15.0 SAMPLE INFORMED CONSENT

NANT 2014-01 A Phase I Study of SF1126 in Patients with Relapsed and Refractory Neuroblastoma.

The word "you" used throughout this document refers to you or your child.

WHAT IS THIS STUDY ABOUT?

This study is a clinical trial, a type of research study. Clinical trials include only patients who choose to take part. Please take your time to make your decision about participating. You may discuss your decision with your friends, family, and health care team. If you have any questions, you may ask your study doctor.

You are being asked to participate in this study because you have been diagnosed with neuroblastoma. Your cancer has either grown back (relapsed) or has never gone away (persistent or resistant tumor) after standard treatment. Standard treatment may have included chemotherapy, surgery, radiation therapy and/or high-dose chemotherapy with a stem cell transplant.

WHY IS THIS STUDY BEING DONE?

The purposes of this study are:

- To find the highest doses of the drug SF1126 that can be given to children with refractory or relapsed neuroblastoma without causing severe side effects.
- To learn about the side effects of the drug SF1126 when given to young people.
- To determine if your tumor gets smaller after treatment with SF1126.
- To measure the levels of SF1126 in the blood in young people.
- To look at changes in the amount of protein products found in blood cells after treatment with SF1126.
- To look at whether certain gene changes in your neuroblastoma makes it more or less likely that your tumor responds to SF1126.
- To describe the amount of neuroblastoma tumor found in the blood and bone marrow by testing samples with a new test (called TLDA).

The research is being done because:

Currently there is no known effective treatment for your type of cancer.

This study involves the use of an experimental drug called SF1126. In laboratory testing, SF1126 blocks the function of proteins that are important in the growth of cancer cells and seems to affect Mycn, a protein important in neuroblastoma growth. SF1126 is considered experimental because it has not been proven to work in a situation like yours. SF1126 has not been approved by the United States Food and Drug Administration (FDA). SF1126 has been used in only a small number of adults so there is a lot we do not know about it yet. SF1126 has not previously been used in children. This study is called a phase I

study because the goal is to find the highest dose of SF1126 that we can give safely. Once we have found out the highest dose of SF1126 that can be given safely, we will treat more neuroblastoma patients with this dose of SF1126 who are known to have changes of certain proteins called Myc and Mycn.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Between 4 and 28 people will take part in this study.

WHAT WILL HAPPEN TO ME IF I TAKE PART IN THIS STUDY?

Medical Tests Before You Begin the Study

You will need to have the following exams, tests or procedures to find out if you can be in the main part of 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. Some of these tests can only be done on an empty stomach, so you will need to fast (not eat anything and not drink anything other than water) for 8 hours before certain tests. These tests will also be done at various times throughout the study and at the end of the study. The purpose of these tests is to see how well the treatment works and to measure the status of your neuroblastoma. If you have had some of them recently, they may not need to be repeated. This will be up to your study doctor.

Physical exam	Bone marrow tests[#]
Blood tests	Various scans*
Pregnancy test**	Echocardiogram/MUGA and EKG to check the heart function
Urine test	

[#] Bone marrow tests are done by inserting a needle into the hip bone to remove the marrow which is inside the bone.

* Various scans that are done for diagnosis and checking the response of the tumor to treatment. These may include CT and /or MRI scans and MIBG or PET scans. We will recommend scans specific for your case and we will answer your questions about these scans**.**

[**] If you are a female at least 10 years old or who could have children, you must have a pregnancy test done by the doctor the week prior to starting treatment and then before each cycle of treatment. If there is ANY chance that you can get pregnant, you must either agree to practice abstinence from heterosexual intercourse or begin two effective methods of birth control.

You will also be expected to join a companion biology study to collect blood, bone marrow and tumor tissue (if available) and reports from radiology scans from patients with neuroblastoma. Your study doctor will talk with you in detail about this study and have you sign a separate consent form.

During the Study

If the exams, tests and procedures show that you can be in the study, and you choose to take part, then you will need the following tests and procedures during the study. Many are part of regular cancer care. Some of these tests can only be done on an empty stomach, so you will need to fast (not eat anything and not drink anything other than water) for 8 hours before certain tests. This will happen once per week in the first month of treatment and then just once per month during the rest of the treatment.

Physical exam	Bone marrow tests[#]
Blood tests	Various scans*
Urine tests	EKG in first course only

[#] Bone marrow tests are done by inserting a needle into the hip bone to remove the marrow which is inside the bone.

* Various scans that are done for diagnosis and checking the response of the tumor to treatment. These may include CT and /or MRI scans and MIBG or PET scans. We will recommend scans specific for your case and we will answer your questions about these scans**.**

Treatment Plan

Each course is 28 days long. You may receive up to 6 courses of therapy as long you are benefiting from treatment and continue to meet the criteria to continue safely on this study. A calendar for one course of therapy is shown here:

All Courses:		
Week	**Day 1**	**Day 4[#]**
1	SF1126	SF1126
2	SF1126	SF1126
3	SF1126	SF1126
4	SF1126	SF1126

To help with patient scheduling, SF1126 can be given on either day 4 or day 5 of the week after course 1/ week 1 is completed.

You will receive SF1126 into the bloodstream (either through your central line or through a small tube placed in a vein in your hand or arm) over 90 minutes on day 1 and day 4 each week without a break between treatment courses. This medicine can be given in the outpatient clinic.

For the first dose only:
You will continue to be monitored after the first dose of SF1126 finishes for at least an hour to make sure you have tolerated the treatment without any bad reactions. In addition, frequent sampling for SF1126 blood levels will be done with this first dose. If you have a central line, it is suggested that the first dose of SF1126 be given through a small tube placed in a vein in your hard or arm (called an "IV line") so the SF1126 blood levels can be drawn from your central line. All future doses of SF1126 can then be given through the central line if you have one.

When you join the study, you will be assigned a certain SF1126 dose. This study will test up to three SF1126 doses in groups of 3-6 patients. The starting SF1126 dose for the first group of patients is about 20% lower than what was given to adults who received SF1126 without bad side effects. If this is tolerated without serious side effects, then the SF1126 dose will be increased ("dose escalation") in groups of 3-6 patients until serious side effects are seen. At that point, investigators will have found the highest dose of SF1126 that can be given without bad side effects.

You can receive up to 6 courses of treatment (approximately 24 weeks or about 6 months) as long as you are not having bad side effects and as long as your tumor is not getting worse. Although other participating patients may receive a different dose of SF1126, your assigned dose of SF1126 will not change during your participation in this study unless you develop certain side effects that necessitate lowering your dose of SF1126.

When you have finished treatment with SF1126

After you stop treatment on this study, you will continue to have tests and scans done (listed below) to measure how much tumor is left. If test results show you have abnormal organ functions, tests are recommended by the study to be repeated monthly until test results are stable or normal. You doctor will tell you how often these tests and evaluations will be done.

Medical Tests after the Study:

Physical exam	Bone marrow tests[#]
Blood & urine tests	Various scans*

[#] Bone marrow tests are done by inserting a needle into the hip bone to remove the marrow which is inside the bone.

* Various scans that are done for diagnosis and checking the response of the tumor to treatment. These may include CT and /or MRI scans and MIBG or PET scans. We will recommend scans specific for your case and we will answer your questions about these scans**.**

A table detailing the tests and procedures required before, during and after the study has been attached to the end of this consent.

Additional Tests in this Study

The results of these tests would not be told to you or your doctor or become part of your medical record. These results would also not be used to make decisions about your care while enrolled on this study. Additional tests can be optional or required as part of study participation. For the optional tests, you can decide not to let the doctors do these tests and still be able to be treated as part of this clinical study. There are checkboxes on the next to last page of this consent form to mark whether you are willing to participate in these voluntary studies.

Determining blood levels of SF1126- These tests are required.

One of the goals of this study is to find out the amount of SF1126 in the blood during this treatment. Since this is one of the main goals of the study, all patients participating in this study are required to submit extra blood samples to perform this test (known as pharmacokinetics). A small amount of blood (1mL, less than ½ a teaspoon) will be drawn 9 separate times before, during and after treatment with the first dose of SF1126 on day 1 in Course 1. If you have a central line (such as a port or a Broviac), these samples can be drawn through that line as long as this dose of SF1126 is given by vein. Otherwise, if you prefer to have the drug given through your central line or you don't have a central line, you will need to have these blood samples drawn through a vein.

This amount of blood is considered safe to donate. Samples will be sent to a company in San Diego, CA known as MicroConstants, Inc. where the levels of SF1126 in the blood will be determined.

Other Research Tests in this Study

You will be asked if you want to participate in 2 optional research tests. **This part of the study is voluntary.**

Evaluating the change in the amount of Myc protein found in blood cells after treatment with SF1126

In the laboratory, SF1126 blocks the function of Myc protein which is important in neuroblastoma growth. One part of the research goal is to look for changes in the amount of Myc protein in blood cells before and after treatment with SF1126. A small amount of blood (1mL, less than ½ a teaspoon) will be drawn at 3 separate times from your central line or port during the first week of treatment. This amount of blood is considered safe to donate. The blood is sent to University of California at San Francisco in San Francisco, CA for testing.

Evaluating gene changes in neuroblastoma tumor tissue and whether these changes affect how the tumor will respond to treatment with SF1126

Researchers would like to look at tumor tissue to determine if there are certain gene changes present that might make your neuroblastoma more or less likely to respond to the drug SF1126. These tests would be done on tumor tissue remaining from diagnosis, or any previous surgery were tumor tissue was removed (removal of primary tumor or removal of tumor at a relapse) in the past. Children's Hospital Los Angeles and University of California at San Francisco will do these tests.

HOW LONG WILL I BE ON THIS STUDY?

You can receive up to 6 courses of treatment (approximately 24 weeks or about 6 months) as long as you are not having bad side effects and as long as your tumor is not getting worse. If your tumor is responding after 6 courses of treatment, there may be a chance to receive up to 6 additional courses depending on drug supply and other considerations. This will need to be discussed with the study chair.

After you stop treatment, you will continue to have tests and scans done to measure how much tumor is left. Your doctor will tell you how often these tests will be done. Researchers will continue to collect information about you for a lifetime. Information will be collected about whether you are still alive; whether your tumor has grown back and at what sites in the body; whether you have developed any side effects from the treatment; or whether you have developed any additional cancer. Your oncologist or family doctor will give the researchers this information at regular intervals.

CAN I STOP BEING IN THE STUDY?

Yes. If you are thinking about stopping your participation on this study, you should talk to your doctor before making a final decision so he/she can tell you how to do this safely.

The study doctor may also 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 study rules; or if the study is stopped.

WHAT ARE THE RISKS OF THE STUDY?

This is a Phase I study. A Phase I study looks at how common and serious side effects can be for each patient at a specific dose of a drug. In a Phase I study, some patients may have very serious side effects and could die as a result of these side effects. You may be one of those patients who have serious side effects as a result of participating in this Phase I study.

In this study, researchers will be looking at side effects seen in patients taking different doses of SF1126. Since subjects will be assigned to different dose levels of SF1126, some subjects may receive doses that are too small to be effective while others may receive higher doses that may cause increased side effects.

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. Other drugs may be given to make side effects less serious and more comfortable (such as for nausea, headache or reaction to SF1126). Many side effects go away soon after you stop taking the study medications but it is always possible that side effects can be serious, long lasting or may never go away. There is also a risk of death. Patients are watched carefully and treatment will be stopped if bad side effects develop. There may also be risks we do not know about. You should talk to your doctor about any side effects that you have while taking part in this study.

While on the study, you are at risk for the side effects listed on the following page:

Possible Risks of SF1126

Likely (happens to 21-100 children out every 100 children)	Less Likely (happens to 5-20 children out every 100 children)	Rare but Serious (happens to < 5 children out every 100 children)
• Nausea • Vomiting • Fatigue or tiredness • Diarrhea • Fever	• Chills • Anorexia or loss of appetite • Anemia or low levels of red blood cells making you feel tired or weak • Pruritis or itching • Headache	• Edema • Elevation in the blood of certain enzymes found in the liver which may indicate liver irritation or damage • Weakness • Hypoglycemia or low blood sugar making you feel shaky or dizzy, hungry, moody or a headache • Urticaria or hives-red itchy bumpy rash or infusion related / allergic reaction that may cause breathing difficulty, dizziness and low blood pressure • Hypokalemia – low levels of potassium in the blood leading to muscle cramps weakness and tiredness. Low levels of potassium can also cause abnormal heart rhythms.

Other medicines that block the same proteins as SF1126 have shown other side effects not listed in the above table. These include high blood sugar, high blood fats, rash, and mouth sores. It is possible that these same side effects will be seen after more people have been treated with SF1126 or it is possible that they will not be seen.

Possible risks to unborn child

Patients who agree to participate in this study should not become pregnant while on this study. It is unknown if SF1126 could be hazardous to an unborn child. Patients and their sexual partners should avoid sex and / or use an effective method(s) of contraception that is medically appropriate based on your personal doctor's recommendation at that time. If you or your partner becomes pregnant while you are participating in this study, please notify your study doctor immediately. For more information about risks and side effects, ask your study doctor.

Possible long term side effects of this treatment
Side effects in adults treated with SF1126 have occurred while patients have been receiving the drug or shortly after finishing the drug. It is not known if some side effects may be seen only after a long time after finishing treatment with SF1126.

Possible risks from having blood drawn
The risks from having your blood taken are minimal, but can include an infection or a blood clot. Experienced doctors or nurses will perform these blood draws to minimize this risk.

Other risks
It is likely that your study doctor will recommend that the first dose of SF1126 be given through a small tube placed in a vein in your hard or arm (called an "IV line"). Having an IV line placed may result in pain, infection, bleeding, or a small blood clot at that site. You will also need to fast (not eat anything and not drink anything other than water) for 8 hours before certain tests. This will happen once per week in the first month of treatment and then just once per month during the rest of the treatment. You may feel lightheaded, jittery, irritable, or hungry while you are fasting.

Unknown risks
The treatment may have side effects that no one knows about yet. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

There may or may not be direct medical benefit to you. The information learned from this study may or may not benefit other children or young people with solid cancers in the future.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT TAKE PART IN THIS STUDY?

Yes there are other options for treatment. Instead of being in this study, you have these options:

- Treatment with other chemotherapy medicines
- Treatment with other experimental agents that may be available.
- No neuroblastoma therapy at this time, with care to help you feel more comfortable.

Please talk about these options with your doctor.

WILL MY MEDICAL INFORMATION BE KEPT PRIVATE?

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 given out 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.

Organizations that may look at and/or copy your medical records for research, quality assurance and data analysis include:

- New Approaches to Neuroblastoma Therapy (NANT) Consortium at Children's Hospital Los Angeles in Los Angeles, CA. The NANT Consortium identifies you by a number.
- Independent auditor evaluating quality assurance for the NANT Consortium.
- The National Cancer Institute (NCI) and other governmental agencies, like the Food and Drug Administration (FDA) or Health Canada, involved in keeping research safe for people.
- Pharmaceutical company which makes SF1126.

NANT has received a Certificate of Confidentiality from the federal government, which will help us protect the privacy of our research subjects. Information about the certificate is included at the end of this consent.

Because this study involves the treatment of a medical condition, a copy of this consent form will be placed in your medical record. This will allow the doctors that are caring for you to obtain information about what medications or procedures you are receiving in the study and treat you appropriately.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

Taking part in this study may lead to added costs to your insurance company. Your health insurance company will be billed for many expenses associated with the costs of this study. These expenses include medications, treatments, hospital charges, and doctors' fees related to your participation in this study.

SF1126 is being provided free of charge for use in this study, but the costs associated with administering the drug is normally covered by your insurance company. The cost of doing a heart test called an EKG after the first dose of SF1126 is being done solely as part of research and will be paid for by the study.

The special research blood and tissue studies will be done at no cost to you. However, you or your health plan may need to pay for the costs of the supplies and personnel who draw the blood from you for these tests.

You may have to pay for other things during this study, such as but not limited to, your time, the cost of food you buy while you are being treated at the hospital, car fare, travel to and from the hospital for treatment, parking, and baby sitter fees.

Taking part in this study may lead to added costs that may not be covered by your insurance company. Please ask about any expected added costs or insurance problems.

You will not be paid for taking part in this study.

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 HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?

It is important that you tell your study doctor, _____ *[investigator's name(s)],* if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call him/her at _____ *[telephone number].*

You will get medical treatment if you are injured as a result of taking part in this study. You and/or your health plan will be charged for this treatment. The study will not pay for medical treatment.

WHAT ARE MY RIGHTS AS A STUDY PARTICIPANT?

Taking part in this study is your choice. You may choose not to take part or not take part in the study. If you decide to take part in this study, you may remove yourself from the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. If you remove yourself from the study, we will still take care of you. We will explain what stopping the treatment may do and we will offer other treatments if they are available.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

In case of injury resulting from this study, you do not lose any of you legal rights to seek payment by signing this form.

A Data Safety and Monitoring Board, an independent group of experts, will be reviewing data from this research throughout the study. We will tell you about new information from this Board or other studies that may affect your health or willingness to stay in the study.

WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?

You can talk to your study doctor about any questions or concerns you have about this study. Contact your study doctor _____ *[name(s)]* at _____ *[telephone number].*

For questions about your rights while taking part in this study, call the _____ *[name of center]* Institutional Review Board (a group of people who review the research to protect your rights) at _____ *(telephone number).*
WHERE CAN I GET MORE INFORMATION?

You may call the NCI's **Cancer Information Service** at

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

You may visit the NCI Web sites 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/

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

You will get a copy of this consent form. If you want more information about this study, ask your study doctor.

CONSENT FOR EXTRA STUDIES FOR RESEARCH

The following tests are optional for all patients in the study. You may still participate in the study even if you do not agree to these tests.

Evaluating the change in the amount of Myc protein found in blood cells after treatment with SF1126

Initial next to YES if you agree to let researchers take blood to study changes in the amount of Myc protein in blood cells before and after treatment with SF 1126. This is 3 extra blood samples and it can be taken from a central line (such as port or Broviac). The results of these tests will be confidential and not made available to you or your treating physician.

Initial next to NO, if you do not want researchers to take extra blood samples to study changes in the amount of Myc protein in blood cells.

_____Yes _____No

Evaluating gene changes in neuroblastoma tumor tissue and whether these changes affect how the tumor will respond to treatment with SF1126

Initial next to YES, if you agree to let researchers send left over tumor to determine if there are certain gene changes present that might make your neuroblastoma more or less likely to respond to the drug SF1126. The results of these tests will be confidential and not made available to you or your treating physician.

Initial next to NO if you do not want researchers to obtain left over tumor to look for certain gene changes that might make your neuroblastoma more or less likely to respond to the drug SF1126.

_____Yes _____No

STATEMENT OF CONSENT

I have already read the information in this informed consent document. I have read all the attachments that were included with this informed consent document. I have asked all of my questions and I have gotten answers. I agree to enroll myself (my child) in this study.

_____
Patient Name

_____ _____/_____/_____
Signature of Parent or Guardian Date

_____ _____/_____/_____
Signature of Parent or Guardian Date

_____ _____/_____/_____
Signature of Patient (If > 7 years old) Date

_____ _____/_____/_____
Signature of Physician or Responsible Investigator Date

_____ ____/_____/_____
Signature of Witness Date

_____ ____/_____/_____
Signature of Translator Date

Consent Addendum I: Tests that will be done on this study.

Observation	Before Entry	Cycle 1	Cycle 2	Subsequent Cycles	End of Therapy
Physical exam	X	Weekly	At start of cycle	At start of each cycle	X
Blood tests	X	Weekly for other tests and twice weekly for blood counts	Weekly for blood counts and twice during cycle for all other blood tests	Start of each cycle	X
Blood test looking at average blood sugar levels (called Hemoglobin A1c)			At start of cycle	Start of cycles 4 & 6	
Heart tests (EKG & Echocardiogram	X	EKG after day 1 treatment is finished			
Pregnancy test (All females >= 10 years old)	X		At start of cycle	At start of each cycle	
Blood for SF1126 drug level tests (Required)		9 times on Day 1			
Blood for Myc protein levels (Optional)		Day 1: 2 times Day 4: 1 time			
Sampling of left over tumor tissue (Optional)	Left over tumor tissue can be sent at any time during the study				
	Disease Evaluation Tests[#]				
Bone marrow aspirate and biopsy	X		Done after day 1 of week 4	Done after day 1 of week 4 of cycle 4,and 6	X
CT/MRI scans and/or MIBG/PET scans	X		Done after day 1 of week 4	Done after day 1 of week 4 of cycle 4,and 6	X
Urine catecholamines	X		Done after day 1 of week 4	Done after day 1 of week 4 of cycle 4,and 6	X

Patients enrolled in the companion biology study may have additional samples of blood and bone marrow collected at study entry and with each disease evaluation time point. Please look at the biology study N04-05 for more information.

Consent Addendum 2

Certificate of Confidentiality Information

NANT has received a Certificate of Confidentiality from the federal government, which will help us protect the privacy of our research subjects. The Certificate protects against the involuntary release of information about subjects collected during the course of our covered studies. The researchers involved in the studies cannot be forced to disclose the identity or any information collected in the study in any legal proceedings at the federal, state, or local level, regardless of whether they are criminal, administrative, or legislative proceedings. However, the subject or the researcher may choose to voluntarily disclose the protected information under certain circumstances. For example, if the subject or his/her guardian requests the release of information in writing, the Certificate does not protect against that voluntary disclosure. Furthermore, federal agencies may review our records under limited circumstances, such as a DHHS request for information for an audit or program evaluation or an FDA request under the Food, Drug and Cosmetics Act. The Certificate of Confidentiality will not protect against the required reporting by hospital staff of information on suspected child abuse, reportable communicable diseases, and/or possible threat of harm to self or others.

16.0 SAMPLE ASSENT FORM

NANT 2014-01: A Phase I Study of SF1126 in Patients with Relapsed and Refractory Neuroblastoma.

A New Approaches to Neuroblastoma Therapy (NANT) treatment protocol

INVESTIGATOR [Insert Name of Investigator]
[Insert Name of Institution]

[Insert Address (include City, State and Zip Code)]
[Insert Telephone/Fax Numbers]
[Insert Email]

1. Dr. _____is doing a research study about using other medicines to get rid of Neuroblastoma.

2. We have been talking to you about your **Neuroblastoma** that has either grown back or has never gone away after treatment. We are asking you to take part in a research study because doctors want to learn more about treating neuroblastoma using a medicine called **SF1126** to see what effects (both good and bad) this medicine has on patients and their cancer. SF1126 is a medicine that is given into the bloodstream (either through your central line or through a small tube placed in a vein in your hand or arm). The doctors think that giving this drug may help get rid of neuroblastoma cancer cells.

- If you agree to be in this study this is what will happen:

  The medicine will be given 2 days a week in cycles that are 4 weeks long. Your doctor will explain to you and your parents the schedule for each cycle. You can continue to be treated with this drug for 6 months (6 cycles) unless you have bad side effects or your tumor gets worse. This medicine works differently than some of the other medicines you have received. It helps your body to kill the cancer cells.

SF1126:

You will take SF1126 by IV twice a week, each week of the cycle. You will be in the clinic on those days.

Coming to See the Doctors:
During and after you have finished the treatment, you will have appointments with the doctors who are taking care of you. This is called "**Follow-Up**". This is to see how well the treatment has worked so far. The doctors will want to do some special tests to find this information out. They will include;

- Blood tests (we will do this twice each week to start with, and then less often). You will need to fast (not eat anything and not drink anything other than water) for 8 hours before certain blood tests. This will happen once per week in the first month of treatment and then just once per month during the rest of treatment. MRI, CT, and MIBG Scans (special pictures of your tumor)
- Bone marrow test (to look for tumor in your bone marrow)
- Feel your belly, look into your eyes and ears, and listen to your heart and lungs.
- Ask you and your parents a lot of questions about how you are feeling, how you are doing in school, and any problems you might be having.
- You will come to visit your doctor every week or so to start with, then less often if everything is going well.
- To measure the amount of medicine in your blood, we will draw 9 blood samples (about 2 teaspoons total) on the very first day of your treatment. We can use your central line to draw these blood samples. If you don't have a central line, you will need to have a needle poke or a small plastic tube placed in a vein of your hand or arm to collect these samples.

When you are in a research study, sometimes good things and bad things can happen

- Sometimes things happen to kids in research studies that may make them feel bad. These are called "risks'. Some of the risks of this study are:
  - You may feel lightheaded, jittery, irritable or hungry while you are fasting before certain tests.
  - You may feel sick to your stomach and you may throw up.
  - You may feel tired.
  - You may have a bad appetite.
  - You may get diarrhea.
  - You might get a fever or chills or a headache.
  - You may feel tired and weak and need a blood transfusion.
  - You may get itchy or have a bumpy rash on your skin or have a hard time breathing.
  - The treatments may not work, and your tumor may grow, or it might come back again after the treatment has finished. If this happens we will try other ways to stop the tumor from growing.
  - You could get a different kind of cancer, this doesn't happen often, but can happen years later.
  - It is possible that you could die from the treatment or cancer.

Not all of these things may happen to you. None of these things may happen. Or things may happen that the doctors don't know about yet.

- Will we do everything possible to keep your information private.

- Things that happen to children in research studies that are good are called "benefits." Some of the good things for this research study could be: this treatment might make your neuroblastoma tumor stay the same size or get smaller for some time. We hope to learn more about this new treatment which could help other children with neuroblastoma.

- Please talk this over with your parents before you decide whether or not to be in this study. We will also ask your parents to give their permission for you to take part in this study. But even if your parents say "yes" you can still decide not to do this.

- Being in this study is up to you. You do not have to be in this study if you don't want to. You may stop being in this study at any time.

- You can ask any questions that you have about the study. If you have a question later that you didn't think of now, you can call me or ask me next time. Study doctor's phone number: _____.

- Special study tests :

You will need to have some special blood tests done to measure the amount of medicine in your blood. You may need to have a needle poke or a small plastic tube placed in a vein of your hand or arm for these samples. If you have a central line, your doctor will be able to tell you if that can be used to draw these bloods.

You may also have the option of giving extra blood. There are 3 extra blood samples which you don't need to agree to provide to be on this study. If you do not have a central line, then you would need to have a needle poke or a small plastic tube placed in a vein of your hand or arm for the blood sample.

_____ YES: It is okay to take extra blood samples even if a needle poke is required.

_____ YES: It is okay to take extra blood samples only if they can be taken from my central line.

_____ NO: It is not okay to take extra blood samples.

- Signing your name at the bottom means that you agree to be in this study. You and your parents will be given a copy of this form after you have signed it.

Name of Subject: _____

_____ _____
Signature of Subject: **Date**

_____ _____
Signature of Investigator **Date**

_____ _____
Signature of Person Conducting Discussion **Date**