Cover Page

NF PROTOCOL 105

A Phase II Study of Cabozantinib (XL184) for Plexiform Neurofibromas in Subjects with Neurofibromatosis Type 1 in Children and Adults

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CONSENT FORM

Protocol Title:	A Phase II Study of Cabozantinib (XL 184) for Plexiform Neurofibromas in Subjects with Neurofibromatosis Type 1 in Children and Adults
IRB Protocol #:	SITE NUMBER
IND#:	118308
Sponsor:	US Army, Department of Defense (DOD) and Exelixis, Inc.
Principal Research Doctor / Institution:	SITE PI/INSTITUTION NAME

WHAT IS THE PURPOSE OF THIS STUDY?

This is a clinical trial, a type of research study. The study doctor will explain the clinical trial to you. Clinical trials include only people who choose to take part. Please spend some time to make your decision about taking part. You may discuss your decision with your friends and family. You can also discuss it with your health care team. If you have any questions, you can ask the study doctor for more explanation.

You have been invited to participate in a research study entitled, "A Phase II Study of Cabozantinib (XL l84) for Plexiform Neurofibromas in Subjects with Neurofibromatosis Type I in Children and Adults" This study is funded by the Department of Defense (DOD). You are being asked to take part in this study because you have been diagnosed with Neurofibromatosis Type 1 and have a type of tumor called a plexiform neurofibroma. Neurofibromas are tumors that develop from the cells and tissues that cover the nerves. Plexiform neurofibromas can be disfiguring, painful, and life-threatening. These types of tumors typically do not respond well to most treatment approaches such as chemotherapy, radiation, and surgery because of their slow growth and location near vital structures of the body such as nerves, blood vessels, and the airway.

The purpose of this Phase II Study is to determine the response rate of NFI patients with plexiform neurofibromas treated with Cabozantinib therapy using MRI scans. Cabozantinib is thought to work on tumors by blocking pathways that are involved in the growth of tumors and blood vessels that supply tumors. Cabozantinib is considered experimental because it has not been approved by the Food and Drug Administration (FDA) for use in plexiform neurofibromas.

Up to 48 subjects ranges age 3 and older will participate at multiple centers in the United States. About # subjects will be enrolled at SITE.

WHAT WILL PARTICIPATING IN THIS STUDY INVOLVE?

If you agree to participate in this study, you will be given the drug Cabozantinib. This drug will be given daily by mouth. The duration of treatment is up to 24 cycles (~2 years). If after 12 cycles (~1 year), your tumor has not decreased in size by 20%, you will be removed from study. Continuing treatment beyond 24 cycles will be at the discretion of you and your physician and may become your financial responsibility if no alternative method of obtaining or paying for the drug can be identified at that time. Your study doctor will go over other treatment options with you at that time. While you are taking Cabozantinib you will be required to fill out a drug administration diary recording the date and time you take the drug, any side effects you experience, and other medications you are taking. This diary should be returned to the clinic, along with the medication bottle (even if it is empty). This will help us to know how much of the drug you take and how it made you feel.

Before starting the study…
Prior to enrolling on this clinical trial, your study doctor will make sure you are eligible to receive this treatment. The following tests will be done:

- Urine Pregnancy Test for females of child-bearing potential (this test must be negative, not pregnant)
- Physical Exam and Medical History
- Laboratory tests including blood tests and urine tests
- MRI (Magnetic Resonance Imaging) scan to evaluate the tumor prior to starting your treatment
- EKG (electrocardiogram) to evaluate the electrical activity of your heart

If these tests show that you are eligible to participate in the clinical trial, you will begin the study treatment. If you do not meet the eligibility criteria, you will not be able to participate in this clinical trial.

During Study Treatment:
The start of receiving Cabozantinib will be within 14 days of study enrollment. Cabozantinib should be taken on an empty stomach (fasting is required 2 hours before and 1 hour after each Cabozantinib dose).

Cabozantinib should NOT be re-taken if vomiting occurs after taking a scheduled dose. Dosing may continue the next day as scheduled. You will take Cabozantinib once a day.

While participating in this trial you will be followed at this center to monitor the safety of this treatment and to evaluate if the tumor is responding well. Once the treatment begins, you will have follow-up visits as outlined below:

STUDIES TO BE OBTAINED	Pre-Study	Cycle 1	Cycle 2-3	Cycles 4-12	Cycles 13-24	End of Study
Clinic Visit for Physical Exam	X	Day 15, 28	Day 15, End	End (each cycle)	End of every even cycle (14, 16, …)	X
*Phone Call^*					End of every odd cycle (13, 15, …)	
Blood lab tests	X	Day 15, End	Day 15, End	End (each cycle)	End (each cycle)	X
Urine Tests	X	End	End (each cycle)	End (each cycle)	End (each cycle)	X
Pregnancy Test (female)	X		End Cycle 2	End of every other cycle	End of every even cycle	X
*EKG^^*	X	Day 28	End Cycle 2	End Cycle 4, 6, 9, 12	End Cycle 16, 20, 24	X
*MRI Scan**	X			End Cycle 4, 8, 12	End Cycle 18, 24	X
*Questionnaires***	X			End Cycle 4, 8, 12	End Cycle 18, 24	X
*Research Blood Draws****	X	Day 1, 15 and End	End of Cycle 2 and 3	End Cycle 4		
Blood Draw for Banking (optional)	X			End Cycle 4, 12		X
Patient Diary		Day 28	End (each cycle)	End (each cycle)	End (each cycle)	X

^**Phone Calls** will be made to you after every other cycle during year 2 of treatment. The calls will ask you about how reliably you are taking your study medication and whether you are having any side effects.

^^**EKGs** may be performed more frequently (at the end of each cycle) if you start a medication that is known to impact the electrical activity of the heart.

***MRI Scans** will be performed to evaluate how well your tumor is responding to this treatment. These scans will be performed during treatment and prior to Cycle 5, Cycle 9 and after Cycle 13. If you remain on study beyond 12 cycles of treatment, you will have an MRI scan done to evaluate your disease every 6 cycles, annually thereafter, and/or one final scan done when you stop participating in this study.

MRI scans will be requested at approximately 4 months and 12 months following completion of therapy for subjects who had a response to Cabozantinib. Subjects who start another tumor directed therapy during the one year follow-up time are off-study and no further MRIs will be requested.

**Questionnaires (Required) – you will be asked to complete questionnaires that are about your disease and how it affects your daily activities. These questionnaires contain approximately 75 questions.

***Blood draws for research (Required) - Blood samples will be drawn to see if we can predict how well the tumor is responding to the treatment. About 2 tablespoons of blood (24 cc) will be drawn pre-treatment,

Cycle 1 Day 15, End of Cycle 2 and End of Cycle 4. In addition, blood samples will be drawn to see how the body breaks down Cabozantinib by measuring the amount of drug in the body at different time points after taking Cabozantinib. About ½ teaspoon (2 cc) will be drawn pre-dose and 4 hours after the dose on Day 1 and the end of Cycle 1 and Day 1 of Cycles 3 and 4.

The research blood samples will be given an assigned number instead of having your name or identifying information on them. The samples will then be stored in a secure, locked laboratory facility indefinitely.

Additional exams, blood draws, etc. may be required if clinically indicated for standard of care.

WHAT RISKS OR DISCOMFORTS ARE INVOLVED?

You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. However, doctors don't know all the side effects that may happen. Side effects may be mild or very serious. Your study doctor may give you medicines to help lessen side effects. Many side effects go away soon after you stop taking the Cabozantinib. In some cases, side effects can be serious, long-lasting, or may never go away. There also is a risk of death. We will tell you if we learn any new information that may affect your health, welfare, or decision to stay in this study.

You should talk to your study doctor about any side effects that you have while taking part in the study.

Risks and side effects related to Cabozantinib include those which are:

Likely: > 20%

- Diarrhea*
- Nausea or the urge to vomit
- Fatigue or tiredness
- Loss of appetite
- Blisters, rash, or pain in hands or feet
- Taste changes
- Vomiting
- Weight loss
- High blood pressure

*Cabozantinib can cause diarrhea or other digestive problems. Not all subjects will have bad diarrhea or other digestive problems. Using the supportive care drug loperamide (also known as Imodium) may help prevent diarrhea. Loperamide should be used at the first sign of diarrhea.

Less Likely: 5% - 20%

- Abnormally low level of thyroid hormone
- Abnormal physical weakness or lack of energy
- Belly pain
- Constipation
- Dry mouth

- Indigestion
- Irritation, sores, swelling or pain in the lining of the mouth
- Changes in blood tests used to monitor the liver, which may indicate liver damage (increase in ALT/SGPT, AST/SGOT, or GGT)
- Decreased number of a type of white blood cell (neutrophil/granulocyte)*
- Decreased number of a type of blood cell that helps to clot blood (platelet)*
- Decreased amounts of red blood cells (anemia)*
- Decrease in the total number of white blood cells (leukocytes)
- Decreased blood level of potassium
- Decreased blood level of magnesium
- Decreased blood level of phosphate
- Leg and/or arm pain
- Muscle spasms
- Dizziness (or sensation of lightheadedness, unsteadiness, or giddiness)
- Headache or head pain
- More protein leaking into the urine than usual, often a sign of kidney injury
- Shortness of breath
- Inflammation of mucus membranes
- Dry skin
- Skin rash with the presence of macules (flat discolored area) and papules (raised bump)
- Voice change
- Hair color change or loss

*If you have a drop in the red blood cell count, the cells that carry oxygen around the body, you may feel tired. If your red blood cell count drops very low you may need a blood transfusion.

If you have a decrease in the white blood cell count, the cells that fight infection, you may be more likely to get an infection, including a serious infection that spreads through the blood stream (sepsis). If this happens, you will have to come to the hospital to be treated with antibiotics. If your white blood cell is very low and you get a fever, you may have to come to the hospital to get treated with antibiotics.

If you have a low platelet count, particles in the blood that help with clotting, you may have easy bruising or bleeding. If the count is very low and there is bleeding, you might need platelet transfusions to help stop the bleeding.

<u>Rare:</u> 1% - <5%

- Bleeding in some organ(s) of the digestive tract and/or of the respiratory tract
- Decreased levels of albumin in the blood
- Fever
- Muscle weakness
- Pain in joint or muscle
- Blood clots in your arteries or veins of the limbs, lung, brain or heart
- Abnormal thickening of the skin
- Change in the feeling of touch (numbness, tingling, pain)

- Cough
- Confusion
- Acne
- Dehydration (when your body does not have as much water and fluid as it should)
- Difficulty swallowing
- Fungal infections including mouth, lung and other locations
- Hemorrhoids
- Increased blood level of fat-digesting enzyme (lipase, amylase) in the blood, which may indicate damage to pancreas
- Decreased blood level of calcium or sodium
- Heartburn
- Swelling of arms or legs
- Ulcers

Very Rare: < 1%

- Gastrointestinal fistula: abnormal hole between an organ of the digestive tract and another organ or tissue
- Gastrointestinal perforation: a tear or hole in the stomach or gut that can lead to serious complications and may require surgery to repair
- Problems with wound healing
- Destruction or bone tissue of jaw
- Abnormal changes in the brain that can cause a collection of symptoms including headache, confusion, seizures, and vision loss associated with MRI imaging findings (known as reversible posterior leukoencephalopathy syndrome or RPLS)
- Abnormal hole between some organ(s) of the respiratory tract and another organ
- Air in the chest between the lungs and chest wall
- Abscess in the body
- Cataract
- Chest pain/discomfort
- Heart attack or heart failure
- Rapid heartbeat
- Damage to muscles
- Decreased brain function or alertness
- Infection such as skin, wound, bone, or blood infection
- Pneumonia and inflammation of the lungs
- Inflammation of abdominal organs
- Temporary paralysis or blockage of the intestines
- Fainting
- Stroke / mini-stroke
- Seizure
- Prolonged QT interval: a heart rhythm disorder that can potentially cause fast, unorganized heartbeats.
- Air in the chest between the lungs and chest wall that can cause the lung to collapse (pneumothorax)*
- Cancer of the mouth or skin

- Inflammation and blockage of channels that carry bile from the liver
- Increased blood level of potassium
- Feelings of fear or anxiety
- Liver failure
- Gallstones
- Tear or inflammation in skin that lines the anus
- Uncoordinated movements
- Throat swelling

* While on this medication, please call your doctor immediately if you experience any symptoms of a collapsed lung, which may include chest pain, chest tightness, fast breathing, shallow breathing, shortness of breath, coughing or a fast heart rate.

Cabozantinib may have an effect on the growth plates of bones of children who are still growing. In a study, a small number of children who received cabozantinib developed growth plate thickening. However, all children with this thickening still experienced bone growth; it is unclear if treatment with cabozantinib has an effect on bone length.

Reproductive risks:
You should not become pregnant or father a baby while on this study because the drugs in this study can affect an unborn baby. Women should not breastfeed a baby while on this study. It is important you understand that you need to use two forms of birth control or not have sex while on this study and for 4 months after your last dose of Cabozantinib. If a female caregiver is pregnant or suspects she is pregnant, she should not handle Cabozantinib. Check with your study doctor about what kind of birth control methods to use and how long to use them. Some methods might not be approved for use in this study. A pregnancy test will be obtained in female patients before beginning treatment with Cabozantinib. Please ask about counseling and more information about preventing pregnancy.

If you are female and pregnant or lactating (breast-feeding), you cannot take part in this study. If it is possible that you could be pregnant, you will be given a pregnancy test before beginning the study to make sure that you are not pregnant. If you become pregnant or your partner becomes pregnant while on the study, you must notify the study doctor and your regular doctor immediately. If you are female or your female partner (if you are male) becomes pregnant within 30 days after stopping treatment, you must inform the study doctor.

Risks of blood drawing or placing an intravenous catheter for blood drawing:
Risks associated with drawing blood are slight, but some risks include: pain, excessive bleeding, fainting or feeling lightheaded, bruising, infection (a slight risk any time the skin is broken), and multiple punctures to locate veins.

There is a possible risk of loss of confidentiality, but standard measures are in place to protect your medical and research information.

For more information about risks and side effects, ask your study doctor.

Risks associated with genetic testing:
If you agree to allow blood and/or tumor tissue to be banked for future research (see "optional consent" below), the research studies on your samples may involve genetic analyses, and these data may be shared with other researchers. The risks related to genetic analyses can be to individuals or to groups. These harms include stigmatization and insurability. To reduce this risk, only coded samples will be stored and used for research. Information about this study will not be recorded in your medical record.

A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that this federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance, nor does it protect you against genetic discrimination by all employers.

WHAT BENEFITS MAY YOU EXPERIENCE FROM THIS STUDY?

You may not directly benefit from participation in this study. You may actually get worse. However, a possible benefit may be that the tumor stops growing or becomes smaller. It is hoped that the information gained from this study will benefit future subjects with neurofibromatosis.

WHAT OTHER OPTIONS ARE THERE?

Taking part in this clinical trial is voluntary. Instead of being in this clinical trial you have other options which may include the following:

- Getting treatment or care for your tumor without being in a study.
- Participate in another clinical trial.
- No therapy directed at stopping the growth or shrinking your plexiform neurofibroma
- Comfort care, also called palliative care. This type of care may help to reduce pain, tiredness, appetite problems and other problems caused by your plexiform neurofibroma. It does not treat the tumor directly, but instead tries to treat the symptoms.

Please discuss these options with your physicians.

WHO IS CONDUCTING THE RESEARCH STUDY?

This study is being conducted here at SITE as part of the Neurofibromatosis Consortium. This group is dedicated to the treatment of NF-related tumors and other problems resulting from NF. It is made up of 21 clinical centers in the United States and an Operations Center at The University of Alabama at Birmingham (UAB). The Neurofibromatosis Consortium is a clinical cooperative group (a network of hospitals working together) funded by the Department of Defense (DOD). Each clinical site has NF specialists, health care providers, nurses and other scientists who are dedicated to the development of new treatments and cures for the tumors of infants, children, adolescents and young adults with NF. We also conduct research on the causes, preventions and treatments of tumors, and the long-term effects of treatment on participants.

VOLUNTARY PARTICIPATION - CAN I STOP BEING IN THE RESEARCH STUDY AND WHAT ARE MY RIGHTS?

You have the right to choose not to sign this form. If you decide not to sign this form, you cannot participate in this clinical trial.

You can stop being in the clinical trial at any time. Tell the research doctor if you are thinking about stopping or decide to stop. He or she will tell you how to stop. Leaving the research study will not affect your medical care outside of the research study.

If you choose to not participate, or if you are not eligible to participate, or if you withdraw from this research study, this will not affect your present or future care and will not cause any penalty or loss of benefits to which you are otherwise entitled.

It is important to tell the research doctor if you are thinking about stopping so your research doctor can evaluate the risks from stopping the drug. In some cases, the abrupt stopping of a drug can have risks in itself. Another reason to tell your research doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful for you.

Your participation in this study may be terminated by the investigator and/or sponsor for any of the following reasons:

A. If you fail to follow the investigator's instructions including not completing the procedures required by the study and/or are unable or unwilling to come for the required doctor visits including any required follow-up visits.
B. If you experience a serious and unexpected side effect that may require evaluation.
C. If your disease gets worse while on this treatment.
D. If you tumor is not responding to Cabozantinib
E. If you experience side effects that are considered to outweigh benefits of your participation.
F. If the investigator feels it is in the best interest of your health and welfare.
G. If the sponsor no longer provides the drug.
H. If you begin another treatment for neurofibromatosis.

WHAT FINANCIAL COSTS ARE INVOLVED IN PARTICIPATING?

Cabozantinib is provided free of charge by Exelixis for up to 24 cycles (~24 months), after which time you may only be able to continue Cabozantinib at your own expense if alternative means of obtaining Cabozantinib are not available. Taking part in this study may lead to added costs to you or your insurance company. Please ask about any expected added costs or insurance problems. Other costs associated with your care, such as laboratory tests, x-rays, MRI scans, clinic visits, medications, and hospitalizations are all considered a part of standard care for someone with your illness; therefore, you will be responsible for these costs. It is also your responsibility to determine the extent of your health care coverage.

The research blood tests will be paid for by the study.

If you are in Medicare Advantage (Medicare managed care plan), you should contact someone at your plan before you start a clinical trial. They can provide more information about additional costs you could incur from participating in clinical trials.
It is also your responsibility to determine the extent of your health care coverage. If you have any questions about your insurance coverage, or the items that you might be required to pay for, please call financial services for information. The contact information for financial services is:

- SITE: ###-###-####

The National Cancer Institute provides an online resources to help people participating in cancer clinical trials understand which services their insurance company is required by law to pay. This can be found at the website below or can be provided by the study team:

http://www.cancer.gov/clinicaltrials/learning/insurance-coverage

WILL I BE PAID FOR PARTICIPATING IN THIS STUDY?

You will not be paid for participating in this study.

WHAT COMPENSATION IS AVAILABLE FOR RESEARCH-RELATED INJURIES?

In the event of physical injury resulting from your participation in this research, necessary medical treatment will be provided to you and billed as part of your medical expenses. Costs not covered by your health care insurer will be your responsibility. It is your responsibility to determine the extent of your health care coverage. There is no program in place for other monetary compensation for such injuries. However, you are not giving up any legal rights or benefits to which you are otherwise entitled.

SITE, Department of Defense, and Exelixis, Inc. have not provided for any payment if you are harmed as a result of taking part in this study. If such harm occurs, treatment will be provided. However, this treatment will not be provided free of charge. No other type of compensation will be provided by Exelixis.

WILL YOUR STUDY RECORDS BE KEPT CONFIDENTIAL?

Information obtained about you for this study will be kept confidential to the extent allowed by law. However, research information that identifies you may be shared with the SITE Institutional Review Board (IRB) and others who are responsible for ensuring compliance with laws and regulations related to research, including people on behalf of the Study Doctor, the Study Team, The University of Alabama at Birmingham, NF Clinical Trials Consortium, Department of Defense and its authorized agents, the U.S. Food and Drug Administration (FDA), governmental agencies in other countries where the study drug may be considered for approval, Safety Monitoring Board (DSMB), and the Office for Human Research Protections (OHRP).

Information relating to this study, including your name, medical record number, date of birth and social security number, may be shared with the billing offices of SITE and SITE Health System affiliated entities, along with SITE and its billing agents so that the costs for clinical services can be appropriately paid for by either the study account or by the patient/patient's insurance.

If any part of this study takes place at SITE, this consent document will be placed in your file at that facility. The document will become part of your medical record chart.

Your medical record will indicate that you are on a clinical trial and will provide the name and contact information for the principal investigator.

The results and other information from this study may be submitted to the FDA and governmental agencies in other countries where Cabozantinib may be considered for approval; however, you will be identified by initials and subject study number only. You will not be identified in any reports or publications resulting from this study.

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.

WHOM MAY YOU CALL WITH QUESTIONS ABOUT YOUR PARTICIPATION IN THIS STUDY?

If you have questions about your participation in this study, or if injury occurs, in addition to your doctor treating you for your neurofibromatosis, you may call Dr. PI. Dr. PI will be glad to answer any of your questions. Dr. PI's number is ###-###-### or ###-###-####. Dr. SITE PI may also be reached after hours by calling ###-###-####.

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the SITE Office of the IRB (OIRB) at ###-###-#### or toll free at ###-###-####. Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday. You may also call this number in the event the research staff cannot be reached or you wish to talk to someone else besides the research team.

WHAT ARE MY LEGAL RIGHTS?

You are not giving up any of your legal rights by signing this informed consent document.

OPTIONAL CONSENT:

Consent for Biological Specimen for Banking

We would like to collect additional blood and tumor tissue sample. The researchers want to bank these samples for future studies. Your samples will only be identified with your study number. The samples will be shipped to and stored at Children's Hospital of Philadelphia. If you agree to take part, we will collect an additional 10 milliliters of blood (2 teaspoons) before you start taking the study drug, and then after cycles 4, 12 and at the end of treatment. Tumor Tissue will be collected if you are undergoing a clinically indicated procedure and agree to provide your tumor tissue for banking.

The choice to consent to participate in the biological specimen for banking is optional and is up to you. You may still participate on this clinical trial if you choose to decline.

Please think about your choice. After reading, **put your initials** next to the "Yes" or "No" statement.

If the subject/parent does not speak English, the person obtaining consent should initial the subject's/parent's choice below.

_____ I will allow additional blood to be taken for research about plexiform neurofibromas, NF1 and other diseases.

_____ I will NOT allow additional blood to be taken for research about plexiform neurofibromas, NF1 and other diseases.

_____ I will allow tumor tissue to be taken for research about plexiform neurofibromas, NF1 and other diseases.

_____ I will NOT allow tumor tissue to be taken for research about plexiform neurofibromas, NF1 and other diseases.

Consent for Use of Leftover Blood for Future Research:

Donating your blood for future research is completely voluntary.

You will have blood collected as part of your participation in this clinical trial prior to starting the study drug, during Cycle 1, and at the end of Cycles 2 and 4 for analysis of cytokines and endothelial progenitor cells, or biomarkers of tumor burden and response to therapy. After the study has been completed, instead of discarding your leftover specimens, with your permission, we will save (bank) them for possible future research to learn more about cancer and other diseases. Any leftover blood samples will be coded and stored indefinitely at Riley Hospital for Children.

The research that may be done with your blood specimens are not designed specifically to help you. It might help people who have plexiform neurofibromas and other diseases in the future.

Reports about research done with your blood will not be given to you or your doctor. These reports will not be put in your health record. The research will not have an effect on your care. If the research is published or presented at scientific meetings, your name and other personal information will not be used.

Please think about your choice. After reading, **put your initials** next to the "Yes" or "No" statement. If you have any questions, please talk to your doctor or nurse, or call our research review board at SITE NUMBER.

The choice to let us keep any leftover blood for future research is optional and is up to you. No matter what you decide to do, it will not affect your care.

If the subject/parent does not speak English, the person obtaining consent should initial the subject's/parent's choice below.

_____ Yes, I will allow my leftover blood to be kept for use for future research about plexiform neurofibromas, NF1 and other diseases.

_____ No, I will NOT allow my leftover blood to be kept for use for future research about plexiform neurofibromas, NF1 and other diseases.

Things to Think About

If you decide now that either your additional blood, leftover blood and/or tumor sample can be collected for research, you can change your mind at any time. Just contact the study doctor, SITE PI, at the INSTITUTION, INSTITUTION ADDRESS, SITE PI's EMAIL and let us know that you do not want us to use your blood.

Then any samples that remain will no longer be used for research. We will destroy any remaining identifiable specimens and information if they are no longer needed for your care. However, if any research has already been done using portions of your specimens, the data will be kept and analyzed as part of those research studies.

Your blood/ tumor samples will be used only for research and will not be sold. The research done with your blood/tumor specimen may help to develop new products in the future. You will not receive any payment or financial benefit from any products, tests, or discoveries derived from these samples.

DOCUMENT OF CONSENT:

PARTICIPATION IN RESEARCH IS VOLUNTARY.

You have the right to decline to participate or to withdraw at any point in this study without penalty or loss of benefits to which you are otherwise entitled. You are not waiving any of your legal rights by signing this consent form.

My signature below indicates that I agree to participate in this study. I am aware that I will receive a copy of this signed agreement:

- I have had enough time to read the consent or have the consent form read to me and think about participating in this study;
- I am willing to participate in this study;
- I have been told that my participation is voluntary and I can withdraw at any time

SIGNATURES

Your signature below indicates you agree to participate in this study. You will receive a copy of this signed consent form.

_____
Name of Participant

_____
Signature of Participant Date

_____
Signature of Parent or Guardian Date
For Participants less than 18 Years of Age

_____
Signature of Person Obtaining Consent Date

_____
Signature of Witness Date

Release of Medical Information

SITE Information

Permission is hereby given:

_____

Name

_____

Address

_____

City State Zip

To release to the SITE, any and all medical information contained in the record of:

_____

Name of Patient

_____

Address

_____

City State Zip

_____

Date

Signed: _____

Patient

Signed: _____

Witness

_____

Address

_____

City State Zip