

SUBJECT INFORMATION AND CONSENT FORM AND AUTHORIZATION TO USE AND DISCLOSE PERSONAL HEALTH INFORMATION FOR RESEARCH

Name of Research Study: A Phase 3 Randomized, Double-Blind, Multicenter Study Comparing the Efficacy and Safety of 6-Day Oral TR-701 Free Acid (FA) and 10-Day Oral Linezolid for the Treatment of Acute Bacterial Skin and Skin Structure Infections

Protocol Number: TR701-112

Sponsor: Trius Therapeutics, Inc

Principal Investigator Name:

Research Site Address(es):

Daytime Telephone Number(s):

24-hour contact number(s):

Introduction

This Subject Information and Consent Form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or procedures that you do not clearly understand.

The purpose of this form is to give you information about the research study. If you sign this form you are giving your permission to take part in the study. The form describes the purpose, procedures, benefits, risks, discomforts, and precautions of the research study. You should take part in this study only if you want to do so. You may refuse to take part or withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled. Please read this Subject Information and Consent Form and ask as many questions as you want. You should not sign this form if you have any questions that have not been answered to your satisfaction. You should not sign this form if you do not want to take part in this study.

SPONSORSHIP/FUNDING

The study doctor (and clinic or hospital) is being paid by Trius Therapeutics, Inc. ("Trius" or "study sponsor") to do this research study.

PURPOSE

You are being asked to take part in a clinical research trial. The purpose of this study is to learn if an experimental antibiotic called TR-701 FA can safely and effectively treat the type of skin infection you have. An “experimental” drug means that the drug is currently being tested and is not approved by the U.S. Food and Drug Administration (FDA) for sale by prescription in the United States. TR-701 FA is not approved in other countries.

BACKGROUND

You are being asked to take part in this study because your doctor has diagnosed you with a skin infection. Skin infections happen when your skin is infected with bacteria. Skin infections may include symptoms such as discharge (“pus”) from the skin, warmth, pain, tenderness, redness, swelling, and/or fever.

Your doctor has decided that you should receive antibiotics to treat your skin infection. The standard treatment for many skin infections is an antibiotic. You should immediately inform the study doctor or staff if you have a history of allergies or other problems when taking any antibiotics or other medications.

DESIGN

Approximately 658 people with skin infections will take part in this study at about 100 medical centers and/or clinics around the world. The study doctor and staff will ask you about your health history and will conduct tests to decide whether you are eligible to take part in this study.

If you decide to participate, you will take either the experimental drug or a comparator drug by mouth twice a day for 10 days while the study doctor and staff check your skin infection.

STUDY DRUGS

The “study drugs” are TR-701 FA and linezolid. TR-701 FA is the experimental drug. Linezolid is a medication approved by the FDA to treat certain skin infections. If you participate in this study you will be assigned by a process called randomization (like the flip of a coin) to receive either TR-701 FA *or* linezolid. There is a 50% chance that you will receive TR-701 FA. Neither you nor the study doctor or staff will know which study drug you will receive. In case of an emergency, this information will be available to the study doctor.

If you decide to participate and are eligible, as determined by your study doctor and laboratory results, you will receive study drug for up to 10 days. You will take either a TR-701 FA 200 mg tablet by mouth once a day plus a matching linezolid placebo tablet twice a day **OR** linezolid 600 mg tablet by mouth twice a day with a TR701-FA matching placebo every day for 20 doses. A placebo is an inactive substance, like a sugar pill, that is made to look like one of the study drugs. It is important that you take all 10 days or 20 doses unless directed otherwise by your study doctor. In this study everyone will receive either TR-701 FA and a placebo or linezolid and a placebo.

If you have a skin infection caused by a wound, your doctor may decide you also need to take the medication aztreonam and/or metronidazole, currently available antibiotics, to also treat your

infection because your infection may be caused by bacteria that neither TR-701 FA nor linezolid work for.

DURATION OF STUDY PARTICIPATION

After screening, you will be asked to return to the clinic at least 6 times (study Days 1, Day 2, 48-72 hours after your first dose of study drug, Day 7, Day 11 and at least one follow-up visit). Your overall study participation will last about 28 to 37 days and you may be asked to make another visit to the clinic during this time.

STUDY PROCEDURES

If you want to participate and sign this consent form, the study staff will do the following so the study doctor can decide if you are eligible take part in the study:

- Ask you about your medical and surgical history, current and prior medicines, and current symptoms.
- Perform a routine complete physical examination and vital signs including taking your temperature, blood pressure, heart rate, breathing rate, and height and weight. Vital signs may be repeated every hour.
- Perform a 12-lead electrocardiogram (also known as ECG), which is a painless test to check the electrical activity of the heart.
- Females only: Collect a urine sample and a blood sample for a pregnancy test, if you are a woman who is able to have children. If you are pregnant or nursing, you **cannot** participate in this study. If you think you are pregnant, you must inform the study staff immediately.
- Collect a urine sample for routine laboratory tests.
- Collect blood samples (about ½ tablespoon) to determine if you are eligible to take part in the study. Your blood sample will also be tested for Hepatitis B and C. Some of this blood sample may also be retained for later research tests by the sponsor, Trius Therapeutics. The research tests would look for markers in the blood that may help to predict which patients may have a better response to a particular drug treatment for the skin infection. You and your physician will not know the outcome of these research tests.
- Collect blood sample (about ½ tablespoon) to check for the presence of bacteria in your blood. Blood will be drawn 2 times from 2 separate veins for a total of 4 draws.
- Perform a complete examination of your skin infection, which may include taking a sample of tissue or fluid from the infection to check for bacteria if the Investigator determines it is appropriate to do so as well as measuring the size of the skin infection.
- Perform routine care of your skin infection to help heal the infection.
- Record your rating of pain on the Visual Analog Scale, which is a 10 centimeter line that you will put a mark on to indicate how severe you feel your pain is. You will also record your rating of pain on the Face Rating Scale, which has a series of faces with expressions indicating different levels of pain.
- Take a digital photograph of the site of your infection if this is acceptable to you.

If you have a skin infection that is close to a bone, your doctor may perform an X-ray, MRI (magnetic resonance imaging) or CT scan (computed tomography) to make sure the infection is not in your bone. You may be asked to sign a consent form to have one of these procedures

performed. Each of these tests is painless and allows the doctor to see whether the bones were affected. If you have a bone infection, you will not be able to participate in this study.

If all the test results indicate that you are eligible to take part in the study, you will be given one of the two study drugs to take by mouth. During the time you take the study drug, your progress will be evaluated by tests like those for a patient who needs antibiotics. Some additional procedures will be done because this is a research study.

If you choose to participate and are accepted into the study, the study staff will:

- Give you a diary to write down the times you take your study drug and the times you take any medication for pain or fever. You will also write down your oral temperature four times daily up until the 48-72 Hour visit and then two times daily until you stop taking the study drug. You will also be asked to bring back your medication and your diary at every visit.
- Ask you about any new symptoms ("how you feel").
- Record your rating of pain on the Visual Analog Scale and Face Rating Scale.
- Perform a routine physical examination and vital signs including taking your temperature, blood pressure, heart rate, and breathing rate. Additional temperature measurements will be taken with other required procedures during the visit.
- Perform a complete examination of your skin infection, which may include taking a sample of tissue or fluid from the infection to check for bacteria if needed.
- Perform routine care of your skin infection to help healing of the infection.
- Collect blood samples (about ½ tablespoon) for routine clinical testing. Some of this blood sample may also be retained for later research tests by the sponsor, Trius Therapeutics. The research tests would look for markers in the blood that may help to predict which patients may have a better response to a particular drug treatment for the skin infection. You and your physician will not know the outcome of these research tests.
- Other blood samples (about ½ tablespoon) may also be collected to check for the presence of bacteria in your blood, if needed. Blood may be drawn 2 times from 2 separate veins for this test.
- Take follow-up digital photographs of the site of your infection if this is acceptable to you at screening
- Request that you avoid large quantities of foods or beverages with high tyramine content. Foods high in tyramine include those that may have undergone protein changes by aging, fermentation, pickling, or smoking to improve flavor. These foods include ones such as aged cheeses, air-dried meats, sauerkraut, soy sauce, tap beers, and red wines.
- Discuss with you medications that cannot be taken while taking these study drugs.
- If your doctor chooses for you to take some of your study drug outside of the clinic, you will be given a diary to write down the date and time you take your medication.

The following will be performed for the study and are not routinely performed for skin infections:

- ECGs (painless heart test) will be done at the 48-72 Hour Visit and Day 7.
- If you are a woman who is able to have children, the blood sample already collected for testing on the last day the study drug is administered will also have a blood pregnancy test.

- Additional blood samples (2 blood samples of about 1 teaspoon each) on the Study Day 1 and 48-72 hours after your first dose of study drug will be collected to measure how much TR-701 FA is in your blood at specific times as follows:
 - One sample approximately 2 to 6 hours after you take the study drug on Day 1
 - One sample prior to the either Dose 5 or Dose 7 at the 48-72 Hour Visit
 - One sample approximately 2-3 hours after Dose 5 or Dose 7 at the 48 -72 Hour Visit
 - One sample approximately 4-6 hours after Dose 5 or Dose 7 at the 48-72 Hour Visit

Some of this blood sample may also be retained for later research tests by the sponsor, Trius Therapeutics. The research tests would look for markers in the blood that may help to predict which patients may have a better response to a particular drug treatment for the skin infection. You and your physician will not know the outcome of these research tests.

If the study doctor decides that the study drug you are taking is not helping cure the infection, you will need additional drugs not allowed in this study. If this happens, your use of the study drug will be stopped.

Follow-Up Phase

Approximately one to two weeks after your last dose of the study drug, you will be asked to return to see the study doctor if the study drug worked for your infection for routine tests and check on how your infection is doing.

- Ask you about any new symptoms ("how you feel").
- Perform a routine brief physical examination and vital signs including taking your temperature, blood pressure, heart rate, and breathing rate.
- Perform a complete examination of your skin infection, which may include taking a sample of tissue or fluid from the infection to check for bacteria.
- Perform routine care of your skin infection to help healing of the infection.
- Collect blood samples (about ½ tablespoon) for routine clinical testing. Some of this blood sample may also be retained for later research tests by the sponsor, Trius Therapeutics. The research tests would look for markers in the blood that may help to predict which patients may have a better response to a particular drug treatment for the skin infection. You and your physician will not know the outcome of these research tests.
- Other blood samples (about ½ tablespoon) may also be collected to check for the presence of bacteria in your blood, if needed. Blood may be drawn 2 times from 2 separate veins for this test.

Your study doctor will have the last follow-up with you 18-25 days after your last dose of medication to see how you are feeling and if the study drug worked for your infection at the previous visit, if your infection has not come back. This visit may be conducted over the telephone if your study doctor does not feel the need to see you in person.

Unscheduled Visit

If you experience any unusual medical problems during the study, you should contact your study doctor immediately. Your study doctor may ask you to visit the study center in between your regularly scheduled study visits. During these visits, your study doctor will advise you if any procedures or tests are necessary or advisable.

SUBJECT'S RESPONSIBILITIES

While participating in this research study, you will need to:

- be truthful and complete in telling the study staff of your medical history, use of medications, and how you feel during the study; this is important for your safety
- need to keep regular appointments with the study staff
- keep a diary of when you take the study medication, what your temperature is at various times during the day, and when you take any pain medication.
- take the study drug and placebo as directed and return all unused supplies (such as the diary and an oral thermometer that will be provided to you).
- keep the study drug away from children and not allow other people to take it
- not eat certain foods
- follow directions regarding the use of birth control, if applicable
- exercise caution and not drive or operate machinery or engage in other activities requiring mental alertness until you know how the medication will affect you

RISKS AND DISCOMFORTS

Antibiotics

Antibiotics may cause side effects including diarrhea, nausea, and vomiting. Fungal infections of the mouth, digestive tract, and vagina may happen while taking an antibiotic and can be treated. Some people have allergic reactions to antibiotics including swelling of the face, itching, and skin rashes and in some severe cases, breathing difficulties. Some of these side effects can be severe, and on rare occasions they may cause death. Not all potential side effects are listed as some may be unknown at this time.

TR-701 FA (the experimental antibiotic being tested in this study). The most common side effects and discomforts observed to date with TR-701 FA 200 mg daily are nausea (14.3%), diarrhea (11.1%), vomiting (6.3%), and headache (4.8%). Since TR-701 FA has been given to only a limited number of people, other side effects may be unknown at this time. Some of these side effects could be severe or cause death.

At the highest dose tested in a research study of healthy subjects (400 mg daily for 21 days), TR-701 FA lowered the number of white blood cells (cells that help fight infection) and platelets (cells that help your blood clot) when taken for more than one week. In the study you are being asked to participate in, TR-701 FA will be taken for a shorter period of time (6 days) and in a lower dose (200 mg).

Linezolid (Zyvox[®], Pfizer; the comparator antibiotic for this study)

Linezolid is a drug that is already approved by the FDA and belongs to the same chemical class of antibiotics as TR-701 FA, called oxazolidinones. The most common side effects reported with linezolid are diarrhea (8.3%), headache (6.5%), feeling sick to your stomach (6.2%),

vomiting (3.7%), trouble sleeping (2.5%), constipation (2.2%), rash (2.0%), dizziness (2.0%), and fever (1.6%). In most cases these side effects are mild or moderate in severity. Low white blood cell counts and low platelet counts in the blood have been reported in patients receiving linezolid for more than two weeks. Nervous system (seizures, inflammation of the nerves) and vision problems have also been reported with the use of linezolid for more than 4 weeks.

Another rare side effect of linezolid is a condition called lactic acidosis, where a patient may have unexplained nausea, vomiting and weakness; if you develop these symptoms and they do not go away, please tell your study doctor.

Aztreonam

Aztreonam is another antibiotic that is also approved by the FDA. Aztreonam can be given intravenously (through a vein) or intramuscularly (into a muscle). Only patients with wound infections may receive this antibiotic during this study. The most common side effects include redness and/or irritation of the skin at the injection site following intravenous administration (1.9%) and intramuscular administration (2.4%). Other common side effects that occur from 1% to 1.3% include diarrhea, nausea and/or vomiting and rash.

Metronidazole

Metronidazole is another antibiotic that is also approved by the FDA. Metronidazole can be given by mouth or intravenously. Only patients with wound infections may receive this antibiotic during this study. The most common side effects have been associated with the gastrointestinal tract, particularly nausea (12%), sometimes accompanied by headache, anorexia, and occasional vomiting. Constipation has also been reported.

CT Scan and MRI Risks

CT scan and MRI are not required per protocol, but may be requested by your study doctor if of potential value.

When a CT scan is performed, you will be exposed to a small amount of radiation. The MRI scan does not expose you to x-ray radiation. However, MRIs use a magnetic field so it is extremely important that you tell your study doctor, study nurse and MRI technician if you have a pacemaker, implantable cardioverter defibrillator (AICD), aneurysm clips, shrapnel or any other metal in your body. You will have to lie still on your back in the MRI scanner, which is a tight space. If you are uncomfortable in small or tight spaces, this may be difficult for you and you may feel panicky.

Most subjects in this study will not require scans. If a scan is required, it is up to the study doctor to decide whether or not contrast dye should be used and he or she will discuss this with you.

Collection of Blood

When blood samples are taken, you may have mild pain and/or bruising around the vein where the needle is inserted. Although rare, blood clots and infection of the vein may occur. Lightheadedness and/or fainting may also occur during or shortly after the blood is taken. The maximum volume of blood to be drawn over the whole study is about 8 tablespoons.

REPRODUCTION RISKS

Women Only:

The effects of TR-701 FA on a pregnant woman, an embryo, fetus (unborn baby), or nursing infant are unknown and may be harmful. TR-701 FA has not been studied in women who are pregnant or nursing. Therefore, women who are pregnant or nursing may not participate in this study.

Woman able to have children must agree to use birth control during the study, such as intrauterine device, double-barrier method (e.g., condoms, diaphragm, or cervical cap with spermicidal foam, cream or gel) or male partner sterilization unless you have been more than 2 years postmenopausal or surgically sterile. **ANTIBIOTICS SUCH AS TR-701 FA, LINEZOLID, AZTREONAM AND METRONIDAZOLE MAY MAKE ORAL CONTRACEPTIVES INEFFECTIVE.** All women who can have children must have a negative result on a pregnancy test before receiving the study drug. Women who may become pregnant and do not agree to use approved methods of birth control may NOT participate in this study.

If you become pregnant or suspect you are pregnant while participating in the study, you must inform your study doctor immediately. If a pregnancy test is confirmed, the study drug you are taking will be stopped, your participation in this study will be ended, and your pregnancy will be followed to outcome.

UNKNOWN AND UNFORESEEABLE RISKS/NEW FINDINGS

In addition to the risks and discomforts listed above, there may be some unknown or uncommon risks from the use of the study drugs. Since TR-701 FA is investigational, there may be other risks, when taken alone or in combination with other medications, which are unknown. It may not be possible to predict some of these risks. Your study doctor will inform you of any relevant new information, findings or changes to the research that might change your willingness to stay in this study. You will also receive this information in writing. If this happens, you should discuss with your study doctor whether or not you want to continue in this study. If you decide to continue in the study you may be asked to read and sign an updated consent form. If new information becomes available and your study doctor thinks that it is in your best interest to remove you from the study, he or she will explain the reasons to you. You may contact the study doctor at any time after your participation ends to find out if any new information about this study has become available

As with any drug, side effects can occur, so please report any unusual symptoms to your study doctor immediately.

If any of your current medications are stopped in order for you to participate in this study, there is a risk that you may lose the benefits of those medications or that you may have reactions from stopping these medications. You should discuss these risks with your study doctor and/or the doctor who prescribed these medications before agreeing to participate in this study.

The study drug is for **your use only**. You must keep the study drug out of the reach of children. Other people must not try or take the study drugs. The use of the study drug by anyone who has not been authorized to use it could be dangerous.

BENEFITS

You may personally benefit from this study if the study drug is able to cure your skin infection. It is possible that you may not personally benefit from being a part of this study. However, the study will also provide additional information about the treatment of skin infections to physicians. Therefore, future patients may benefit from the increased knowledge of physicians who treat them.

ALTERNATIVE TREATMENTS

You do not need to take part in this research study to get treatment for your skin infection. If you decide not to take part in this study, you may ask your doctor for approved antibiotic(s) to treat infections like yours. There is no penalty or loss of benefit of other treatments if you do not participate. Ask the study doctor to tell you about these alternative treatments, including how they work.

COSTS

There will be no charge to you for your participation in this study. You will not have to pay for any of the study drug, medical examinations, tests, hospitalization, or laboratory tests that are used only for purposes of this study. You will be required to pay for costs associated with what your physician would normally do to treat your skin infection.

You may incur additional costs as a result of participating in this study. This includes, but may not be limited to time away from home or work, meals away from home, transportation to the clinic or parking fees, or childcare expenses. These costs will not be reimbursed.

COMPENSATION

For your participation, you will be paid \$_____ for your time and inconvenience for each completed visit, for a possible total of up to \$_____. If you withdraw from the study early, you will be paid for each of the visits you have completed. You will not receive any other compensation for your participation in this study, and you will not have any right in any inventions, new techniques or technology that may result from this study.

CONFIDENTIALITY AND RELEASE OF MEDICAL RECORDS

The study doctor and clinic will protect your medical information and information about your taking part in this research study to the best of their ability. If you agree to allow photographs of your skin infection site, you will not be identifiable in the picture. The pictures may be published or used to show how the infection looked before and after treatment. If information about this study is published, your name will not be given. However, the FDA or other countries regulatory health agencies, the Institutional Review Board (IRB), and Trius Therapeutics or their representative/designee may look at or inspect your medical records and study information if you part in this study. A court of law could order medical records shown to other people, but that is unlikely. Therefore, absolute confidentiality cannot be guaranteed.

COMPENSATION FOR RESEARCH RELATED INJURY

To the extent not otherwise covered by your insurance, medical treatment will be made available through (study doctor) and (this institution) and provided at no cost to you for a research-related illness or injury. The term "research-related illness or injury" means physical illness or injury caused by the study drug or procedures required by the trial, which are different from the medical treatment you would have received if you had not participated in the trial. You must follow the directions of the study doctor to be eligible for this coverage.

Neither the sponsor nor the study doctor has a program or a policy in place to provide additional compensation beyond the cost of treatment in the event of a research-related illness or injury and no financial payment of any type is being offered by the company responsible for this study. You understand that compensation for research-related side effects or harm or for lost wages or lost time is not available.

LIABILITIES

All forms of medical diagnosis and treatment--whether routine or experimental--involve some risk of injury/illness. In spite of all precautions, you might develop medical complications from participating in this study. If such complications arise, the study staff will assist you in obtaining appropriate medical treatment. This study does not provide financial assistance for additional medical or other costs. You do not waive any liability rights for personal injury or illness by signing this form. You understand that side effects are possible in any research study despite the use of high standards of care and could occur through no fault of you or the study doctor involved. However, unforeseeable harm may also occur and require care. If you are injured as a result of the research procedures, medical care will be provided by the study staff. Trius agrees to reimburse costs for treatment and hospitalization which results from any medical complications caused by the study drug or study-related procedures, if not covered by your medical insurance and provided you followed the study doctor's instructions. You understand that compensation for research-related side effect or harm or for wages or time lost is not available.

LEGAL RIGHTS

The above section does not restrict your right to seek legal assistance. You do not waive any legal rights by signing this Subject Information and Consent Form.

COMMERCIAL RIGHTS

Trius may have plans to develop commercial products using the information obtained from analysis of your biologic specimens (such as blood, urine, or tissue samples), if any. You will not be compensated for any commercial use or other use of this information, nor will you have any financial or property interest in any products or processes which may result from research on your biologic samples.

VOLUNTARY PARTICIPATION

Your decision to take part in this study is completely voluntary (your choice). There will not be any penalty or loss of benefits to which you are otherwise entitled should you decide not to participate or to withdraw from the study at any time. Before withdrawing from the study, you should notify the study doctor that you wish to withdraw. This notice will allow your study doctor to inform you if there are any potential medical risks of withdrawal. You may be asked to return to the clinic for tests. All information that has already been collected for study purposes will be sent to the study sponsor. Any photographs or laboratory specimens already collected or stored for later testing will be sent and used by the sponsor.

WITHDRAWAL

Your doctor, the sponsor company, or the FDA has the right to stop your participation in the study at any time, with or without your consent, for any of the following reasons: if you have an adverse effect from the study drug the doctor feels requires you to stop taking the study drug, if you need a treatment not allowed in this study, if you do not keep appointments, if you do not take the study drug as instructed, if you become pregnant, if enrollment has been met, or if the study is canceled by the FDA or the sponsor company. The sponsor may decide to stop the study and your access to the study drug under certain circumstances even if the study drug appears to be safe and effective.

WHOM TO CONTACT FOR QUESTIONS

- If you have any questions or problems during this study you should contact the study doctor:
- If you feel that you have experienced a study or research-related illness or injury, you must promptly notify the study doctor:

Investigator (Doctor) Name:

Address:

Telephone number:

If you have questions about your rights as a research subject, you contact may the IRB at XXX-XXX-XXXX. (California requires the address, too) An IRB is a group of scientific and non-scientific individuals who perform the initial and ongoing ethical review of the research study with the study subject's rights and welfare in mind. An IRB (name of IRB) has reviewed and approved the research study described in this Subject Information and Consent Form. If you have study-related comments, complaints or concerns, you should first contact the study doctor. Please call the IRB if you want to talk to someone other than the study doctor or have difficulty reaching the study doctor.

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

<For California Sites>

Any person who is requested to consent to participate as a subject in a research study involving a medical experiment, or who is requested to consent on behalf of another, has the right to:

1. Be informed of the nature and purpose of the experiment.
2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be used.
3. Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.
4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.
5. Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.
6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.
7. Be given an opportunity to ask any questions concerning the experiment or the procedures involved.
8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time, and the subject may discontinue participation in the medical experiment without prejudice.
9. Be given a copy of a signed and dated written consent form when one is required.
10. Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

Signature of Subject

Date

SUBJECT'S STATEMENT OF CONSENT

I have read the statements in this Subject Information and Consent Form related to my participation in this research study.

- I have been given adequate time to read this consent form and time to consider my study participation.
- I have discussed all aspects of the study with the study doctor or study staff, have been able to ask any and all questions, and I am satisfied with the answers provided.
- I understand that I can ask other questions at any time.
- I have been told that I may withdraw from the study at any time or refuse procedures without affecting my ongoing medical care.
- I agree to the use and disclosure of my information in connection with the study as described in this Subject Information and Consent Form.
- I give my permission for the study sponsor and its representatives, the FDA, and the IRB to have access to my medical and study records.
- I have been told that I will receive a signed and dated copy of this consent and authorization form.

Please initial and date the appropriate line below to indicate your preference regarding the Digital Photographs of your infection site as part of the research study.

_____ I agree to have Digital Photographs taken.
Initials Date

_____ I do not agree to have Digital Photographs taken.
Initials Date

I voluntarily and freely consent to participate in this research study and understand that none of my legal rights are being waived.

Signature of Subject

Date (personally by Subject)

Printed name of Subject

I certify that the information provided was given in language that was understandable to the subject.

Signature of Person conducting the
Informed Consent Discussion

Date (personally by Person
conducting Informed Consent discussion)

Printed name of Person conducting Informed Consent Discussion

AUTHORIZATION TO USE AND DISCLOSE PERSONAL HEALTH INFORMATION FOR RESEARCH

The United States government has issued a privacy rule to protect the privacy rights of patients. This rule was issued under a law called the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The Privacy Rule is designed to protect the confidentiality of your personal health information. The document you are reading, called an “Authorization,” describes your rights and explains how your health information will be used and disclosed (shared).

The information collected during this study will be kept confidential (private) to the extent permitted by the applicable laws and regulations. Only a study identification number will be used to identify you. You will not be personally identified (for example, mentioned by name) in any reports or publications that may result from this research study. Because of the research goals of this study, however, your study records cannot be kept completely confidential. Medical records which identify you and the consent form signed by you will be looked at and/or copied for research or regulatory purposes by authorized representatives of the following:

- The study personnel
- The sponsor and its agents
- The FDA (the U.S. drug agency) and other countries' regulatory agencies may review your medical records in order to review the study findings
- The Institutional Review Board/Independent Ethics Committee (IRB/IEC))
- The hospital where you are being treated

The following sections provide a specific description of how your information will be used and disclosed (shared) if you take part in this research study. If you decide to take part in the study, you will be asked to authorize (legally agree to) those uses and disclosures by signing this form. If you choose not to authorize these uses and disclosures of your information, you will not be able to participate in the study.

The medical information that will be collected from you if you take part in the study includes (but is not limited to):

- Information obtained from procedures to determine whether you are eligible to take part, including a routine medical history, physical examination, ECG, blood and urine tests, and urine pregnancy test.
- Information that is created, or collected from you, during the study, including all tests performed during the study.
- Information contained in your medical records related to your medical history and treatment.

The above information may identify you by name, address, telephone number, social security number, health plan number, study number, date of birth, dates relating to various medical procedures, or other identifying information, as appropriate for the area in which you live. If you sign this form and take part in the study, the study staff will be authorized to use the information described above to carry out the research study. The study staff will also be authorized to disclose the information described above to the following parties involved in the research study:

- The study sponsor, Trius Therapeutics, Inc., or other agents designated by Trius Therapeutics, Inc., to collect or review study data.
- the IRB
- Government regulatory agencies including the FDA and other governmental agencies in other countries.

Once your information is disclosed to the study sponsor, the IRB, or government agencies as described above, it is possible that your medical information will be re-disclosed and will no longer be protected by U.S. federal privacy regulations. Other laws may provide further protection. Because of the need to disclose information to these parties, absolute confidentiality cannot be guaranteed.

You have the right to see and get a copy of your records related to the study for as long as the study doctor has this information. However, by signing this Authorization you agree that you might not be able to review or receive some of your records related to the study until after the study has been completed.

Your agreement to share the information from the study does not end when the study ends. In signing this form, you agree to the use and disclosure of your information for purposes of the study at any time in the future.

You may change your mind and decide to withdraw your approval to share this information at any time by sending a written request to: [insert name of responsible study personnel] [insert address].

If you withdraw your approval, you will no longer take part in the study and no new information will be collected for study purposes unless the information concerns an adverse event (bad effect) related to the study. If an adverse event occurs, your entire medical record may be reviewed. All information that has already been collected for study purposes, and any new information about an adverse event related to the study, will be sent to the study sponsor.

With the exception of adverse events, the study staff will stop using your information and will stop disclosing your information to the groups described above, except to the extent the study staff has depended on information that has already been collected from you. For example, the study staff may need to use or disclose information obtained before you withdrew your approval in order to preserve the scientific truth of the study.

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

This Authorization does not have an expiration date (for California, sites will need to insert an expiration date--generally 20 years). If you do not withdraw this Authorization in writing, it will remain in effect indefinitely. Your study doctor will keep this Authorization for at least 6 years.

If you do not sign this Authorization, you cannot participate in this research study or receive study-related treatment. If you withdraw this Authorization in the future, you will no longer be

able to participate in this study. 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

I authorize the release of my medical records and personal health information related to this study to the sponsor and its representatives, the Institutional Review Board, the FDA, and other countries regulatory health agencies as described above. I have been told that I will receive a signed and dated copy of this Authorization for my records.

Printed Name of Subject

Signature of Subject

Date

Printed Name of Person Obtaining Authorization

Signature of Person Obtaining Authorization

Date