THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH WITH OPTIONAL PROCEDURES

Therapy of Early Chronic Phase Chronic Myelogenous Leukemia (CML) with Dasatinib (BMS-354825)
2005-0422

Study Chair: Lucia Masarova

_____ _____
Participant's Name Medical Record Number

This is an informed consent and authorization form for a research study. It includes a summary about the study. A more detailed description of procedures and risks is provided after the summary.

STUDY SUMMARY

The goal of this clinical research study is to learn if BMS-354825 (dasatinib) can help to control CML in chronic phase. The safety of this drug will also be studied.

This is an investigational study. Dasatinib is investigational and is approved by the FDA for clinical trials only. Dasatinib is provided free of charge to participants.

Treatment on this study may help to control the disease. Future patients may benefit from what is learned. There may be no benefits for you in this study.

Your participation is completely voluntary. Before choosing to take part in this study, you should discuss with the study team any concerns you may have, including side effects, potential expenses, and time commitment.

You can read a full list of potential side effects below in the Possible Risks section of this consent.

Treatment may be continued for up to 15-18 years or as long as the doctor feels it is necessary to control the leukemia.

All required study procedures and tests are considered standard of care and will be the financial responsibility of you and/or your insurance provider.
You may choose not to take part in this study. Instead of taking part in this study, you may choose to receive standard therapy outside of this study such as imatinib mesylate (Gleevec), hydroxyurea, chemotherapy combinations, or interferon alone or with cytarabine. Eligible patients with potential donors may choose to be treated with a marrow transplant. You may choose to receive other investigational treatment, if available. You may choose not to have treatment at all. In all cases, you will receive appropriate medical care, including treatment for pain and other symptoms of cancer. Refusal to take part in this study will not cause penalty or loss of benefits to which you are otherwise entitled.

1. STUDY DETAILS

Dasatinib is an anticancer drug that is designed to block the function of BCR-ABL, which is the abnormal protein responsible for causing leukemia in certain cells.

A total of 150 patients will take part in this study. All will be enrolled at MD Anderson.

Before you can start therapy on this study, you will have what are called "screening tests." These tests will help the doctor decide if you are eligible to take part in the study. You will have a complete medical history and physical exam. Blood (about 2 tablespoons) will be collected for routine tests and to check for hepatitis B infection. You will also have a bone marrow biopsy and aspiration. To collect a bone marrow biopsy and aspiration, an area of the hip or chest bone is numbed with anaesthetic and a small amount of bone marrow and bone is withdrawn through a large needle. Women who are able to have children must have a negative blood or urine pregnancy test.

If you are found to be eligible to take part in this study and you agree, you will take dasatinib once every day while on study. Dasatinib should be taken by mouth with water.

Every 1-2 weeks during the first 4 weeks of the study, you will have around 2 tablespoons of blood drawn for routine blood tests. The blood tests will be repeated every 4-6 weeks until 1 year from when you started therapy and then every 3-4 months until 2 years, then as often as the doctor thinks it is needed. A bone marrow aspiration will also be taken to check the status of the disease every 3-4 months for the first year and then as often as the doctor thinks it is needed for as long as you are on the study.

You will be given a medication diary to monitor any missed doses. You will also be asked to visit the doctor for a physical exam and to have vital signs measured periodically. These visits will be scheduled at least every 3-4 months for the first year, then recommended every 6 to 12 months while you are on the study. The visits may be scheduled more often depending on the status of the disease.

If the disease gets worse or you experience any intolerable side effects, you will be taken off the study and your doctor will discuss other treatment options with you. If you decide to stop participating in the study, you are encouraged to discuss your decision with your study doctor.

For Patients Already Enrolled

If you have already been enrolled on this study and were assigned to receive dasatinib twice a day, you will be able to continue to receive the study drug on that schedule. However, if you experience side effects, the study doctor may choose to switch you to the once daily schedule if he feels that it may help to get rid of or decrease the risk of side effects.

2. POSSIBLE RISKS

While on this study, you are at risk for the side effects listed in this form. You should discuss these with the study doctor or your regular doctor. The known side effects are listed in this form, but they will vary from person to person. Many side effects go away shortly after the study drug is stopped, but in some cases, side effects maybe serious, long-lasting or permanent, and may even cause death.

Dasatinib Side Effects

Common (occurring in more than 20% of patients)

• swelling • headache • fatigue • skin rash (possible itching, blistering, shedding, irritation, and/or redness)	• diarrhea • nausea • low blood cell counts (red, white, platelets) • pain	• build-up of fluid in and/or around the lungs (possible difficulty breathing) • difficulty breathing

Dasatinib may commonly cause low blood cell counts (red blood cells, platelets, and/or white blood cells):

- A low red blood cell count (anemia) may cause difficulty breathing and/or fatigue. You may need a blood transfusion.
- A low platelet count increases your risk of bleeding (such as nosebleeds, bruising, stroke, and/or digestive system bleeding). You may need a platelet transfusion.
- A low white blood cell count increases your risk of infection (such as pneumonia and/or severe blood infection). Infections may occur anywhere and become life-threatening. Symptoms of infection may include fever, pain, redness, and difficulty breathing.

Occasional (occurring in 3-20% of patients)

• irregular heartbeat • build-up of fluid in the tissue around the heart • decreased blood supply to the heart • heart failure • severe heart problems • enlarged heart • fever • central nervous system bleeding	• itching • constipation • vomiting • abdominal pain • digestive system bleeding • abnormal liver tests (possible liver damage or yellowing of the skin and/or eyes)	• muscle spasms • abnormal kidney test (possible kidney damage) • increased blood pressure in the lungs (possible difficulty breathing and/or heart failure) • infection

Exact frequency unknown but occurring in between 1 and 10% of patients:

• fast heartbeat • chest pain • flushing • high blood pressure • chills • depression • dizziness • difficulty sleeping • acne • hair loss (partial or total) • eczema (skin inflammation) • dry skin • sweating • high blood levels of uric acid (possible painful joints and/or kidney failure)	• abdominal swelling • loss of appetite • upset stomach • inflammation of the stomach and/or intestines • mouth blisters/sores (possible difficulty swallowing) • abnormal taste • weight loss/gain • nerve damage (possible numbness, pain, and/or loss of motor or sensory function)	• weakness • blurry vision • dry eyes • vision problems • ringing in the ears • cough • lung inflammation (possible difficulty breathing) • severe life-threatening infection (possible low blood pressure, kidney failure, and/or heart failure)

Rare but serious (occurring in fewer than 3% of patients)

• chest pain due to heart trouble • low blood pressure (possible dizziness/fainting) • heart attack • sudden stopping of the heart • heart and lung failure • heart inflammation • inflammation of the tissue around the heart (possible chest pain) • abnormal blood test (possible heart problems) • stroke • blood clots in a vein (possible pain, swelling, and/or redness) • abnormal blood clotting • seizure • memory loss • dementia (loss of mental capacity) • fainting • difficulty walking • inflammation of the fatty layer under the skin • skin condition with fever and skin lesions • painful skin bumps • hand-foot syndrome (palms of hands/soles of feet having pain, swelling, and blistering) • very severe blistering skin disease (with ulcers of the skin and digestive tract) • inflammation of the thyroid gland (possible tenderness in the neck)	• overactive thyroid gland (possible weight loss, heart rate changes, and/or sweating) • underactive thyroid gland (possible weight gain, heart failure, and/or constipation) • high blood levels of fat (possible heart disease and/or stroke) • low blood levels of albumin (possible swelling, weakness, and/or fatigue) • diabetes • fluid in the abdomen • dehydration • gum bleeding • stomach ulcer • abnormal connections or passageways between organs or vessels • intestinal blockage • gallbladder inflammation (possible abdominal pain) • severe inflammation of the pancreas (possible sudden abdominal pain) • blood in the urine • uterine and/or vaginal bleeding • decreased bone marrow function and inability to make red blood cells	• blockage of the bile tract (possible body yellowing and/or abdominal pain) • liver damage • liver damage • paralysis of nerves controlling the head and neck • bone destruction • eye bleeding • inflammation of an eye nerve • hearing loss • kidney failure • breakdown of muscle tissue (possible kidney failure) • difficulty breathing due to narrowing of the airways • blockage in the lung (possible pain, shortness of breath, and/or failure to breathe) • coughing up blood • breakdown products of the cancer cells entering the blood stream (possible weakness, low blood pressure, muscle cramps, kidney damage, and/or other organ damage) • allergic reaction

Dasatinib may cause harm to a fetus if taken during pregnancy.

Other Instructions about Dasatinib

Call your doctor at the first sign of diarrhea. You should keep some Loperamide (Imodium) at home, in case you have diarrhea. You should call your doctor right away or go to the hospital if there are any signs of bleeding from your stomach (vomiting bloody or dark stomach contents) or bleeding from the intestines (dark or bloody bowel movements).

Call your doctor right away, and go to a hospital if you have signs of heart problems such as abnormal heartbeat or chest discomfort.

Anybody other than the participant should wear protective gloves when handling dasatinib.

You should not eat grapefruit or drink grapefruit juice while taking dasatinib.

You may experience pain, bleeding, and/or bruising from the blood draws. You may faint and/or develop an infection with redness and irritation of the vein at the site where blood is drawn. Frequent blood collection may cause anemia (low red blood cell count), which may create a need for blood transfusions.

Having bone marrow biopsies and aspirations performed may cause pain, bruising, bleeding, redness, low blood pressure, swelling, and/or infection at the site of the collection. An allergic reaction to the anesthetic may occur. A scar may form at the collection site.

This study may involve unpredictable risks to the participants.

Pregnancy Related Risks

4a. Because taking part in this study can result in risks to an unborn or breastfeeding baby, you should not become pregnant or breastfeed a baby while on this study. You must use 2 methods of birth control during the study if you are sexually active.

Birth Control Specifications: Women must continue birth control for at least 3 months after they take the last dose of study drug.

Females: If you are pregnant, you will not be enrolled on this study. If you become pregnant or suspect that you are pregnant, you must tell your doctor right away.

Getting pregnant may result in your removal from this study.

OPTIONAL PROCEDURES FOR THE STUDY

Optional Procedure # 1: You are being asked to have extra blood samples taken. These samples will be used to study the effect of the treatment on leukemia cells, the amount of drug in your blood and the factors, including molecules in your blood, that may predict for a good response or for side effects. Other samples will be used to test the effect of the treatment on the function of your platelets and the effect on your bones.

If you agree, you will have about 1 tablespoon of blood collected before therapy and every 3-4 months for as long as you are on the study. If you agree you will also have 1 teaspoon of blood collected to measure the function of the platelets before the start of therapy, approximately 1 hour, 6 hours and 24 hours after your first dose, and then after 3 months of therapy. You may also agree to have 1 additional tablespoon collected at any time during the course of your therapy, and a teaspoon after 1 and 2 years from the start of therapy for investigation of molecules in your blood that may predict your response.

Optional Procedure # 2: You are being asked to have extra bone marrow samples taken. These samples will be used to study the effect of the treatment on leukemia cells, the amount of drug in your blood and the factors, including molecules in your blood, that may predict for a good response or for side effects. Other samples will be used to test the effect of the treatment on the function of your platelets and the effect on your bones. If you agree, you will also have bone marrow collected (about 1/2 teaspoon) before therapy and every 3-4 months for 1 year and then every 6-12 months for as long as you are on the study whenever a bone marrow aspiration is done to evaluate the status of your disease. If you agree, you will also have a bone marrow biopsy done before the start of therapy and 1, 2 and 4 years after the start of therapy.

Optional Procedure # 3: You are being asked to have blood drawn for pharmacokinetic (PK) testing. PK testing measures the amount of study drug in the body at different time points. If you agree, blood (about 1 teaspoon) will be drawn for PK testing. Samples will be drawn before you take the medication, and then 1, 2, 4, 6, 8-10, and 24 hours after you take the first dose, and again one time every 3 months when blood is being drawn for routine follow-up visits.

Optional Procedure # 4: You are being asked to rate the severity of 20 symptoms frequently experienced by patients with CML, to rate how much these symptoms are interfering with 6 daily activities, and to rate the overall quality of your life. If you agree, before starting the study medication, you will be asked to rate the severity of 20 symptoms frequently experienced by patients with CML, to rate how much these symptoms are interfering with 6 daily activities, and to rate the overall quality of your life. You may be asked to complete these ratings on paper or on a tablet computer. These 27 questions should take less than 5 minutes to complete.

Optional Procedure # 5: You are also being asked to rate the same 20 symptoms, 6 areas of activity interference, and quality of life over a longer period of time using an automated telephone system. If you agree, during the study, you will be asked to rate the same 20 symptoms and 6 areas of activity interference every week for 3 months and then

every other week for the remainder of the study. If you are at home, an automated telephone system will call you to collect the ratings at a time that is convenient for you. You will be taught how to use the automated telephone system at the start of the study. If you have a scheduled clinic visit, you may be asked to answer these questions on paper or on a tablet computer. At each clinic visit, you will be asked to rate the overall quality of your life either on paper or on a tablet computer. All of the ratings by automated telephone system or in clinic should take no more than 5 minutes to complete.

All of the optional samples will be collected during routine draws so that no additional needle sticks are required. The optional procedures will be performed free of charge.

You do not have to agree to take part in the optional procedures in order to receive treatment on this study.

Optional Procedure Risks:
As the optional blood and bone marrow samples will be drawn at the time of routine collection, there are no additional risks expected.

CONSENT/PERMISSION/AUTHORIZATION FOR OPTIONAL PROCEDURES

Circle your choice of "yes" or "no" for each of the following optional procedures:

Optional Procedure # 1: Do you elect to have blood collected as an optional procedure?

YES NO

Optional Procedure # 2: Do you elect to have bone marrow collected as an optional procedure?

YES NO

Optional Procedure # 3: Do you elect to have blood drawn for PK testing as an optional procedure?

YES NO

Optional Procedure # 4: Do you elect to rate the severity of 20 symptoms frequently experienced by patients with CML, to rate how much these symptoms are interfering with 6 daily activities, and to rate the overall quality of your life as an optional procedure?

YES NO

Optional Procedure # 5: Do you elect to rate the same 20 symptoms, 6 areas of activity interference, and quality of life over a longer period of time using an automated telephone system as an optional procedure?

YES NO

3. COSTS AND COMPENSATION

If you suffer injury as a direct result of taking part in this study, MD Anderson health providers will provide medical care. However, this medical care will be billed to your insurance provider or you in the ordinary manner. You will not be reimbursed for expenses or compensated financially by MD Anderson *or* Bristol Myers Squibb for this injury. You may also contact the Chair of MD Anderson's IRB at 713-792-6477 with questions about study-related injuries. By signing this consent form, you are not giving up any of your legal rights.

Certain tests, procedures, and/or drugs that you may receive as part of this study may be without cost to you because they are for research purposes only. However, your insurance provider and/or you may be financially responsible for the cost of care and treatment of any complications resulting from the research tests, procedures, and/or drugs. Standard medical care that you receive under this research study will be billed to your insurance provider and/or you in the ordinary manner. Before taking part in this study, you may ask about which parts of the research-related care may be provided without charge, which costs your insurance provider may pay for, and which costs may be your responsibility. You may ask that a financial counselor be made available to you to talk about the costs of this study.

Samples that are collected from you in this study may be used for the development of treatments, devices, new drugs, or patentable procedures that may result in commercial profit.

There are no plans to compensate you for any patents or discoveries that may result from your participation in this research.

You will receive no compensation for taking part in this study.

Additional Information

4. You may ask the study chair (Dr.Lucia Masarova, at832-750-4211) any questions you have about this study. You may also contact the Chair of MD Anderson's Institutional Review Board (IRB - a committee that reviews research studies) at 713-792-6477 with any questions that have to do with this study or your rights as a study participant.

5. You may choose not to take part in this study without any penalty or loss of

benefits to which you are otherwise entitled. You may also withdraw from participation in this study at any time without any penalty or loss of benefits. If you decide you want to stop taking part in the study, it is recommended for your safety that you first talk to your doctor. If you withdraw from this study, you can still choose to be treated at MD Anderson.

6. This study or your participation in it may be changed or stopped without your consent at any time by the study chair, Bristol Myers Squibb, the U.S. Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP), or the IRB of MD Anderson.

7. You will be informed of any new findings or information that might affect your willingness to continue taking part in the study, and you may be asked to sign another informed consent and authorization form stating your continued willingness to participate in this study.

8. MD Anderson may benefit from your participation and/or what is learned in this study.

9. This study is sponsored and/or supported by: Bristol Myers Squibb.

10. In a medical emergency, you may be cared for by someone who has a financial interest with the study sponsor(s)/supporter. If you have any questions about this, you may call the IRB at 713-792-6477.

Future Research

Your personal information and/or samples are being collected as part of this study. These data and/or samples may be used by researchers at MD Anderson or shared with other researchers and/or institutions for use in future research.

Before being shared for future research, every effort will be made to remove your identifying information from any data and/or samples. If all identifying information is removed, you will not be asked for additional permission before future research is performed.

In some cases, all of your identifying information may not be removed before your data or samples are used for future research. If this research is performed at MD Anderson, the researchers must get approval from the Institutional Review Board (IRB) of MD Anderson before your data and/or samples can be used. At that time, the IRB will decide whether or not further permission from you is required. The IRB is a committee of doctors, researchers, and community members that is responsible for protecting study participants and making sure all research is safe and ethical.

If this research is not performed at MD Anderson, MD Anderson will not have oversight of any data and/or samples.

Genetic Research

Samples collected from you as part of this study may be used for genetic research, which may include whole genome sequencing. Whole genome sequencing is a type of testing in which researchers study your entire genetic makeup (DNA). This may help researchers learn how changes in the ordering of genes may affect a disease or response to treatment.

Conflict of Interest

Dr. Lucia Masarova (Study Chair) has received compensation from Bristol-Myers Squibb as a Consultant. The financial interests are within the limits of the conflict of interest policy.

Outside Care

Part of your care may be provided outside of MD Anderson by your home doctor(s).

Authorization for Use and Disclosure of Protected Health Information (PHI):

A. During the course of this study, MD Anderson will be collecting and using your PHI, including identifying information, information from your medical record, and study results. For legal, ethical, research, and safety-related reasons, your doctor and the research team may share your PHI with:
   - Federal agencies that require reporting of clinical study data (such as the FDA, National Cancer Institute [NCI], and OHRP)
   - The IRB and officials of MD Anderson
   - Bristol Myers Squibb, who is a sponsor or supporter of this study, and/or any future sponsors/supporters of the study
   - Dr. Calin at M.D. Anderson, and Dr. Beumer at the University of Pittsburgh Cancer Institute Clinical Pharmacology Analytical Facility
   - Study monitors and auditors who verify the accuracy of the information
   - Individuals who put all the study information together in report form

   Dr. Beumer at the University of Pittsburgh Cancer Institute Clinical Pharmacology Analytical Facility will receive PK samples. Dr. Calin at M.D. Anderson will receive blood samples for investigation of molecules in your blood that may predict your response.

   Study sponsors and/or supporters receive limited amounts of PHI. They may also view additional PHI in study records during the monitoring process. MD Anderson's contracts require sponsors/supporters to protect this information and limit how they may use it.

B. Signing this consent and authorization form is optional but you cannot take part in this study or receive study-related treatment if you do not agree and sign.

C. MD Anderson will keep your PHI confidential when possible (according to state and federal law). However, in some situations, the FDA could be required to reveal the names of participants.

Once disclosed outside of MD Anderson, federal privacy laws may no longer protect your PHI.

D. The permission to use your PHI will continue indefinitely unless you withdraw your authorization in writing. Instructions on how to do this can be found in the MD Anderson Notice of Privacy Practices (NPP) or you may contact the Chief Privacy Officer at 713-745-6636. If you withdraw your authorization, you will be removed from the study and the data collected about you up to that point can be used and included in data analysis. However, no further information about you will be collected.

E. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by 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.

List of Drugs that Cannot be Taken During this Study

- Acetaminophen
- Aldrin
- Alfentanil
- Amiodarone
- Astemizole
- Benzphetamine
- Budesonide
- Carbamazepine
- Cyclophosphamide
- Cyclosporin
- Dapsone
- Digitoxin
- Diltiazem
- Diazepam
- Erythromycin
- Ethinylestradiol
- Etoposide
- Flutamide
- Hydroxyarginine
- Ifosphamide
- Imipramine
- Lansoprazole
- Lidocaine
- Loratadine
- Losartan
- Lovastatin
- Midazolam
- Nifedipine
- Omeprazole
- Quinidine
- Paclitaxel
- Rapamycin
- Retinoic Acid
- Steroids (e.g., cortisol)
- Tacrolimus (FK 506)
- Tamoxifene
- Teniposide
- Terfenadine
- Tetrahydrocannabinol
- Theophylline
- Toremifene
- Triazolam
- Troleandomycin
- Verapamil
- Zatosetron
- Zonisamide

CONSENT/AUTHORIZATION
(Adult Participants Only)

I understand the information in this consent form. I have had a chance to read the consent form for this study, or have had it read to me. I have had a chance to think about it, ask questions, and talk about it with others as needed. I give the study chair permission to enroll me on this study. By signing this consent form, I am not giving up any of my legal rights. I will be given a signed copy of this consent document.

_____ _____
SIGNATURE OF PARTICIPANT DATE

_____
PRINTED NAME OF PARTICIPANT

LEGALLY AUTHORIZED REPRESENTATIVE (LAR)

The following signature line should only be filled out when the participant does not have the capacity to legally consent to take part in the study and/or sign this document on his or her own behalf.

_____ _____
SIGNATURE OF LAR DATE

_____
PRINTED NAME and RELATIONSHIP TO PARTICIPANT

WITNESS TO CONSENT

I was present during the explanation of the research to be performed under Protocol **2005-0422**.

_____ _____
SIGNATURE OF WITNESS TO THE VERBAL CONSENT PRESENTATION (OTHER THAN PHYSICIAN OR STUDY CHAIR) DATE

A witness signature is only required for vulnerable adult participants. If witnessing the assent of a pediatric participant, leave this line blank and sign on the witness to assent page instead.

_____
PRINTED NAME OF WITNESS TO THE VERBAL CONSENT

PERSON OBTAINING CONSENT

I have discussed this research study with the participant and/or his or her authorized representative, using language that is understandable and appropriate. I believe that I have fully informed this participant of the nature of this study and its possible benefits and risks and that the participant understood this explanation.

_____ _____
PERSON OBTAINING CONSENT DATE

_____
PRINTED NAME OF PERSON OBTAINING CONSENT

PARENT/GUARDIAN PERMISSION
I have read and understand the description of this research. I have had a chance to discuss the study and ask questions. My questions have been answered. I give permission for my child or ward to take part in this study.

_____ _____
SIGNATURE OF PARENT/GUARDIAN DATE

_____
PRINTED NAME OF PARENT/GUARDIAN

_____ _____
SIGNATURE OF PARENT/GUARDIAN DATE
Signature of Other Parent (Optional, unless required by the IRB.)

_____
PRINTED NAME OF PARENT/GUARDIAN

____The IRB has determined that the signature of both parents is required.

If not obtaining both parental signatures, please indicate reason below:

____Other parent is deceased, unknown, incompetent, or not reasonably available.

____Parent/Guardian signing above has sole legal responsibility for the care and custody of the child.

_ X _The IRB has determined that the signature of both parents is NOT required.

WITNESS TO PARENTAL/GUARDIAN PERMISSION
I was present during the explanation of the research to be performed under Protocol **2005-0422**. The child participant was also present. In my opinion, the parent(s)/guardian provided permission for the child to participate in the research.

_____ _____
SIGNATURE OF WITNESS TO THE PARENTAL/GUARDIAN PERMISSION (OTHER THAN PARENT/GUARDIAN OR MEMBER OF THE STUDY TEAM) DATE

_____
PRINTED NAME OF WITNESS TO THE PARENTAL/GUARDIAN PERMISSION

ASSENT OF MINOR

(Entire section must be completed if the participant's intellectual age is at least 7 and less than 18 years. Participants with an intellectual age of 7 - 12 are not required to sign.)

If written assent is not obtained on an age-appropriate participant, check reason why not:

____ 1.) The participant's intellectual age is less than seven.

____ 2.) The participant dissented, but the participant's parent(s)/guardian felt that the intervention(s) or procedure(s) involved in the research hold out the possibility of a direct benefit that is important to the health and/or well being of the participant and is available only in the context of this research study.

____ 3.) Other: _____

I have been told what I will be asked to do in this study.

I have been told that I do not have to be in this study. If I decide not to be in this study, no one will be mad at me. I may quit at any time, but if I do, I may need to take a different treatment.

I have had a chance to talk about the study and ask the study doctor questions. All of my questions have been answered. I agree to be in this study and do what I am asked to do so long as I want to stay in this study. I agree that the study doctor can put me on this study. By signing this paper, I am not giving up any of my legal rights. I have been given a copy of this document.

_____ _____
SIGNATURE OF MINOR (Age 13-17) DATE

_____
PRINTED NAME OF MINOR

WITNESS TO ASSENT

I was present during the explanation of the research to be performed under Protocol **2005-0422**. The child participant was also present. In my opinion, the child assented to participate in the research. (Note: If obtaining assent, a witness signature is required.)

_____ _____
SIGNATURE OF WITNESS TO THE ASSENT (OTHER THAN PARENT/GUARDIAN OR MEMBER OF THE STUDY TEAM) DATE

_____
PRINTED NAME OF WITNESS TO THE ASSENT

TRANSLATOR

I have translated the above informed consent as written (without additions or subtractions) into_____and assisted the people
(Name of Language)
obtaining and providing consent by translating all questions and responses during the consent process for this participant.

_____ _____ _____
NAME OF TRANSLATOR SIGNATURE OF TRANSLATOR DATE

☐ Please check here if the translator was a member of the research team. (If checked, a witness, other than the translator, must sign the witness line below.)

_____ _____
SIGNATURE OF WITNESS TO THE VERBAL TRANSLATION DATE
(OTHER THAN TRANSLATOR, PARENT/GUARDIAN,
OR STUDY CHAIR)

_____
PRINTED NAME OF WITNESS TO THE VERBAL TRANSLATION