

Information and Consent Form  
For Parent/Guardian or Participants Age 18+  
Optimer Pharmaceuticals, Inc.  
101.1.C.003

INFORMATION AND CONSENT FORM  
For Parent/Guardian or Participants Age 18+

Protocol Title: <<study title>>  
Protocol #: <<protocol number>>  
Sponsor: <<sponsor>>  
Study Doctor: <<investigator>>  
<<firm name>>  
<<street address>>, <<city>>, <<state>> <<zip>>  
Telephone Number: <<000-000-0000>>  
After Office Hours: <<000-000-0000>>

The study doctor wants to know if you would like to be part of a research study. This form describes the study in order to help you decide if you want to participate. This form will tell you what you will have to do during the study and the risks and benefits of the study.

If you have any questions about or do not understand something in this form, you should ask the study doctor. You should discuss your participation with anyone you choose in order to better understand this study and your options. Do not sign this form unless the study doctor or study staff has answered your questions and you decide that you want to be part of this study.

Being in this study does not replace your regular medical care.

When reading this form, please note that the words "you" and "your" refer to the person in the study rather than to a parent <<or guardian>><<, guardian, or legally authorized representative>> who might sign this form on behalf of the person in the study.

WHAT IS THE BACKGROUND OF THIS STUDY?

*Clostridium difficile* (*C. difficile*) is a bacterium that causes infection of the colon (large bowel or intestines). *C. difficile* produces toxins (chemicals) that cause diarrhea, stomach pain, fever, vomiting, and dehydration. *C. difficile* is a significant problem in hospitals and long-term care facilities.

WHAT IS THIS STUDY ABOUT?

You have *C. difficile*-associated diarrhea (CDAD). Researchers want to find out if an investigational drug called PAR-101 can help people with CDAD.

PAR-101 is an investigational drug. An "investigational drug" is a drug that is being tested and is not approved for sale in the United States by the U.S. Food and Drug Administration (FDA).

The study doctor will give PAR-101 to some people in this study to see if it is safe and tolerable, and can help them with their CDAD. Another purpose of this study is to find out if taking PAR-

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101 is better than taking vancomycin. The FDA has approved vancomycin for the treatment of infections by certain bacteria, including *C. difficile*.

It is planned that about 664 people with CDAD who are at least 16 years old will be in this study. About half of the participants will get PAR-101, and about half of the participants will get vancomycin.

You do not have to be in this study to take vancomycin for your CDAD.

#### IS THERE ANYTHING ELSE I CAN DO FOR MY CDAD?

You do not have to be in this study to get help for your CDAD. The study doctor will talk to you about other things you can do for CDAD, including the risks and benefits. Some other things you can do are:

- Take vancomycin outside this study.
- Use metronidazole
- Use bacitracin.
- Use anionic resins.
- Use traditional supportive therapy.

#### WHO IS PAYING FOR THIS STUDY?

A company called Optimer Pharmaceuticals, Inc., the sponsor of the study, is paying for this study. Optimer Pharmaceuticals, Inc. is also paying the study doctor to do this study.

<<if Board determines a potential conflict of interest exists at site level: <<The study doctor has <<a significant financial interest>><<a significant interest>> associated with the study which could influence your decision to participate and the study doctor's decision to recruit you in the study. Ask the study doctor for more information.>>

<<Additional conflict of interest language as applicable: <<The study doctor <<has a relationship with the sponsor outside of this study>> <<is a paid consultant to the sponsor>> <<receives speaking fees from the sponsor>>. This relationship with the sponsor may influence your decision to participate and the study doctor's decision to recruit you in the study. Ask the study doctor for more information.>>

#### WILL IT COST ANYTHING TO BE IN THIS STUDY?

While you are in the study, you still need to get regular medical care. You (and/or your health care payer) will still have to pay for the costs of your regular medical care that are not a part of this study.

You do not have to pay for study drug (PAR-101 or vancomycin), study visits, or tests that are part of the study. To find out more about costs, you can ask the study doctor or study staff.

During the study, the study doctor may give you antibiotic therapy if your CDAD becomes worse. You (and/or your health care payer) will have to pay for the antibiotic therapy. Before

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you agree to be in this study, you should contact your health care payer to see if your plan will cover the costs required as part of your participation.

You may have to pay the costs of diagnosing and treating a condition or injury that you or others think is a direct result of your being in the study. This could happen if:

- The sponsor and/or the study doctor do not think the condition or injury is a direct result of your being in the study.
- You have not followed the directions the study doctor or study staff gave you about the study.

#### HOW DO I KNOW IF I CAN BE IN THIS STUDY?

The first part of the study is called a screening period. The screening period can last a few hours. During this time, the study doctor will decide if you qualify to be in the main part of the study.

To be in this study, you will have to:

- Read and sign this consent form.
- Follow the instructions you are given.
- Come to the study center for all visits with the study doctor.
- Tell the study doctor or study staff about any changes in your health.
- Tell the study doctor or study staff if you want to stop being in the study at any time.

You will not be able to be in this study if:

- You have received any investigational drug within 1 month of your first visit.
- You are currently receiving vancomycin, metronidazole, oral (by swallowing) bacitracin, or any drugs used for the treatment of CDAD for more than 1 day.
- You need to take antibiotics for more than 7 days after the start of the study.

#### Other restrictions

You will not be able to be in the study if:

- You are a pregnant or nursing woman.
- You have certain other intestinal disorders, such as ulcerative colitis or Crohn's disease. Ulcerative colitis is a serious, chronic (long-lasting) inflammation (pain, swelling, heat) of the large intestine and rectum characterized by returning episodes of abdominal pain, fever, chills, and diarrhea. Crohn's disease is a chronic inflammation that causes stomach pains, diarrhea, and weight loss.
- You currently have toxic megacolon, an inflation of the colon that occurs when inflammation spreads from the mucosa (moist tissue layers) through the remaining layers of the colon.
- You have had more than 1 recurrence of CDAD within the past 3 months.

People with life-threatening CDAD will not be able to be in the study. This includes people with any of the following:

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- very high white blood cell counts
- a high fever of more than 104° Fahrenheit (40° Celsius)
- evidence of hypotension (low blood pressure)
- septic shock (shock caused by endotoxin in the blood)
- peritoneal (abdominal cavity) signs
- significant dehydration

#### HOW LONG WILL I BE IN THE STUDY?

If you decide to be in this study and the study doctor says you can be in the study, your participation will last about 6 weeks. You will have to come to the study center about 3 times during the study. The study staff will tell you when to come in for your study visits. You should ask the study staff how long your visits will last.

#### WHAT WILL HAPPEN DURING THIS STUDY?

If the study doctor says you can be in the study and you want to be in the study, you will be assigned to 1 of the 2 study groups:

- Group 1: PAR-101, 400 mg each day for 10 days
- Group 2: Vancomycin, 500 mg each day for 10 days

You will take capsules 4 times a day for 10 days. The capsules will be study drug (PAR-101 or vancomycin) and placebo (a capsule that looks like one of the study drugs but has no active ingredient). The purpose of giving you placebo is so you will not know whether you are in Group 1 or Group 2 and so it will appear to everyone in the study that they are taking the same thing. Ask the study doctor or study staff if you have questions about placebo.

You have a nearly equal chance of being in either study group. You will not know and the study doctor will not know which study group you are in. However, the study doctor can find out if there is an emergency or if it is necessary to know for your health. If this happens, the study doctor may not be able to tell you which study group you were in until everyone finishes the study.

The study doctor or study staff will call you each day while you are taking study drug to check on your health. If you are hospitalized, the study doctor or study staff will visit you in the hospital each day to check on your health.

After you take study drug for 10 days, the study doctor will check if your CDAD has gone away. If it has gone away, the study doctor will check your health over the next 28 days to see if your CDAD comes back. The study doctor or study staff will call you 2 to 4 days after your last dose of study drug. After this, the study doctor or study staff will call you each week. You will have a final visit at the end of the 28 days.

If your CDAD comes back after you stop taking study drug, you will need to come to the study center. The study doctor may put you on standard antibiotic therapy for your CDAD. If you need to take standard antibiotic therapy, you will have to leave the study.

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You are the only one who should take the study capsules. You should make sure that no one else takes them.

What happens when I come for study visits?

Before you can start the study, the study doctor or study staff will talk to you about the study. Then you have to sign this form before the study doctor or study staff can begin the screening period to see if you qualify to be in the study. If you are a parent or guardian who is signing this form on behalf of a child in the study, be aware that your child will have to sign a separate assent form before the study doctor or study staff can begin the screening period.

After you sign this form, the study doctor or study staff will do the things listed below when you come in for study visits. If you would like more information about which tests and procedures will be done at each study visit, ask the study doctor or study staff.

- Health and Medication Questions: Ask you to answer questions about your health, your medical history, and the medications you take.
- Physical Exam: Do a physical exam. You should ask the study doctor about what will happen during this exam.
- Blood Pressure, Pulse, Temperature: Check your blood pressure by putting a band around your arm. This will squeeze your arm for about a minute. Check your pulse and take your temperature.
- Height, Weight: See how tall you are, and see how much you weigh.
- Blood Tests: Take some blood to do laboratory tests.
- Pregnancy Test: If you are a woman and can have children, you will have at least 1 pregnancy test. The study doctor or study staff will tell you if the pregnancy test results are positive. The results of the pregnancy test(s) must be negative in order for you to be in the study. If you are the parent or guardian of a child in the study, be aware that the study doctor or study staff may or may not tell you the results of your daughter's pregnancy test(s), depending on state law.
- Stool Sample: Take a stool sample after you have a bowel movement. Do lab tests on the stool sample.
- ECG: Do an ECG test. An "ECG" or "electrocardiogram" is a test that measures the electrical activity of your heart.
- Take-Home Worksheet: Give you a "Take-Home Worksheet," which you will use to record information about your health.
- Study Drug: Give you a supply of study drug (PAR-101 or vancomycin) and tell you how to take it. Ask you to bring back all unused study drug to each visit.

Your regular medical care might include some of the study tests and procedures. The study doctor or a member of the study staff can answer any questions you may have about the tests and procedures that are not part of your regular medical care.

After the study is over, you should talk to the study doctor about your future treatment for CDAD.

Ask the study doctor for the estimated recovery time of your participation in this study.

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#### WILL BEING IN THIS STUDY HELP ME?

The study drug may help your CDAD, but there is no guarantee that being in this study will help you. Your CDAD might not get better or may even get worse while you are in this study. Information from this study might help researchers to come up with new tests or medications to help others in the future.

#### ARE THERE RISKS TO ME IF I AM IN THIS STUDY?

##### What can happen if I take PAR-101?

Some participants in a study involving people taking PAR-101 had the following side effects or events:

- heart failure
- lower bowel bleed
- inflammation (pain, swelling, heat) of the pancreas
- chest pain
- bronchitis
- bacterial infections
- retention of fluid (bloating)
- pain in the arms or legs
- bleeding in the brain
- breathing difficulties
- hypotension (low blood pressure)
- headache
- dizziness
- weakness
- fatigue (tiredness)
- running nose
- nasal congestion
- pharyngitis (sore throat)
- conjunctivitis (pinkeye—itching around the eyes)
- upper respiratory infection
- urinary tract infection
- kidney stones

Researchers have decided that these side effects and events were unrelated to PAR-101. However, it is possible that you could have 1 or more of these side effects or events in this study. Ask the study doctor or study staff if you have questions about the signs or symptoms of the side effects and events listed above.

Please tell the study doctor or study staff right away if you have any side effects. Please tell them if you have any other problems with your health or the way you feel during the study, whether or not you think they are related to the study drug.

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What can happen if I take vancomycin?

Some people who have taken vancomycin had the following side effects:

- a severe allergic reaction that is possibly life-threatening (please see below for the section titled, “*Could I have an allergic reaction?*”)
- hypotension (low blood pressure)
- inflammation (pain, swelling, heat) of the walls of the veins, followed by a blood clot
- inflammation of the kidneys
- kidney failure
- a loss of hearing
- hearing a ringing or buzzing
- sense of fullness in the ears
- a decrease in a type of white blood cell, which may or may not be reversible
- a decrease in platelets (parts of the blood that help with blood clotting), causing abnormal bleeding and bruising
- abdominal cramping
- diarrhea
- an increase in certain bacteria that are resistant to vancomycin
- an inflammation of small blood vessels
- an abnormal reddening, flaking, and thickening of the skin
- a severe, possibly life-threatening rash that causes skin peeling and sores on mucous membranes
- a reaction known as red-man syndrome, which appears as a rash usually in the face, neck, and torso (body), and is accompanied by itching, muscle aches, rapid heart rate, low blood pressure, and hives
- fever
- chills
- an increase in a type of white blood cell
- discoloration of the skin
- bitter or unpleasant taste
- inflammation of the walls of the veins
- dizziness
- vertigo (spinning feeling)

Most of the side effects go away once you stop taking vancomycin.

If you have another condition besides CDAD (for example, a condition related to the heart, lungs, liver, kidney, or urinary tract), vancomycin could make your other condition worse or lead to your death. Ask the study doctor or study staff if you have questions about this.

Could I have an allergic reaction?

Sometimes people have allergic reactions to drugs. If you have a very bad allergic reaction, you could die. Some things that happen during an allergic reaction are:

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- a rash
- having a hard time breathing
- wheezing when you breathe
- nausea and vomiting
- itching
- sudden drop in blood pressure with loss of consciousness (blackout)
- swelling around the mouth, throat, or eyes
- fast pulse
- sweating
- seizures

You should get medical help and contact the study doctor or study staff if you have any of these or any other side effects during the study.

Could I have any other problems with my health if I do this research study?

It is possible that you could have problems and side effects of PAR-101 or vancomycin that nobody knows about yet, which include your CDAD getting worse or even death. If the study doctor learns any new information about PAR-101 or vancomycin that might change your mind about continuing in the study, the study doctor or study staff will tell you about it.

It is possible that taking PAR-101 or vancomycin with your regular medications or supplements may change how PAR-101, vancomycin, your regular medications, or your regular supplements work. It is very important that you tell the study doctor about all medications or supplements you are taking during the study.

What are the risks of giving blood for this study?

The study doctor or study staff will take your blood by sticking a needle in your arm. Some problems you might have from this are:

- It may hurt.
- You may have inflammation (pain, swelling, heat, redness) where the needle enters your skin.
- You may get a bruise.
- You may feel dizzy.
- You may get an infection.

You will give about 2 tablespoons of blood during the study.

Are there risks if I am pregnant during the study?

If you are a woman, you cannot be in this study if you are:

- pregnant
- planning to become pregnant during the study

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- nursing a child

If you are pregnant or nursing a child while taking PAR-101 or vancomycin, there may be risks to your unborn baby or nursing child. Nobody knows what these risks are right now. Some drugs cause women to have their babies prematurely (early) or to have babies with birth defects.

If you are a woman who can have children, the study doctor will talk to you about birth control methods you must use during the study and for 4 weeks after you stop taking study drug. Some methods of birth control will not work when you are taking certain drugs.

The study doctor may require women who join the study to have pregnancy tests during the study. A pregnancy test does not keep you from becoming pregnant.

If you are a man, there may be risks to an unborn baby you father during or after the study. The study doctor will talk to you about the birth control options you and/or your partner must use during the study and for 4 weeks after you stop taking study drug.

If you think you are pregnant during the study, you must tell the study doctor immediately. If you become pregnant, you will have to leave the study. The study doctor may ask for information about the pregnancy and the birth of the baby. The study doctor may share this information with the sponsor and Quorum Review Institutional Review Board (IRB).

#### WILL I GET PAID?

You will get \$000 if you finish the whole study. If you do not finish the whole study, you will get \$000 for each study visit you finish, <<not>> including the screening visit. The study doctor or study staff can tell you more about when you will get paid.

*<<If applicable (if participants will not be paid for participation): You will not get paid for being in this study.>>*

*<<if applicable (if participants will be paid for travel and parking costs): <<if applicable: In addition to payment for being in the study, you>> <<You>> <<will get \$000 for travel and parking costs.>>*

*<<if applicable (if participants will receive gifts or study equipment): <<if applicable: In addition to payment for being in the study, you>> <<You>> <<will get <<gifts, study materials>> worth \$000.>>*

#### WHAT IF I GET HURT OR SICK WHILE I AM IN THIS STUDY?

If you get hurt or sick as a direct result of being in this study, medical treatment will be available. The sponsor will pay the costs of reasonable medical treatment so long as your medical insurance, government programs, or another third party will not cover the costs. Be aware that your health care payer might not cover the costs of study-related injuries or illnesses.

The sponsor has no plans to provide other forms of compensation, including compensation for pain, suffering, or lost wages. You do not give up any of your legal rights by signing this form.

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To ask questions about any of this, talk to the study doctor or study staff.

#### DO I HAVE TO BE IN THIS STUDY?

Your decision to be in this study is voluntary. You do not have to be in the study if you don't want to, and you can change your mind at any time. There will be no penalty to you, and you won't lose any benefits.

The study doctor or sponsor can remove you from the study at any time, even if you want to stay in the study. This could happen if:

- The study doctor believes it is best for you to stop being in the study.
- You do not follow directions about the study.
- The sponsor stops the study for any reason.

If you want to stop being in the study, tell the study doctor or study staff and return all unused study capsules. If you stop being in the study early, the study doctor or study staff may ask you some questions about being in the study. To help you leave the study safely, the study doctor may ask you to participate in more tests.

#### WHO CAN I TALK TO ABOUT THIS STUDY?

You can ask questions about the study at any time. You can call the study doctor at any time if you have any concerns or complaints. You should call the study doctor if you have questions about the study procedures, study costs (if any), study payment (if any), or if you get hurt or sick during the study.

Study Doctor: <<investigator>>  
Telephone Number: <<000-000-0000>>  
After Office Hours: <<000-000-0000>>

Quorum Review Institutional Review Board (IRB) reviewed this study. Quorum Review IRB is a group of people who review research studies to protect the rights and welfare of research participants and is not affiliated with the study doctor or the sponsor. If you have questions about your rights as a research participant, if you are not able to resolve your concerns with the study doctor, or if you have general questions about what it means to be in a research study, you can call Quorum Review IRB or visit the Quorum Review IRB website at [www.quorumreview.com](http://www.quorumreview.com).

Quorum Review IRB is located in Seattle, Washington.  
Office hours are 8:00 AM to 5:00 PM Pacific Time, Monday through Friday.  
Ask to speak with a Research Participant Liaison at 888-776-9115 (toll free).

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## WHO WILL USE AND SHARE INFORMATION ABOUT MY BEING IN THIS STUDY?

This section explains who will use and share your study-related health information if you agree to be in this study. If you do not sign this form, you cannot be in the study.

During the study, the study doctor and study staff will use, collect, and record health information about you (your “records”). Your records will include any information about you that the study doctor needs to do the study, including information from the tests described above. Your records also will include other information about you, such as your name and address.

By signing this form:

- You allow the study doctor and study staff to use your records to carry out this study.
- You allow the study doctor to share your records with the sponsor, Optimer Pharmaceuticals, Inc.; people who work with or for the sponsor; and other researchers involved in this study. These people will use your records to review the study, to check the safety and results of the study, and to seek government approval of PAR-101.
- You allow the study doctor or sponsor to use some facts about your being in the study in books, magazines, journals, and scientific meetings. If this happens, no one will use your name or other information that could be used to identify you.
- You allow the study doctor to share all of your records and this signed consent form with the FDA and other government agencies in the United States and other countries. The study doctor may also share your records with regulatory agencies, like Quorum Review Institutional Review Board (IRB). These agencies may use your records to check the study information, how researchers are doing the study, participants’ safety, and the results of the study.
- You allow the study doctor to share your records with your health care payer to resolve your claim if you are hurt because of being in this study. If this happens, the study doctor or the sponsor may share

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your records with their insurance carriers to resolve your insurance claim, and the study doctor may also request medical records from your other health care providers to learn more about your condition.

- You allow the study doctor to share your records with your health care payer in order to collect payment for study costs (even if your health care payer does not cover those costs).

There are national and state laws that make the study doctor protect the privacy of your records. However, you do not have a guarantee of absolute privacy because of the need to share your information. After the study doctor shares your records with the sponsor and others, the laws may no longer protect the privacy of your records. The sponsor or others may share your records with other people who do not have to protect the privacy of your records.

If you would like to know how the sponsor will protect the privacy of your records, ask the study doctor how to get this information.

You have a right to see a copy of your study records. However, if you sign this form, you might not be able to see and copy some of your records until after all participants finish the study.

You can cancel this consent to use or share your study records at any time. If you want to cancel your consent, you must write a letter to the study doctor. If you cancel your consent:

- You will not be able to continue in this study.
- The study doctor will not be able to use or share your records unless it is necessary to protect the integrity of the study.

This consent to use and share your records expires in 50 years.

You will receive a signed copy of this form for your records.

Indicate your agreement to the use and sharing of your records by checking the box below and signing:

☐ I agree to the use and sharing of my records related to this study as described above.

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\_\_\_\_\_  
Signature of Participant <<or Legal Representative>>

\_\_\_\_\_  
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DO YOU WANT TO BE IN THIS STUDY?

I have read this form, and I have been able to ask questions about this study. The study doctor or study staff has talked with me about this study. They have answered all my questions. I voluntarily agree to be in this study.

By signing this form, I have not given up any of my legal rights as a research participant. I will get a signed copy of this consent form for my records.

REGULAR DOCTOR OR SPECIALIST NOTIFICATION OPTION

Please indicate below whether you want us to notify your regular doctor or your specialist of your participation in this study.

☐ Yes, I want the study doctor to inform my regular doctor/specialist of my participation in this study:

\_\_\_\_\_  
Name of Doctor

\_\_\_\_\_  
Phone

☐ No, I do not want the study doctor to inform my regular doctor/specialist of my participation in this study.

☐ I do not have a regular doctor/specialist.

☐ The study doctor is my regular doctor/specialist.

\_\_\_\_\_  
Printed Name of Participant

\_\_\_\_\_  
Date of Birth

\_\_\_\_\_  
Signature of Adult Participant

\_\_\_\_\_  
Date

I certify that under state law I am the <<legally authorized representative or>> parent/guardian of the participant named above and that I am authorized to sign this consent to his/her participation in the research study described above.

\_\_\_\_\_  
Printed Name of Parent/Guardian<</Legal Representative>>

\_\_\_\_\_  
Signature of Parent/Guardian<</Legal Representative>>

\_\_\_\_\_  
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I attest that the participant and/or parent/guardian<</legal representative>> named above had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to be in this study.

\_\_\_\_\_  
Printed Name of Person Explaining Consent

\_\_\_\_\_  
Signature of Person Explaining Consent

\_\_\_\_\_  
Date

I attest that I or my representative discussed this study with the participant and/or parent/guardian<</legal representative>> named above.

\_\_\_\_\_  
Signature of Principal Investigator or Sub-Investigator