

APPROVED: Dec 29, 2011

Approved: «Approved»

SUBJECT INFORMATION AND CONSENT FORM AND HIPAA AUTHORIZATION

Name of Research Study: Phase 2 Open-Label Safety and Exploratory Skin Lesion Measurement Study of 6-Day Oral TR-701 FA in Skin Abscess and Cellulitis Patients

Protocol Number: TR701-126

Sponsor: Trius Therapeutics, Inc.

Principal Investigator Name: «FirstName» «MiddleName» «LastName» «Suffix»

Research Site Address(es):

«Company»	«Company2»	«Company5»
«Address» «SuiteDept»	«Address2»	«Address5»
«City» «State» «Zip»	«City2» «State2» «Zip2»	«City5» «State5» «Zip5»
«Company3»	«Company4»	
«Address3»	«Address4»	
«City3» «State3» «Zip3»	«City4» «State4» «Zip4»	

Daytime Telephone Number(s): «Phone»

24-hour contact number(s): «Phone2»

PURPOSE OF THE SUBJECT INFORMATION AND CONSENT FORM

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 study. The purpose of this study is to learn if an experimental antibiotic called TR-701 FA can safely 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 you are 18 years of age or older and 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 200 people with skin infections will take part in this study at 5-15 medical centers and/or clinics in the United States. You will sign and date this consent form before any study procedures are done. 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 the experimental drug by mouth once a day for 6 days while the study doctor and staff check your skin infection if your study doctor determines that you meet certain criteria.

STUDY DRUG

The “study drug” is the experimental drug TR-701 FA. If you decide to take part and are eligible to take part based on inclusion and exclusion criteria, your laboratory results, and your doctor's evaluation, you will receive study drug for up to 6 days. You will take a TR-701 FA 200 mg tablet by mouth once a day. It is important that you take all 6 doses unless directed otherwise by your study doctor. In this study, everyone will receive TR-701 FA.

DURATION OF STUDY PARTICIPATION

After screening, you will be asked to return to the clinic at least 5 times (study Day 1, 48-72 hours after your first dose of study drug, within 2 days of your last dose of study drug, and at least 2 follow-up visits). Your overall study participation will last about 24 to 34 days and you may be asked to make another visit to the clinic during this time.

STUDY PROCEDURES

If you want to take part, you will first sign this Subject Information and Consent Form and then the study staff will do the following so the study doctor can decide if you are eligible take part in the study:

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- Ask you about your medical and surgical history, current and prior medicines, and current symptoms.
- Perform a routine complete physical examination, including a basic neurologic exam to check your nervous system and a visual acuity examination, which is a basic eye exam, to check your vision.
- Measure your vital signs, including taking your temperature, blood pressure, heart rate, breathing rate, and height and weight.
- Perform 12-lead electrocardiograms (also known as ECG). Three ECGs will be performed one minute apart. This is a painless test to check the electrical activity of the heart.
- Females only: Collect 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 1 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. If you have positive test results for HIV or hepatitis B or C, we will notify and counsel you on future medical treatment; we are required to notify the state health authorities of positive results. We will not share the test results with anyone else. If you do not want to be tested, you should not take part in this research study.
- Collect blood sample (about ½ tablespoon each) 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 (about 2 tablespoons total).
- Perform a complete examination of your skin infection. This will include measuring the size of the skin infection and taking a sample of tissue or fluid from the infection to check for bacteria that caused your infection if your doctor determines it is appropriate to do so.
- Perform routine care of your skin infection to help heal the infection.

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 be informed of the risks before you 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 your first dose of study drug 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 are chosen to take part and are accepted into the study, the study staff will:

- Ask you about any new symptoms (“how you feel”).
- Perform a routine physical examination, including a basic neurologic exam to check your nervous system and a visual acuity examination, which is a basic eye exam, to check your vision.

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- Measure your vital signs, including taking your temperature, blood pressure, heart rate, and breathing rate.
- Perform 3 ECGs one minute apart (painless heart test) at the 48-72 hour visit.
- Measure your skin infection (the area of redness and swelling).
- Perform routine care of your skin infection to help healing of the infection.
- Collect blood samples (about 1 tablespoon) for routine clinical testing.
- 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 be used for a blood pregnancy test.
- Other blood samples (about ½ tablespoon each) 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.
- 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 the study drug.
- 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. You will be instructed to take your study drug at approximately the same time every day. You will also be required to return to see the doctor approximately 48-72 hours after your first dose of study drug and again within 2 days of your last dose of study drug to see how you are feeling and to check on how your infection is doing.

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 to see how you are feeling and check on how your infection is doing. The study staff will perform the following assessments during this visit:

- Ask you about any new symptoms (“how you feel”).
- Perform a routine brief physical examination, including a basic neurologic exam to check your nervous system and a visual acuity examination, which is a basic eye exam, to check your vision.
- Measure your vital signs, including taking your temperature, blood pressure, heart rate, and breathing rate.
- Measure your skin infection.
- Perform routine care of your skin infection to help healing of the infection.
- Collect blood samples (about 1 tablespoon) for routine clinical testing.

Your study doctor will have the last follow-up visit with you 18-25 days after your last dose of drug to see how you are feeling; and if the study drug worked for your infection at the previous visit, your doctor will ask if your infection has not come back. This follow-up 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 taking part 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.
- Take the study drug as directed and return all unused supplies (such as the diary 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 and vision problems. 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 (in 5% or more of patients) were nausea, secondary abscess, headache, vomiting, and diarrhea. Adverse events were generally mild. 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.

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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).

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 radiation. All radiation has some risk. More specific radiation risks will be shared with you in a separate consent process if you have a CT scan.

When a CT scan is performed, sometimes a contrast dye is given in the vein with a CT scan. This contrast dye is iodine-based. You may have an allergic reaction to the dye. People with allergies may be more likely to have an allergic reaction. This reaction may be mild, such as skin rash or hives, to severe, such as breathing difficulties or shock. A severe allergic reaction would require immediate medical treatment and could result in permanent disability or death. You will be closely monitored and treated should this occur. You should discuss any history of allergies or concerns with your doctor or research staff.

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. The MRI makes a loud, banging noise while it is taking pictures. You will be given a set of ear plugs to help with the noise. You will be asked to lie on a flat table that will move into a horizontal tube that is within a large magnet. You may experience feelings of claustrophobia or anxiety. There is an intercom so you can talk to the staff if you feel anxious.

For some MRI scans, you may get a MRI contrast material (a dye). This is given in your vein using a small needle or plastic tube. The MRI contrast material will be given in amounts that have been approved by the FDA. You will not get the MRI contrast material if you have abnormal kidney function. Side effects from the dye may include nausea, vomiting, or headache. You may feel local warmth or pain in the area where the dye is injected. Serious allergic reactions that may be life-threatening are very rare.

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 7 tablespoons.

ECGs

Electrocardiogram (ECG) is a tracing of the heart's electrical rhythm. You will have pads placed on different parts of your body. Removing the pads may cause some irritation to your skin.

UNKNOWN AND UNFORESEEABLE RISKS

In addition to the risks and discomforts listed above, there may be some unknown or uncommon risks from the use of the study drug. Since TR-701 FA is experimental, 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.

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 take part 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.

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 take part in this study.

Women 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 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 take part in this study.

If you become pregnant or suspect you are pregnant while taking part 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, you will no longer be able to take part in this study, and your pregnancy will be followed to outcome.

NEW FINDINGS

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.

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.

PAYMENT TO SUBJECT FOR PARTICIPATION

For your participation, you will be paid **\$XX.00** for your time and inconvenience for each completed visit. 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.

Payment received as compensation for participation in research is considered taxable income to the research subject. If payment to an individual exceeds \$600.00 in any one calendar year, the study doctor/clinic is required to report this information to the Internal Revenue Service (IRS) in a 1099 (Miscellaneous Income) form being issued to the individual and a copy sent to the IRS.

COSTS

There will be no charge to you for taking part 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.

The costs of the MRI or CT scan, if required by your doctor, may be your responsibility. Speak to your study doctor if you have questions or concerns about this.

You may incur additional costs as a result of taking part 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.

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 take part. The study doctor will tell you about these alternative treatments, including how they work.

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 information about this study is published, your name will not be given. However, the FDA or other countries' regulatory health agencies, the [REDACTED] Independent Review Board (IRB), and Trius Therapeutics or their representative/designee may look at or inspect your medical records and study information if you take 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.

A description of this clinical study will be available on www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

COMPENSATION FOR RESEARCH-RELATED INJURY

To the extent not otherwise covered by your insurance, medical treatment will be made available through «FirstName» «MiddleName» «LastName» «Suffix» and «Company» 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 study which are different from the medical treatment you would have received if you had not participated in the study. 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. 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 taking part 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. 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. Compensation for research-related side effects 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: «FirstName» «MiddleName» «LastName» «Suffix»

Daytime telephone number(s): «Phone»

24-hour contact number(s): «Phone2»

If you have questions about your rights as a research subject, you may contact the [REDACTED] IRB at [REDACTED] (toll free). An Independent Review Board 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. [REDACTED] 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 investigator. Please call the IRB if you want to talk to someone other than the study investigator or have difficulty reaching the study investigator. For further information regarding the clinical trials process and your role as a research subject, you may visit the [REDACTED] IRB website at [REDACTED]

SUBJECT'S STATEMENT OF CONSENT

Phase 2 Open-Label Safety and Exploratory Skin Lesion Measurement Study of 6-Day Oral TR-701 FA in Skin Abscess and Cellulitis Patients

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

- I have been given adequate time to read this consent form and time to consider my taking part in this study.
- 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 have been told 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 [REDACTED] 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.

I voluntarily and freely consent to take part in this research study and have been told 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
Informed Consent Discussion

Date (personally by person conducting
informed consent discussion)

Printed Name of Person Conducting
Informed Consent Discussion

HIPAA AUTHORIZATION

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 [REDACTED] Independent Review Board (IRB)
- The clinic or 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 take part 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 serum pregnancy test.

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- 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 [REDACTED] Independent Review Board (IRB).
- Government regulatory agencies, including the FDA and other governmental agencies in other countries.

Once your information is disclosed to the study sponsor, the [REDACTED] 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.

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You may change your mind and decide to withdraw your approval to share this information at any time by sending a written request to your study doctor to the address on page one of this form.

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 will expire December 31, 2050, unless you withdraw it in writing before then. 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 [REDACTED] Independent 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