COVER PAGE:

OFFICIAL TITLE: Phase II Study of Everolimus (RAD001, AFINITOR®) for Children with Recurrent or Progressive Ependymoma
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The University of Texas Southwestern Medical Center at Dallas
Parkland Health & Hospital System
Children's Medical Center
Retina Foundation of the Southwest
Texas Scottish Rite Hospital for Children
Texas Health Presbyterian Hospital of Dallas

CONSENT TO PARTICIPATE IN RESEARCH

Title of Research:	Phase II Study of Everolimus (RAD001, AFINITOR®) for Children with Recurrent or Progressive Ependymoma
Funding Agency/Sponsor:	UT Southwestern Medical Center Novartis Pharmaceuticals Corporation
Study Doctor:	Daniel C. Bowers, MD

You may call the study doctor or research personnel during regular office hours at 214-456-2382. At other times, you may call them at 214-456-7000.

Note: If you are a parent or legal guardian of a child who may take part in this study, permission from you is required. The assent (agreement) of your child may also be required. When we say "you" in this consent form, we mean you or your child; "we" means the doctors and other staff.

Instructions:
Please read this consent form carefully and take your time making a decision about whether to participate. As the researchers discuss this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. The purpose of the study, risks, inconveniences, discomforts, and other important information about the study are listed below. If you decide to participate, you will be given a copy of this form to keep.

Why is this study being done?
This study is being done to find out if the investigational drug Everolimus (Afinitor®) is safe and has beneficial effects for children who have a recurrent or progressive brain tumor called an ependymoma. At present, there are no standard-of-care medications or medications approved by the U.S. Food and Drug Administration (FDA) for children with recurrent ependymomas.

The goals of this study are to:

- Determine the response rate of children with recurrent or progressive ependymoma following treatment with Everolimus (Afinitor®) for children with recurrent or progressive ependymomas.
- Determine the duration of response of children with recurrent or progressive ependymoma following treatment with Everolimus (Afinitor®) for children with recurrent or progressive ependymomas.
- Determine safety and tolerability of Everolimus (Afinitor®) among children with recurrent or progressive ependymomas.
- Examine whether certain proteins present on ependymoma tumor tissue is associated with a tumor's response to Everolimus (Afinitor®).

Why is this considered research?
This is a research study because Everolimus (Afinitor®) is investigational and has not been approved by the U.S. Food and Drug Administration (FDA) for the treatment of recurrent or progressive Ependymomas.

The following definitions may help you understand this study:

- Standard medical care means the regular care you would receive from your personal doctor if you choose not to participate in this research.
- Researchers means the study doctor and research personnel at the University of Texas Southwestern Medical Center at Dallas and its affiliated hospitals.

Why am I being asked to take part in this research study?
You are being asked to take part in this study because you have a recurrent or progressive ependymoma. Ependymomas are types of childhood brain tumors that have historically been considered resistant to standard chemotherapy drugs. There is no standard treatment for children with recurrent or progressive ependymomas.

Do I have to take part in this research study?
No. You have the right to choose whether you want to take part in this research study. If you decide to participate and later change your mind, you are free to stop participation at any time.

If you decide not to take part in this research study it will not change your legal rights or the quality of health care that you receive at this center.

It is important for you to know why this study is being done before you decide to take part in this research study. This consent will tell you about the study. This consent will also tell you about risks and side effects that might happen to you if you take part in this study. You also need to know you do not have to take part in this study. You can talk to your doctor about other cancer treatments. Taking part in this study is voluntary.

Please read this consent form carefully and take your time to make your decision. Discuss

it with your friends and family. We encourage you to include your child in the discussion and decision to the extent that he or she is able to understand and take part.

How many people will take part in this study?
About 10 people will take part in this study at UT Southwestern or Children's Medical Center. This study also is taking place at a number of other medical facilities around the country. There will be a total of 18 people participating in this research study throughout the United States.

What is involved in the study?
If you choose to take part in this research study, you will be asked to sign this consent form and will have the following tests and procedures. Some of the procedures may be part of your standard medical care, but others are being done solely for the purpose of this study.

Screening Procedures
You will need to have the following exams, tests or procedures to find out if you can be in the study. These exams, tests or procedures are part of regular cancer care and may be done even if you do not join the study. If you have had some of them recently, they may not need to be repeated. This will be up to your study doctor.

- A medical history and demographic information (age, sex, ethnic origin)
- Review of medications you are currently taking and have taken in the past including herbal medications
- Physical exam, including a neurological exam
- You will be asked about the symptoms you are having from your disease and evaluated to determine your performance status
- Vital signs (blood pressure, respirations, heart rate, temperature, weight, height, and body surface area)
- Blood tests
- Pulse oximetry (test to evaluate the amount of oxygen in your blood)
- Pregnancy test (if you are a female who could have children)
- MRI of brain and spine*
- Baseline adverse event assessment
- Any other studies or tests your treating doctor thinks are necessary in order to give you the best care
- If a lumbar puncture (spinal tap) is performed as part of your clinical care, the results of that test will also be used for this research. However, a lumbar puncture is not done separately for this research study.

*Magnetic Resonance Imaging or MRI is a scan that provides multiple detailed pictures of the inside of the body. MRI does not use radiation. In order to better view some structures in the body, including tumors, a special dye or contrast agent will be injected intravenously (through a vein).

If you are female and have the potential to become pregnant, you will be tested to see if you are pregnant with a urine pregnancy test prior to your first dose of study medication. All participants of reproductive potential must use an effective method of birth control throughout the study and for at least 8 weeks following termination of treatment. Your doctor will discuss appropriate means of birth control with you if required.
In addition, it is also important to inform your study doctor if you:

- Have had hepatitis B and/or hepatitis C;
- Have had blood transfusions(s) before 1990;
- Are now or have been an intravenous drug user;
- Are having or have had dialysis;
- Have someone in your household who has hepatitis B or C;
- Are having or have had high-risk sexual activity;
- Have had body piercing or tattoos;
- Have a mother who had hepatitis B.

Tests will be done for hepatitis B and/or C if:

- You have a risk of having hepatitis B and/or C or;
- You live in or have lived in Asia, Africa, Central and South America, Eastern Europe and Spain, Portugal or Greece;
- Your study doctor thinks it is appropriate.

If you test positive for hepatitis B, your study doctor will inform you if you need to take an anti-viral drug. An anti-viral drug is used to treat infections caused by viruses. You will not be able to participate in this study. If you test negative for hepatitis B, the study doctor may continue to monitor your blood for the genetic material of the hepatitis B virus and to see if your liver is damaged or inflamed. If the amount of the genetic material and your liver test increases, then your study doctor will inform you of the treatment. This may mean that you are given an anti-viral drug and also, you will need to stop taking the study drug.

If you test positive for hepatitis C, you will not be allowed to participate in the study. If you test positive for hepatitis C while you are taking the study drug, you will need to stop taking the study drug because the treatment for hepatitis C has serious side effects.

Biology Studies-
We would like to use tumor tissue that was removed during surgery (either when you were first diagnosed or at a subsequent surgery) to determine if proteins present in your tumor are associated with response to everolimus. Participating in these extra tests will not require that you undergo any additional procedures. These tests use tumor tissue left over after diagnostic tests are completed. These extra tests will help us learn about predicting outcomes of children with ependymoma, but they will not directly help you.

Study Medication/Intervention

If you decide to participate in this study, you will take Everolimus (Afinitor®) by mouth at a starting dose that will be determined by your weight and height. Each Course of therapy will last for 28 days.

Procedures and Evaluations during the Research

You will have the following tests and/or evaluations:

Prior to each Course of treatment (every 28 days):

- Medical history and physical exam, including neurological exam;
- Vital signs
- Drug diary review
- Adverse event assessment
- Review of medications you are currently taking and have taken in the past including herbal medications
- Blood tests to evaluate bone marrow, blood clotting, kidney and liver function;
- If you are a female who could become pregnant, you will have a pregnancy test.
- Pulse oximetry (test to evaluate the amount of oxygen in your blood)
    - If oxygen levels are low, then a chest x-ray will be done monthly until oxygen levels in the blood are appropriate.
- If a lumbar puncture (spinal tap) is performed as part of your clinical care, the results of that test will also be used for this research. However, a lumbar puncture is not done separately for this research study
- You will be given a medication diary to complete daily.
- Prescription for medication will be dispensed.

Two weeks after you receive the first dose of Everolimus:

- Blood test (about ½ a teaspoon) to evaluate the level of study drug in your blood. If the dose is outside of the target range, the dose will be adjusted to achieve an appropriate level. Study drug levels will be repeated two weeks after any change in dose of Everolimus or changes to other medications that could affect the study drug.

Prior to Courses 3, 5, 7, 9, 11 and 13, then prior to Courses 16, 19, 22, and after Course 24:

- MRI of the brain and spine to reassess tumor response to treatment.

End of Treatment Visit
Within 30 days of completing course 24, you will have the following tests and/or evaluations:

- Physical exam, including neurological exam;
- Vital signs
- Drug diary review
- Adverse event assessment
- Review of medications you are currently taking and have taken in the past including herbal medications
- Blood tests to evaluate bone marrow, blood clotting, kidney and liver function;
- If you are a female who could become pregnant, you will have a pregnancy test.
- MRI of the brain and spine to reassess tumor response to treatment.
- If a lumbar puncture (spinal tap) is performed as part of your clinical care, the results of that test will also be used for this research. However, a lumbar puncture is not done separately for this research study

How long can I expect to be in this study?
You may be in the study for up to two years if you are responding to therapy and not having side effects that are dangerous for you. After you are taken off treatment or after you have completed your treatment, your treating doctor will ask you to return for follow up exams and tests to ensure that you are not having dangerous side effects. Please continue to follow these instructions to ensure your safety.

After completing 24 courses of Everolimus (Afinitor®), if your tumor is responding favorably to Everolimus (Afinitor®) and you are tolerating the drug, you can discuss with your treating physician whether you should continue taking Everolimus outside of the clinical trial.

After you have completed study treatment, we would like to continue to follow-up with you (about every six months) by phone or at regularly scheduled clinic visits regarding your medical condition.

What are the risks of the study?
Because of your participation in this study, you are at risk for the following side effects. You should discuss these with the researchers and your regular health care provider.

Everolimus (Afinitor®) may cause some, all or none of the side-effects listed below.

Most Likely (more than 50% of subjects experienced these side effects):

- Stomatitis: Mouth lining changes such as redness, soreness, swelling in the mouth or mouth ulcers. To help avoid these effects, you should brush your teeth with a very soft toothbrush and if your gums bleed, rub your teeth with gauze instead. Use an alcohol-free mouthwash up to 3 times a day. Eat soft, bland foods like puddings, milkshakes,

and cream soups, and avoid spicy, crunchy, acidic and very hot foods.

Likely (more than 10% of subjects experienced these side effects) :

- Infections
- Anemia
- Decreased appetite
- Hyperglycemia – high blood glucose
- Hypercholesterolemia – high cholesterol
- Dysgeusia – change in taste
- Pneumonitis
- Epistaxis
- Diarrhea
- Nausea
- Rash
- Pruritis
- Fatigue
- Peripheral edema
- Asthenia - weakness
- Weight decreased

Unlikely (more than 5% of subjects experienced these side effects):

- Vomiting
- Cough
- Skin or nail changes (including acne, rash, redness, itching, dryness or irritation)
- Hypertension
- Pyrexia
- Dyspnea
- Headache
- Hemorrhage
- AST and ALT increased
- Hypertriglyceridemia
- Thrombocytopenia – low platelet count
- Neutropenia – low number of neutrophils in blood that help to fight infections.

Rare (Less than 5% of subjects experienced these side effects):

- Leukopenia
- Lymphopenia
- Diabetes mellitus
- Hypophosphatemia – low phosphate level in blood
- Hyperlipidemia – high level of fats in the blood
- Dehydration
- Insomnia
- Dry mouth
- Abdominal pain
- Dyspepsia – stomach pain
- Acne
- Erythema
- Hand-foot syndrome
- Arthralgia
- Proteinuria – high protein in urine
- Menstruation irregular
- Mucosal inflammation
- Blood creatinine increased

Very Rare (Less than 1% of subjects experienced these side effects):

- Pancytopenia – too few red and white blood cells, and platelets
- Pure red cell aplasia
- Hypersensitivity – allergic reactions
- Ageusia
- Congestive cardiac failure
- Deep vein thrombosis
- Haemoptysis – coughing up blood

- Pulmonary embolism – blood clot in the lung
- Acute respiratory distress syndrome
- Angioedema – swelling beneath skin surface
- Increased daytime urination
- Acute renal failure
- Amenorrhea – absence of menstruation
- Non-cardiac chest pain
- Impaired wound healing

Drugs like Everolimus can cause the patient's immune system to not work as well. A patient with hepatitis B or hepatitis C who takes Everolimus could be susceptible to the virus becoming more active. If you had or have hepatitis B or C, you will not be allowed into the study.

Changes to the levels of blood sugar (glucose), which could lead to diabetes, could occur while taking Everolimus, so your blood sugar levels will be checked regularly throughout the study. Another diabetes test (Hemoglobin A1c) will be checked at the beginning of the study. The levels of cholesterol and triglycerides or liver enzymes (transaminases) in your blood could increase (increased levels of cholesterol are an important factor of risk of heart disease), so your blood cholesterol and triglyceride levels will be regularly checked in this study, as well as your liver enzymes. There could also be an increase in a waste product of your liver (bilirubin), which could mean that your liver is not working as well. In addition there could be a lowering of electrolytes (potassium, phosphate).

Everolimus may cause toxicity to your kidneys and cause the levels of creatinine in your blood and protein in your urine to increase. In very rare cases, this toxicity could lead to kidney failure. Therefore, your blood creatinine levels and urine protein levels (and other urine tests) will be regularly monitored in this study.

This research study may involve unpredictable risks. Problems or side effects that are not now known could also occur. You will be given any new information that may affect your willingness to start or continue in the study.

All problems or side effects need to be reported to the study doctors or study nurses looking after you either by phone or at the next visit.

For more information about risks and side effects, you should feel free to ask your study doctor. If you are concerned about your health between visits due to participating in this trial, please call the emergency telephone numbers provided at the end of this document.

<u>Risks to Sperm, Embryo, Fetus or Breast-fed Infant</u>

Males: Being in this research may damage your sperm, which could cause harm to a child that you may father while on this study. If you take part in this study and are sexually active, you must agree to use a medically-acceptable form of birth control. Medically-acceptable forms of birth control include:

(1) surgical sterilization (vasectomy) with use of a condom, or

(2) a condom used with a spermicide (a substance that kills sperm).

In case you father a child while in this study you are asked to report the pregnancy to the Study Doctor. Consent from your partner will be needed to allow your Study Doctor to medically follow this pregnancy until delivery to monitor the mother`s and child`s safety.

Females: If you are part of this study while pregnant or breast-feeding an infant, it is possible that you may expose the unborn child or infant to risks. For that reason, pregnant and breast-feeding females cannot participate in the study. If you can become pregnant, a blood pregnancy test will be done (using 1 teaspoon of blood drawn from a vein by needle-stick), and it must be negative before you participate in this study. If you take part in this study and you are sexually active, you and any person that you have sex with must use medically-acceptable birth control (contraceptives) during the study and for at least 8 weeks after completion of study treatment. Medically-acceptable birth control (contraceptives) includes:

(1) surgical sterilization (such as hysterectomy or "tubes tied"),
(2) approved hormonal contraceptives (such as birth control pills, patch or ring; Depo-Provera, Implanon),
(3) barrier methods (such as condom or diaphragm) used with a spermicide (a substance that kills sperm), or
(4) an intrauterine device (IUD).

If you become pregnant or suspect being pregnant during study treatment, you must inform the study doctor immediately and you have to stop ongoing study treatment immediately. You will not be allowed to continue study treatment if you are pregnant. Your study doctor will medically follow your pregnancy until delivery to monitor you and your child`s safety. .

Pregnancy tests performed during the early stages of pregnancy do not always reveal pregnancy. Therefore, radiation exposure that includes the reproductive organs will be limited to the first ten days after a woman who can become pregnant (age 10-50 years) has begun her most recent menstrual period. This is standard policy in clinics and hospitals within UT Southwestern. This policy applies unless there is an important medical reason requiring radiation outside this time frame

<u>Radiation Risks</u>
The radiation dose that you will get from diagnostic tests is medically indicated for your condition and it is the same that you would get if you were not involved in this research study.

<u>Risks of MRI</u>
There are no known risks from exposure to magnetic fields. You may experience nervousness and/or anxiety due to the loud banging made by the machine while it is taking pictures and from confinement in a tight space (claustrophobia). If you become anxious, you can stop the procedure at any time
You may also experience some discomfort and fatigue from lying still during imaging.

If you have any metal clips or plates in your body, you should tell the investigator. MRI may not be appropriate if you are pregnant or are trying to become pregnant. MRI may not be appropriate if you have permanent eyeliner or eyebrows or any pieces of metal in your body, such as the following:

- heart pacemaker, heart valve replacement, or aortic clips
- metal fragments in your eyes, skin, or elsewhere in your body
- brain clips or pieces of metal used in aneurysm surgery or intercranial bypass
- venous umbrella
- pieces of metal in the body resulting from work as a sheet-metal worker or welder
- clips placed in an internal organ
- prosthetic devices, such as middle ear, eye, joint, or penile implants
- joint replacement.
- hearing aid that cannot be removed
- neurostimulator
- insulin pump
- intrauterine device (IUD)
- shunts or stents
- metal mesh or coil implants
- metal plate, pin, screws, or wires, or any other metal implants.

Gadolinium Contrast:
A risk associated with the use of MRI contrast material has been identified recently. Because some of the procedures used in this study include the administration of MRI contrast, you should read and understand the following information before deciding to continue in the study:

Special Note: In June 2006, the FDA released a public advisory regarding contrast agents containing gadolinium. They are investigating the potential relationship between gadolinium and the development of Nephrogenic System Fibrosis/Nephrogenic Fibrosing Dermopath (NSF/NFD) in patients with renal (kidney) failure. A rare condition termed NSF, or nephrogenic systemic fibrosis, has been reported in patients receiving gadolinium in the setting of acute or chronic kidney failure or in the period of time surrounding liver transplantation. This condition can result in fibrosis of the skin, muscles, heart and lung. There have been a few fatalities. In the cases reported, symptoms began from 2 weeks to up to 18 months after receiving the contrast material. Approximately 90% of the cases of NSF occurred after the use of specific brands of contrast material (Omniscan and Optimark). These brands are **NOT** used in this study. No cases have been reported in people with normal or mildly impaired kidney function. We perform a simple blood test (serum creatinine) to ensure the kidney function is normal prior to administering the gadolinium. If kidney function is abnormal, we will inform you and will not proceed with this aspect of testing.

A small percentage of patients (less than 5%) have experienced temporary headaches after the MRI contrast (gadolinium) is injected and a small number (less than 5%) have experienced nausea. Severe allergic reactions are exceedingly rare (1/100,000). Patients with a prior allergic reaction to gadolinium should not participate in this study.

Risks of Blood Drawing

Risks associated with drawing blood from your arm include minimal discomfort and/or bruising. Infection, excess bleeding, clotting, and/or fainting also are possible, although unlikely. Blood will be taken at every visit during the study and approximately 2.5 mL (1/2 teaspoon) of blood will be collected each time. The blood pressure cuff may also cause discomfort or bruising to the upper arm.

Before the start of study drug (screening visit), approximately 10 milliliters (2 teaspoons) of blood may be collected to assess the baseline for Hepatitis B and Hepatitis C. A monitoring test for Hepatitis B might be performed every 4-8 weeks depending on the result of your screening test. A monitoring test for Hepatitis C might be performed every 4-8 weeks if you have a history of past infection. Your study doctor will inform you if you need these tests to be performed and about the frequency of the monitoring tests.

Loss of Confidentiality

Any time information is collected; there is a potential risk for loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

Other Risks

There may possibly be other side effects that are unknown at this time. If you are concerned about other, unknown side effects, please discuss this with the researchers.

How will risks be minimized or prevented?

Potential risks and discomforts will be minimized and/or prevented by the researchers, who will perform routine physical exams, laboratory tests, imaging studies and provide supportive care when needed during your clinic and/or inpatient visits. Also, the researchers will be informed if any unexpected events occur on the study that requires changes to the study procedures.

What will my responsibilities be during the study?

During your participation in this study, the researchers will follow you closely to determine whether there are problems that need medical care. It is your responsibility to do the following:

- Ask questions about anything you do not understand.
- Keep your appointments.
- Follow the researchers' instructions.
- Let the researchers know if your telephone number or address changes.

- Store study materials and study medications in a secure place at home away from anyone who is unable to read and understand labels, especially children.
- Tell the researchers before you take any new medication, even if it is prescribed by another doctor for a different medical problem or something purchased over the counter.
- Tell your regular doctor about your participation in this study.
- Carry information about the research in your purse or wallet.
- Report to the researchers immediately any injury or illnesses while you are on study, even if you do not think it is related.

If I agree to take part in this research study, will I be told of any new risks that may be found during the course of the study?
Yes. You will be told if any new information becomes available during the study that could cause you to change your mind about continuing to participate or that is important to your health or safety.

What should I do if I think I am having problems?
If you have unusual symptoms, pain, or any other problems while you are in the study, you should report them to the researchers right away. Telephone numbers where they can be reached are listed on the first page of this consent form.

If you have a sudden, serious problem, like difficulty breathing or severe pain, go to the nearest hospital emergency room, or call 911 (or the correct emergency telephone number in your area). Tell emergency personnel about being in this study. Ask them to call the researchers immediately.

What are the possible benefits of this study?
We hope that you will get personal medical benefit from taking part in this clinical trial, but we cannot be certain. You may not get any benefits by taking part in this study.

We expect that the information learned from this study will benefit other patients in the future.

What options are available if I decide not to take part in this research study?
Your other choices may include:
- Treatment with other chemotherapy drugs that have been previously tried with your type of brain tumor.
- Other types of investigational trial (if available).
- No further treatment and comfort care only.

Please discuss these options with your treating doctor as well as other trusted persons or family members.

Will I be paid if I take part in this research study?

No. You will not be paid to take part in this research study. There are no funds available to pay for parking expenses, transportation to and from the research center, lost time away from work and other activities, lost wages, or child care expenses.

Will my insurance provider or I be charged for the costs of any part of this research study?
Yes. The costs related to standard medical care for your ependymoma (which includes the exams and procedures outlined in this consent form) will be billed to you or your insurance provider. Some health plans will not pay the costs for people taking part in studies. Taking part in this study may or may not cost your insurance provider or government program more than the cost of getting regular cancer care.

The pharmaceutical company which makes Everolimus (Afinitor®) will provide the Everolimus (Afinitor®) at no charge while you take part in the study. You will not be charged for the biology studies that are being done for research purposes only.

For more information on clinical trials and insurance coverage, you can visit the National Cancer Institute's Web site at http://cancer.gov/clinicaltrials/understanding/insurance-coverage/. You can print a copy of the "Clinical Trials and Insurance Coverage" information from this Web site.

Another way to get the information is to call 1-800-4-CANCER (1-800-422-6237) and ask them to send you a free copy.

What will happen if I am harmed as a result of taking part in this study?
It is important that you report any illness or injury to the research team listed at the top of this form immediately.

Compensation for an injury resulting from your participation in this research is not available from the University of Texas Southwestern Medical Center at Dallas, Children's Medical Center, or the drug supplier.

You retain your legal rights during your participation in this research.

Can I stop taking part in this research study?
Yes. You can decide to stop at any time. Tell the study doctor if you are thinking about stopping or decide to stop. He or she will tell you how to stop safely. It is important to tell the study doctor if you are thinking about stopping so any risks from Everolimus (Afinitor®) can be evaluated by your doctor. Another reason to tell your doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful for you. The study doctor may stop you from taking part in this study at any time if he/she believes it is in your best interest; if you do not follow the study rules; or if the study is stopped.

If I agree to take part in this research study, can I be removed from the study without

my consent?
Yes. The researchers may decide to take you off this study if:

- The side effects of Everolimus (Afinitor®) are too harmful for you
- You need a treatment that is not allowed on this study
- Your tumor has grown back or become larger despite receiving Everolimus (Afinitor®)
- You are not able to follow study-related treatment instructions
- New information becomes available
- The study is not in your best interest
- The study is stopped because there is no benefit for your type of brain tumor

Will my information be kept confidential?
Information about you that is collected for this research study will remain confidential unless you give your permission to share it with others, or if we are required by law to release it.

We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Your personal information may be revealed if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Your medical records are available to those caring for you at this hospital. Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- Novartis, the drug supplier, and its authorized agents
- The FDA, the National Cancer Institute (NCI), or other governmental agencies involved in keeping research studies safe for children, and governmental agencies in other countries where the study drug may be considered for approval.
- The Institutional Review Board of your hospital

A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by the U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

In addition to this consent form, you will be asked to sign an "Authorization for Use and Disclosure of Protected Health Information." This authorization will give more details about how your information will be used for this research study, and who may see and/or get copies of your information.

Are there procedures I should follow after stopping participation in this research?
Yes. If you, the researchers, or the sponsor stops your participation in the research, you may be asked to do the following:

- Let the researchers know immediately that you wish to withdraw from the research.

- Return to the research center for tests that may be needed for your safety.
- Return any unused study materials, including empty containers.
- Discuss your future medical care, if any, with the researchers and/or your personal doctor.

Is there anything else I should know before I decide?
Dr. Laetsch has financial interests in the sponsor and maker of a drug used in this study. You should feel free to ask questions about this.

Whom do I call if I have questions or problems?
For questions about the study, contact Dr. Daniel Bowers at 214-456-2382 during regular business hours and at 214-456-7000 after hours and on weekends and holidays.

For questions about your rights as a research participant, contact the UT Southwestern Institutional Review Board (IRB) Office at 214-648-3060.

Where can I get more information?
If you are in the United States, you may call the National Cancer Institute's Cancer Information Service at:

1-800-4-CANCER (1-800-422-6237) or TTY: 1-800-332-8615

You may also visit the NCI Web site at http://cancer.gov/

- For NCI's clinical trials information, go to: http://cancer.gov/clinicaltrials/
- For NCI's general information about cancer, go to http://cancer.gov/cancerinfo/

You will get a copy of this form. You will be given a copy of the protocol (full study plan) upon request.

YOU WILL BE GIVEN A COPY OF THIS CONSENT FORM TO KEEP.

Your signature below certifies the following:

- You have read (or been read) the information provided above.
- You have received answers to all of your questions and have been told who to call if you have any more questions.
- You have freely decided to participate in this research.
- You understand that you are not giving up any of your legal rights.
- You understand that a copy of this signed consent document, information about this study and the results of any test or procedure done may be included in your medical record and this information may be available to health care providers and authorized persons including your insurance company.

_____
Participant's name

_____ _____ _____AM / PM
Participant's signature Date Time

_____
Parent or Legally authorized representative's name (printed)

_____ _____ _____AM / PM
Parent or Legally authorized representative's Signature Date Time

_____
Name (printed) of person obtaining Consent

_____ _____ _____AM / PM
Signature of person obtaining consent Date Time

ASSENT OF A MINOR:
I have discussed this research study with my parent or legal guardian and the researchers, and I agree to participate.

_____ _____ _____AM / PM
Signature of participant (age 10 through 17) Date Time

INTERPRETER/WITNESS STATEMENT:
I have interpreted this consent form into a language understandable to the participant and the participant has agreed to participate as indicated by their signature above.

_____
Name of Interpreter (printed)

_____ _____ _____AM / PM
Signature of Interpreter Date Time

WITNESS [Needed when the interpreter is not physically present, i.e. a language line is used]:

I attest that the information in the consent form was accurately explained to, and apparently understood by the subject or the subject's legal authorized representative, and that informed consent was freely given by the subject or the subject's legal authorized representative.

_____ _____ _____AM / PM
Name of Witness (Printed) Date Time

_____ _____ _____AM / PM
Signature of Witness Date Time