of this study. The study doctor will discuss these methods with you prior to you receiving the study drug.

What are the possible benefits of taking part in this study?
If you agree to participate in this study, there may or may not be a direct benefit to you. If you receive the active study drug, SER-109, another episode of CDI may be prevented but there is no guarantee. Study participants receiving the placebo are not expected to benefit. The information we get from this study may help the study Sponsor and the study doctor and staff to provide better treatments in the future for patients with recurrent CDI.

What happens when the research study ends?
Because this is a research study, SER-109 will be given to you only during this study and not after the study is over.

If you have a CDI recurrence up to 8 weeks after the study treatment, you will have the opportunity to take part in an open label extension study. Open label means that all subjects will take SER-109 and there will be no placebo.

Compensation for study related illness or injury
If you think that you have experienced an illness or injury caused by the study drug, you should get immediate medical help and let the health care provider know you are in a research study. Also, contact the study doctor as soon as possible.

The Sponsor will cover the reasonable costs of treatment for a research illness or injury that are not covered by your insurance or a government program. However, the Sponsor does not intend to reimburse the medical costs resulting from an illness or injury in the following circumstances:

- if the illness or injury is a result of normal progression of your disease rather than the research.
- if you do something that contributes to the illness or injury.
- if you do not follow the instructions of study doctor or the protocol, or
- if the study doctor and staff do not follow the research protocol or if they have acted negligently.

A research illness or injury is any injury or illness directly caused by your participation in the study. If you are injured by a medical treatment or procedure that you would have received even if you were not in the study, that is not a research injury. The Sponsor has not set aside funds to compensate you for such things as lost wages, expenses other than medical care, or pain and suffering. To help avoid illness or injury, it is very important to follow all study directions.

If you have medical insurance please check with your insurance company that taking part in this study will not affect your policy. You do not give up any of your legal rights by signing this consent form. For example, your legal right to claim compensation for illness or injury where you can provide negligence is not affected by signing this form.

What if new information becomes available?
Sometimes new information affecting the study is received. You will be told if any relevant new information becomes available that may affect your willingness to carry on taking part in the study. If this happens, your study doctor will contact you as soon as possible, and will discuss whether you should continue in the study. If you decide not to carry on, your study doctor will make arrangements for your care to continue. If you decide to continue in the study you may be asked to sign a new consent form.

Also, if new information becomes available, your study doctor may stop your participation without your consent. If this happens the reasons will be explained and arrangements made for your care to continue.

Can I stop treatment or withdraw from the study?
There are several reasons why you may stop taking part in the study completely. These are described below.

Withdrawal of Consent:
You can stop taking part in the study at any time without giving any reason. This will not affect your future treatment or your relationship with your study doctor. If you want to stop taking part, please tell your study doctor immediately. For your safety, you will be asked to return to the study center for an end-of-study assessment.

If you decide to take part in this study, but later withdraw for any reason, study data, blood, urine, and stool samples collected before your withdrawal may still be used as described in this form. After you withdraw from the study, no new information will be collected from you, unless you were experiencing an adverse event at the time of your withdrawal. Any adverse event will be followed until it has resolved. Your research records remain part of this clinical study even if you withdraw from the clinical study.

The study doctor or Sponsor may end your participation in the study without your permission at any time if they decide that it is in your best interest or for the reasons below:

- You have a side effect from the study drug;
- You experience any change in your medical condition that might be harmful to you;
- You fail to follow the study doctor’s instructions;
- Administrative purposes;
- Termination of the study by Seres Therapeutics, regulatory authorities (such as FDA), or the IRB;
- Seres Therapeutics asks that you be removed from the study; and/or
- You become pregnant.

Withdrawal of treatment
You may choose to stop taking the study treatment but continue to come for further visits and assessments.

If the study is stopped, you will be told and your study doctor will make arrangements for continuation of your care.

Will my taking part in this study be kept confidential and how will my personal information be used?

The study doctor and research team will collect, record and use personal information about you for the study purposes. Your personal information collected during the study may include your sensitive information about your physical or mental health or condition, and health information about you in medical records, and other personal information such as your name, address, telephone number, partial date of birth and gender and ethnicity. If you experience an invasive infection during the study, all attempts will be made to obtain records from the treating hospital or clinic to determine the cause of infection. Your privacy and your personal information will be protected using measures which follow the requirements applicable in your country for the protection of your personal information. Any information about you that is collected during this study will remain confidential.

During the study, your collected personal information including your medical files may be disclosed to the Sponsor, its representatives assisting with the study research, including the central laboratory, study monitors, and to auditors, government or regulatory health authorities (such as the FDA), Copernicus Group Independent Review Board (CGIRB). Your medical files will be reviewed only at the hospital (or study doctor's office) in order to check the information and verify the clinical study procedures, without breaking your confidentiality.

All information which is collected about you in records that leave the study center for the purposes of medical, laboratory, statistical or regulatory activities related to the study research will be identified by your study subject number. Your full name or any address details will not be included in these records.

The information from the study may be published or sent to regulatory authorities or health insurers in your country or other countries where regulatory approval or payment for the medication is required. Your identity will not be released except with your permission, unless necessary for the vital interests of your safety.

By signing this consent form, you are giving permission for the processing and use of your personal information for this study. You are also giving permission for the processing of your personal information or any part of it to be transferred to people and organizations (mentioned above) outside your country, where personal data protection laws may be may be different. You may access and correct your personal information or ask for it to be deleted. However, during the study, this right will be temporarily suspended in order to protect the integrity of the study data. You can object to any further processing of your information by telling your study doctor.

If you withdraw from the study, no new information about you will be collected, but information that was already collected may continue to be used for the study. You can object to any further processing of your personal information by telling your study doctor. Information collected for and used in the study that does not identify you will not be affected by these conditions.

Your study doctor may tell your family doctor/general practitioner about you taking part in the study and ask them for medical information about you.

If you have any questions or concerns, you may discuss this in detail with the study doctor or study staff and ask any questions that you may have about the sharing of your health information.

Will you do any genetic tests?
We will evaluate bacterial DNA and RNA in your stool samples as part of this research study, however, if you consent to Future Biomedical Research sample collection, there may be human genetic testing performed as noted above. No human genetic testing will be conducted on your body's tissues or cells and human DNA or RNA in a stool sample will be excluded from analyses for this study.

What will happen to the results of this clinical research study?
The knowledge that we get from doing this research may be used to develop another study with SER-109. The results may be shared with regulatory agencies, at scientific conferences, or through publications so that other interested people may learn from our research. Confidential or personal identification information will not be shared. After the study has completed, you may contact the study doctor for any published materials as a result of the study.

A description of this clinical trial will be available on *http://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.

Who has reviewed the study?
All research studies are reviewed by an independent group of people, called a research ethics committee to protect your safety, rights, well-being and dignity. This study has been reviewed and has been given a favorable opinion by Copernicus Group Independent Review Board (CGIRB).

Who should I contact for more information or in case of questions?
If you have any questions, concerns, or complaints about this study, or about what to do if you become ill or if you or your partner become pregnant while you are participating in the study, please contact the study doctor. The study doctor's contact information can be found on page one of this form.

You should contact the study doctor first at the number(s) listed on page one if you have questions, complaints, or concerns about the study.

This research is being overseen by an Institutional Review Board ("IRB"). You may talk to them at (888) 303-2224*, irb@cgirb.com* if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

Thank you for reading this and considering if you will take part in this study.

CONSENT FORM

ECOSPOR III: A Phase 3 Multicenter, RandomizeEd, Double Blind, -Placebo COntrolled, -Parallel Group- Study to Evaluate the Safety, Tolerability, and Efficacy of SER-109 vs. Placebo to Reduce Recurrence of ClOstRidium difficile Infection (CDI) in Adults Who Have Received Antibacterial Drug Treatment for Recurrent CDI (RCDI)

I confirm the following:

- I have read and understand the information sheet for the above study, and have had enough time to think about taking part.
- I know who to contact if I have further questions.
- I am satisfied with the answers given to all of my questions.
- I voluntarily agree to be part of this research study, to follow the study procedures and to provide the information the study doctor, nurses or other staff members ask from me.
- I understand that my taking part is confidential and that I am free to withdraw from this study at any time without giving a reason and without my medical care or rights being affected.
- I have received a copy of this information sheet and consent form to keep for myself.
- I agree if my study doctor is not my family doctor, my family doctor may be told about my taking part in this study and asked for medical information about me.
- I agree to my biological samples (blood, urine, stool) being taken and used for the purposes of this study.
- I give permission for my personal information to be collected and used as part of this clinical study and to be:

    - identified only with my subject ID number;
    - reviewed, processed and disclosed by and to the Sponsor and its authorized representatives and study monitors for the purposes described in the study protocol;
    - reviewed or audited by the appropriately authorized organizations;
    - published and sent to regulatory authorities or health insurers in my country or other countries; and
    - transferred if required to any country, where laws protecting my personal information may be less strict.

- I understand I may also be contacted at a later date(s) for my permission in connection with this or any related sub study.

I have read and understand the information sheet for the above study, and have had enough time to think about taking part.

I am satisfied with the answers given to all of my questions.

By signing this document I agree to take part in this study, as set out in this information sheet and consent form.

Subject Name: _____
(Please print)

Subject Signature: _____ **Date:**_____

Investigator/Authorized Designee

- I have fully and carefully explained the study to the person named above and confirm that, to the best of my knowledge, they clearly understand the nature, risks and benefits of taking part in this study. The information about the study was described to the subject in language he/she understood.
- I confirm that I gave them all opportunities to ask questions about the study, and that I answered all the questions they asked correctly and to the best of my ability.
- I confirm that they have not been forced into giving consent, and that they have given their consent freely and voluntarily.
- I confirm they have been given a copy of this information sheet and consent form.

Investigator Name: _____
(*Or designee*, please print)

Investigator Signature: _____ **Date:** _____
(*Or designee*)

Impartial Witness Signature (if applicable)**
I confirm that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject and that informed consent was freely given by the subject.

_____
Printed Name of Impartial Witness

_____ Date: _____
Signature of Impartial Witness

[**AN IMPARTIAL WITNESS SIGNS WHEN THE INFORMATION SHEET AND INFORMED CONSENT FORM HAS BEEN READ TO THE SUBJECT - (I) IN ADDITION TO THE SUBJECT OR (II) IN LIEU OF THE SUBJECT - FOR SUBJECTS WHO ARE LEGALLY CAPABLE OF PROVIDING CONSENT BUT UNABLE TO READ OR UNABLE TO READ & WRITE.].

An impartial witness is:

- a person who is independent of the trial,
- who cannot be unfairly influenced by people involved with the trial,
- who attends the informed consent process, and
- who reads the informed consent form and any other written information supplied to the subject.

HIPAA AUTHORIZATION

Federal regulations give you certain rights related to your health information. These include the right to know who will receive the information and how it will be used. The study doctor must obtain your authorization (permission) to use or release any health information that might identify you.

What information may be used and shared?
The study doctor and study staff will use and share your health information as part of this research study. Except when required by law, you will not be identified by name, address, telephone number or other facts that could identify the health information as yours.

Examples of the information that may be used are:

- Medical records (from any doctor, hospital or other healthcare provider)
- Information created or collected during the research. This could include your medical history, and dates or results from any physical exams, laboratory tests or other tests.

Who will receive information about you?
The study doctor and study staff will share your personal health information with:

- the sponsor, including persons or companies working for or with the sponsor
- Copernicus Group Independent Review Board (CGIRB)
- the U.S. Food and Drug Administration (FDA)
- Department of Health and Human Services (DHHS) agencies
- other regulatory agencies in the United States and other countries

Why will this information be used and/or given to others?
The sponsor and the groups above will use your health information:

- to complete this research
- to evaluate the results of the study
- to check that the study is being done properly
- to obtain marketing approval for new products resulting from this research

Your data might be transferred to a country that may not have the same level of personal data protection as the United States. If your data is transferred outside the U.S., the sponsor is responsible for protecting your data. By signing this Authorization, you are giving your permission for this transfer to happen. There is a risk that once your information is disclosed, it may no longer be protected under HIPAA and may be given to others without your permission.

You do not have to sign this form. If you do not sign this form, you cannot take part in this research study.

You may withdraw your authorization to use your personal data at any time by sending a written notice to the study doctor, however, you will not be able to continue in this study if you revoke (take back) your permission to use your personal data. If you revoke your permission to use your personal data, no new information will be collected; however information that is already in use will continue to be used.

If you decide to stop taking part in the study, no new data will be added to the database and you may ask for your previously retained identifiable samples to be destroyed, to prevent further analysis. However, we may contact you to obtain some information about your health in case there is an ongoing side effect that poses a potential health safety risk after the decision to stop taking part.

If you withdraw from the study but do not withdraw your Authorization, new health information may be collected until this study ends.

All your study data will be protected in accordance with U.S. and/or European Data Protection legislation and protected to the extent permitted by law.

If you do not withdraw this Authorization, it will remain in effect.

If the research site is located in California, Delaware, Indiana, Washington, or Wisconsin this authorization will expire on 31Dec2060.

There is no expiration of this authorization except for research conducted in the states listed above.

The study doctor will keep this Authorization for at least 6 years.

You have the right to access and to ask for the correction of the information collected about you during the study. However, during the study, this right will be temporarily suspended in order to protect the integrity of the study data.

Your decision to withdraw your Authorization or not to participate will not involve any penalty or loss of access to treatment or other benefits to which you are entitled.

AUTHORIZATION
By signing this form, I allow the use or disclosure of my health information. I will receive a signed and dated copy of this Authorization.

_____
Printed Name of Subject

_____
Signature of Subject Date

Impartial Witness Signature (if applicable)**
I confirm that the information in the Authorization was accurately explained to, and apparently understood by, the subject and that informed consent was freely given by the subject.

_____
Printed Name of Impartial Witness

_____ Date _____
Signature of Impartial Witness

[**AN IMPARTIAL WITNESS SIGNS WHEN THE INFORMATION HAS BEEN READ TO THE SUBJECT - (I) IN ADDITION TO THE SUBJECT OR (II) IN LIEU OF THE SUBJECT - FOR SUBJECTS WHO ARE LEGALLY CAPABLE OF PROVIDING CONSENT BUT UNABLE TO READ OR UNABLE TO READ & WRITE.].

An impartial witness is:

- a person who is independent of the trial,
- who cannot be unfairly influenced by people involved with the trial,
- who attends the informed consent process, and
- who reads the informed consent form and any other written information supplied to the subject.