

### 16.1.3.2 Sample Consent Forms

#### 16.1.3.2.1 Sample Consent Form - USA

{Date}  
Protocol No. OPT-80 2A

#### Final- INFORMED CONSENT

**STUDY TITLE: An Open-Label, Dose Ranging, Randomized Clinical Evaluation of OPT-80 in Patients with *Clostridium difficile*-Associated Diarrhea (CDAD)**

**Principal Investigator:** \_\_\_\_\_

#### **INTRODUCTION**

The following information will describe the research study and your role as a participant. The investigator (study doctor) will answer any questions you may have about this informed consent form and about the study. Please read it carefully and do not hesitate to ask any questions about the information provided below.

#### **PURPOSE OF THE STUDY**

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

As your doctor has explained to you, the cause of your diarrhea may be the result of an infection caused by *C. difficile*. Your voluntary participation in this research study will help determine the effectiveness and safety of a drug called OPT-80 for the treatment of CDAD. Approximately 45 men and women with CDAD will participate in this study.

#### **DESCRIPTION OF THE STUDY AND PROCEDURES**

If you agree to take part in this study, you will undergo a screening process to determine if you can participate. The screening process includes the following: a questionnaire, medical history, physical examination, vital signs (blood pressure, pulse, temperature, weight, and height), laboratory blood and urine tests, an electrocardiogram, pregnancy test (if applicable), and stool tests (for the presence of *C. difficile* or *C. difficile* toxin).

If you are pregnant or nursing, or are able to have children and are not using effective contraception you will be excluded from participation in the study. If you are a woman of childbearing potential, you must use an effective contraception method for the duration of the study. Should you become pregnant during the study, you must tell your doctor immediately.

After completion of the screening process, the study doctor will determine whether you remain eligible for inclusion in the study. If you remain eligible and still wish to participate you will receive the study medication and diary cards. It is very important that all who participate in this study complete the diary correctly. You will then be instructed

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on how to use the diary cards and when to take the study medication. The study doctor or one of their staff will contact you every day you are on the study medication to discuss how you are feeling.

On day 10, when treatment is discontinued, you will again have a physical examination, a check of vital signs (blood pressure, pulse, temperature, weight, and height), laboratory blood and urine tests, and an electrocardiogram. You will be asked to provide a stool sample that may be used for tests to measure level of study drug or *C. difficile*.

One week and 6 weeks after the end of treatment, you will be contacted by the physician or his staff to discuss if you are still having symptoms.

If the symptoms of CDAD recur within that period, you will be asked to provide a blood and stool sample. If there is a recurrence of your symptoms, you will be placed on standard therapy for CDAD by your doctor.

If your physician feels that it is in your best interest to receive CDAD therapy other than OPT-80, you will be withdrawn from the study. OPT-80 treatment will also be stopped if severe side effects occur, if you or your physician wish to discontinue treatment, or if Optimer Pharmaceuticals (the Sponsor of the study) finds it necessary to limit or terminate this study. You will continue to be monitored for forty -two days following the last dose of OPT-80.

Participants will receive one of three dose levels of OPT-80. The doses will be randomly assigned by Optimer Pharmaceuticals in the order subjects are entered into the study. The dose of OPT-80 you receive will remain the same during the study.

### **DISCOMFORT AND RISKS**

All study medications have the potential to cause some adverse events or other reactions. The adverse events reported in two previous studies, in healthy volunteers, included headache, dizziness, weakness, fatigue, running nose, nasal congestion, pharyngitis, conjunctivitis and upper respiratory infection, all of these events were decided to not be related to the study drug. In an earlier study, one subject experienced rash and itching, which were possibly related to the treatment. The most frequent side effects of drugs that are similar in chemical structure to OPT-80 are abdominal pain and cramping, nausea and vomiting, diarrhea, hepatitis or jaundice, ringing of the ears or dizziness.

As with any drug, it is possible that you could experience an allergic reaction to the study drug. Such allergic reactions include: nausea, vomiting, itching, skin rash, hives, facial swelling, an acute or sudden drop in blood pressure to shock levels with loss of consciousness and/or associated with seizures, including the possibility of death. You may also experience an acute asthma-like attack with difficulty in breathing or swelling of the throat with blockage of the breathing passage. There is a potential of death with the

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acute asthma-like attack. As with many drugs, there is a small possibility of death or serious illness from a number of causes such as heart, lungs, liver, kidney, intestines and urinary tract problems.

Most of these side effects or allergic reactions are reversible once the medication is stopped.

There is a slight risk of side effects from the routine blood test that will be required throughout the study. There could be bruising at the site where you will be getting your blood drawn, as well as possible inflammation of the vein or an infection at this site. Of course, care will be taken to avoid these complications.

There may also be side effects and discomforts, which are not known at this present time. However, you will be informed of any significant new findings about the drug developed during the course of this study, which may or may not affect your willingness to continue participation.

### **ALTERNATIVES**

The following medications, which are not experimental, are available as alternatives to the study drug: vancomycin, metronidazole, bacitracin or anionic resins as well as traditional supportive therapy.

You may decide to receive other available treatments instead of OPT-80. Your doctor will discuss these options with you. If you choose not to participate in this study, other choices are available to you without prejudice.

### **ELIGIBILITY AND EXCLUSION**

#### ***Compliance and availability***

- You will be required to sign an informed consent form.
- You must be able to comply with the dosing instructions given to you, and be available to complete the study schedule.

#### ***Mild to Moderate CDAD***

Patients with life threatening CDAD will be excluded. This includes patients with white blood cell counts over 30,000, or patients with a fever more than 104° Fahrenheit (40° Celsius).

#### ***Medications***

**You will be ineligible for the study if:**

- You have received any investigational drug within one month of screening or within 5 half-lives of the drug, whichever is longer

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- You are currently receiving vancomycin, metronidazole, bacitracin, or related drugs, or any drugs used for the treatment of CDAD.
- You are taking other antibiotics

***Other Restrictions***

**You will be ineligible for the study if:**

- You are a pregnant or nursing woman
- You have donated blood within 30 days of dosing
- You have ulcerative colitis or Crohn's disease
- Your screening blood tests or ECG results are abnormal in the opinion of the study doctor

**POSSIBLE BENEFITS TO PARTICIPANTS**

If the test drug is effective, you may benefit by having symptomatic relief within 4 days of treatment. If you do not respond within this time, you will be transferred to the standard therapy for CDAD recommended by your doctor. It is possible, however, that no therapeutic or other direct health benefits may result during or following completion of this study.

**COSTS**

You will not receive money or any other form of compensation for participating in this clinical trial. All costs for your treatment, other than those that are solely for this study, are your responsibility. OPT-80 will be provided free of charge. In the event that your participation in this study results in a medical problem, treatment will be made available. No reimbursement for such treatment or financial compensation of any kind, including compensation for pain and suffering, lost wages or the like, will be given.

**COMPENSATION FOR MEDICAL TREATMENT**

If you suffer any adverse drug experience resulting directly from the study drug, Optimer Pharmaceuticals will provide reimbursement for the reasonable costs of medical treatment to the extent such costs are not covered by your medical or hospital insurance or by third party or governmental programs providing such coverage. No other form of compensation of any kind, including compensation for pain and suffering, lost wages or the like, is available,

**CONFIDENTIALITY**

Unless required by law, only the Investigator, the sponsor (Optimer Pharmaceuticals, Inc.) and government regulatory agencies will have access to confidential data, which identify you by name. You will not be identified in any reports or publications resulting from this study.

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v. 0.7

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All or part of your medical records may be reviewed and analyzed by the United States Food and Drug Administration (FDA) and representatives of Optimer Pharmaceuticals, the study sponsor. If information from this study is presented publicly or published in a medical journal, you will not be identified by name or any other personally identifying information. The FDA and Optimer Pharmaceuticals monitor's may inspect the research and clinical records without removal of identifying information. However, the usual medical record precautions will be taken to maintain the privacy and confidentiality of your records.

#### **TERMINATION OF SUBJECT PARTICIPATION**

Your participation in this clinical trial may be ended at any time for medical reasons or because Optimer Pharmaceuticals finds it necessary to limit or terminate this clinical trial.

#### **SUBJECT WITHDRAWAL PROCEDURES**

Participation in this study is voluntary. You are free to withdraw your consent and to discontinue participation in the study at any time. Should you decide to withdraw, your regular treatments or medical care will not be affected in any way. If you fail to comply with the instructions of the investigator or physician feels it is in your best interest, she or he may withdraw you from the study at any time and without your consent. Your participation in this project will also be stopped if it is felt at any time that your participation could be detrimental to your health.

Any time your participation is ended you will be asked to go through the termination procedures the study doctor considers necessary for your safety. You must return all unused study medications and diary cards to the investigator.

#### **NEW FINDINGS**

You will be informed of any new findings developed during the course of this study, which may influence your willingness to continue your participation.

#### **QUESTIONS**

You have the right to ask questions concerning this study at any time, and you are urged to do so. If you have any questions about the study and/or its procedures or safety, please contact Dr. {Name} at {Phone Number}. In the event of any injury, please contact Dr. {Name} at {Phone Number}.

Any questions about your rights as a research participant and/or any complaints about this clinical trial may be directed to the following impartial third party: {Name} Chair of {site} IRB at {Phone Number},{address}.