Official Study Title: A Phase II Trial of Surgery and Fractionated Re-Irradiation for Recurrent Ependymoma

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Informed Consent for Research

A Phase II Trial of Surgery and Fractionated Re-irradiation for Recurrent Ependymoma

NOTE: *When we say "you" throughout this document, we mean "you or your child."*

1. What are my rights in this study?

You are being asked to volunteer for the research study described below. This consent form gives you information about the study, which will be discussed with you. Please take your time making a decision and feel free to discuss it with your friends and family. Before agreeing to take part in this research study, it is important that you read this consent form that describes the study. After you understand the study, and if you agree to take part, you will be asked to sign this consent form. You will be given a copy to keep.

Before you learn about the study, it is important that you know the following:

- Whether or not you take part in this study is entirely up to you.
- If you decide not to be in the study, or to leave the study at any time, you may still be able to get routine medical care at St. Jude.
- This study is being sponsored by St. Jude Children's Research Hospital.
- The principal investigator (researcher) in charge of this study is Dr. Thomas Merchant, who can be reached at (901) 595-3300, if you have any questions or concerns.

2. Why is this study being done?

You are being invited to take part in this research study because you have a brain tumor called ependymoma that has come back after initial treatment. Your initial treatment involved surgery and radiation therapy. Children and young adults with ependymoma that has come back have few treatment options. Surgery and chemotherapy alone are not likely to cure ependymoma that has come back.

One way to treat ependymoma that has come back is with a second course of radiation therapy. This is called re-irradiation. Most children and young people will need more surgery before re-irradiation to confirm that the tumor that has come back is ependymoma. This surgery may also help relieve symptoms and reduce the amount of tumor that radiation therapy is to treat.

The primary purpose of this study is to see if surgery and re-irradiation will help treat ependymoma that has come back after initial treatment. The combined doses of the first and second courses of radiation are higher than what is usual standard of care. We will study the effects and side effects of surgery and re-irradiation. We will evaluate and study tumor tissue and blood to learn more about the tumor and how it does or does not respond to treatments and we will use magnetic resonance imaging (MRI) and positron emission tomography (PET) scans to see if they can predict tumor response and tumor recurrence.

3. What will be done in this study?

Tests and procedures will be done while you are taking part in this study. Some of the tests and procedures are done for research purposes only and some are done as routine standard of care for the treatment of ependymoma.

The standard of care tests and procedures that are done at baseline and before you receive re-irradiation include:

Standard of Care Tests and Procedures	Description
MRI of brain: Research only portion performed at the same time of the SOC testing	This exam may be clinically indicated and considered standard of care (SOC), but special sequences will be performed that are not SOC. These will be done for research purposes only. The research portion of the test will add approximately 14-22 minutes of additional time to each MRI scan performed. This scan may or may not require sedation.
Physical Examination	Including height, weight and body mass index
Blood Tests: CBC, Chemistries, Endocrine	To look at the levels and functions of white cells, red cells, platelets, kidney, liver, pancreas, and endocrine glands which secretes different types of hormones that regulate metabolism, growth and development, tissue function, sexual function, reproduction, sleep and mood, and other things
Pregnancy Test	All females of childbearing age
Bone Tests: QCT (quantitative computed topography) and DEXA scans, x-ray	You must be at least 3 years of age to have these bone tests. These scans will look at the growth and development of your bones. An x-ray of your left hand and wrist will be done to compare your bone growth with your numerical age. A QCT is a special CT scan that measures the volume and density of bones. A DEXA is a special x-ray that is used to measure bone density. This information will be used to estimate the strength of your bones and help us determine how healthy your bones are.
Audiometry (hearing test)	To look at ears and hearing
Ophthalmology (eye test)	To look at eyes and vision
Lumbar Puncture (LP)	To look at cerebral spinal fluid (CSF) for cancer cells. This test tells us if tumor cells have spread beyond the brain into the fluid surrounding the brain and spinal cord. If you need surgery, the LP may be done at that time.

Neurological Test	To look at symptoms such as seizures, headache, tremors and to assess nerve and sensory function, coordination, fine motor skills, tone, strength, and gait
Pathology Test	Review of tumor samples to confirm diagnosis
Neuropsychological and Neurocognitive Test	To evaluate and measure things such as intelligence, reasoning, attention, problem solving, planning, organizing, memory, behavior, language, and motor function. This testing involves questionnaires, games, completing specific tasks, as well as computerized testing techniques.
CT Scans and MRI (magnetic resonance imaging) Scans	To help the doctors plan your re-irradiation treatment and to evaluate if the cancer has spread to the spine

Research only imaging scans:
***You will only be able to participate in these scans if you do not require sedation.**

Research Only Imaging	Description	Approximate Time For Tests and Procedures
*FDG (Fluorodeoxyglucose) and PET (Positron emission tomography) imaging	This imaging will evaluate the cancer. This scan uses a special radioactive material to determine the level of activity in both the tumor and normal tissue. Before a PET scan, you cannot eat or drink for at least 4 hours. A small amount of radioactive sugar called F-FDG will be injected into your vein.	10 minutes
*C-methionine (MET) Positron emission tomography (PET) imaging	This imaging will evaluate the cancer. This scan uses a special radioactive isotope or chemical element called carbon 11 or C-11 to see how much methionine your brain tumor absorbs. The C-11 will be injected into your vein and then a PET scan is done. This test has been shown to be useful in finding new tumors not seen on MRI and when using other types of PET scans. Since MET is not commercially available, it is considered investigational and is produced at St. Jude under an IND (Investigational New Drug) granted by the FDA (Food and Drug Administration).	40 minutes
*PET scans	To check the path of the proton beam with the purpose of verifying treatment delivery. At the doctor's decision, you may have several of	30 minutes

	these scans done during proton therapy. This scan will immediately follow proton therapy and will require that you lay in the PET scanner for about 20-30 minutes.	

Research only test and procedures not requiring sedation:

Research Only Tests and Procedures Not Requiring Sedation	Description	Approximate Time For Tests and Procedures
Skull X-ray	To confirm it is safe for you to have an MRI done. This X-ray may be done again in the future if your doctor thinks it is needed.	15 minutes
Provocative endocrine testing	To evaluate growth and stress hormones. These tests may not be done if you recently stopped steroid medication or you are taking growth hormone or adrenal insufficiency medication.	4 hours
Actigraphy	To measure rest and activity cycles. You will be asked to wear a device called an Actigraph for 5 days. It is worn on your non-dominant wrist and looks and feels like a wristwatch. The Actigraph measures movement and can tell us how active you are and how well you are sleeping. You will also be given a log to record your time to bed and time awakening while wearing the Actigraph. The Actigraph should be removed for bathing, showering and any imaging test (MRI, X-ray, CT).	5 days
Quality of Life questionnaires	To measure how your daily life and satisfaction is impacted by the cancer and treatments. The quality of life (QOL) of children and adolescents with brain tumors can be affected by their diagnosis and the respective therapy. You will complete a series of age-appropriate questionnaires related to your sleep habits, fatigue and quality of life.	20 minutes
Biological studies of tumor tissue	To learn more about ependymoma and how to improve treatment.	Collected at the time of surgery
Blood samples for genomics	This is the study of DNA or genes. Genes are a set of instructions that determine what we are like, and make each of us what we are. You will be asked to sign another consent called "TBANK", giving your permission to	5 minutes

	store and use your blood and tumor samples and health information for research. The research that may be done is unknown at this time. Storing samples for future unspecified research is called "banking".	
Blood samples for cytokines	Cytokines control the amount and level of inflammatory responses in the body. Studying cytokine levels in the blood may help predict some of the side effects of the radiation. This test will only be collected if you enrolled on the study before August 30, 2019	5 minutes
Physical Function Laboratory	Physical function laboratory testing to evaluate physical fitness, strength, balance, flexibility and motor performance. These tests include: cardiopulmonary fitness to evaluate your heart and lung function and electrocardiogram (ECG) to evaluate your heart function.	3 hours

The following treatments may be administered during this study and are considered standard treatments depending on the plan you and your doctor decide is best for you:

- Chemotherapy is not a planned part of this protocol. However, chemotherapy prior to or after radiation therapy will be allowed. Chemotherapy will be administered according to clinical standards or according to another research study.
- Surgery to remove as much tumor as possible. If you have already undergone surgery prior to joining the study, or if you have a very small amount of tumor, surgery may not be necessary.

All study participants will receive the following radiation therapy treatment:

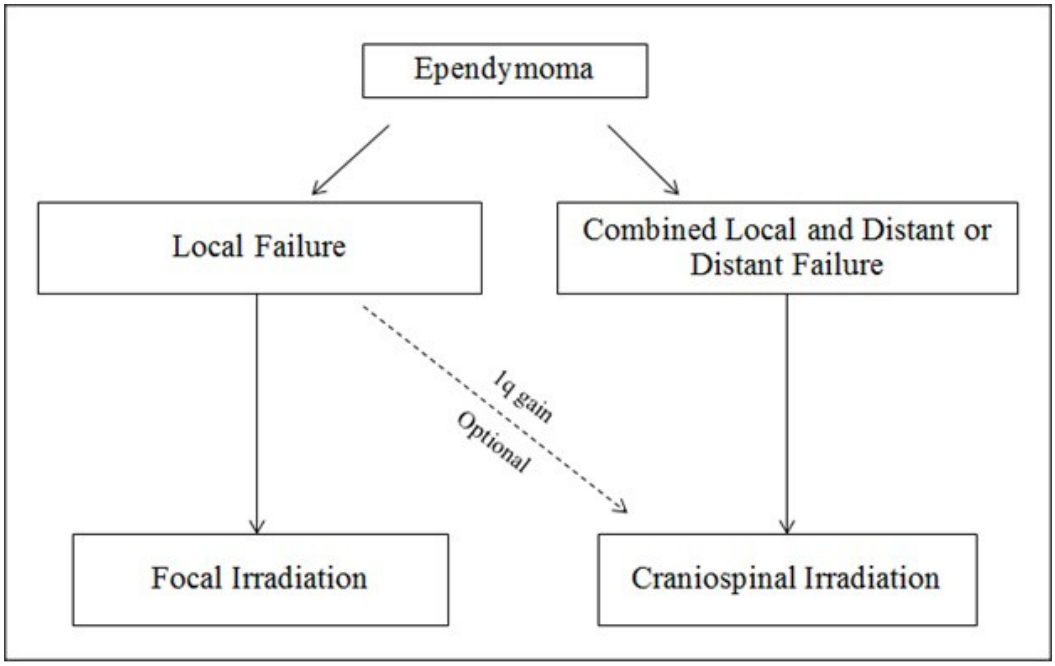
- Radiation therapy will be started once the final treatment plan has been developed and approved. There is no limit on the time from study enrollment to when re-irradiation begins. However, the goal is to begin radiation therapy within 12 weeks of surgery. Radiation will be given 5 days a week for about 6-7 weeks with each treatment lasting about 20 minutes to 1 hour. The total number of radiation therapy days will depend on the amount of tumor remaining after surgery. Radiation therapy using photons (X-rays) or protons (charged particle) will be given on this study. The type of radiation therapy will be determined by the radiation doctor. The radiation doctor will use methods that focus most of the radiation energy on the tumor, with less energy directed at the areas surrounding the tumor. The goal is to limit the side effects of radiation therapy. Some patients may require craniospinal irradiation which is treatment of the brain and spine at the same time using radiation therapy.

  Different types of radiation are used to treat brain tumors in children. The most common types are photons (X-rays) and protons. The photon type of radiation

therapy is available in most hospitals. The proton type of radiation therapy is available only at a limited number of centers. Photon radiation passes through the patient after reaching the target. Proton radiation stops at the target. The researchers involved in this study think that both forms of radiation therapy are equal in terms of their ability to control the tumor. There are some differences between photons and protons in terms of the amount of radiation exposure of normal tissues. Whether one type of radiation therapy is better than another is not a question to be addressed by this study. Assessing differences in radiation type is made difficult by the fact that all patients will have been previously treated with radiation therapy (photons or protons).

The five categories in this study are outlined below:

- If the tumor came back in the original site only, you may have focal irradiation (treatment to tumor and its borders).
- If the tumor came back in a new site (has spread to another part of your body – distant failure), you will have craniospinal irradiation.
- If the tumor came back in the original site and a new site, you will have craniospinal irradiation.
- If the tumor came back in the original site and it shows the presence of 1q gain (information in Optional Research Treatment below), you will need to choose between focal irradiation and craniospinal irradiation. If you choose to select the optional treatment plan, craniospinal irradiation will be offered.
- If the tumor comes back in the original site only, you may have craniospinal irradiation if the doctor thinks it is the best treatment option.



If it is decided you are able to take part in this study, you will undergo the following tests and procedures to evaluate your disease and to monitor for safety. The standard of care tests and procedures that are done during radiation therapy include:

- Physical exam done weekly.
- Blood tests to evaluate blood cell counts and blood chemistries will be done at week 3.

Tests and procedures done during radiation therapy and for research purposes only include:

- Quality of life questionnaire done weekly.
- Blood tests to measure cytokines done every 3 weeks.
- PET scans may be done several times (maybe 3-5) during treatment.

Standard of care tests and procedures done after radiation therapy include:

- Physical Exam, conducted every 3 months through month 24, then every 6 months through month 60.
- Blood tests for CBC, blood chemistries and endocrine every 3 months through month 24, then every 6 months through month 60.
- Pregnancy test every 3 months through month 24, then every 6 months through month 60.
- Audiometry, ophthalmology, neurological exam every 12 months through month 60.
- MRI of the spine every 12 months through month 60, or more often if medically necessary.
- Provocative endocrine testing at month 12 and month 24. Neuropsychological and neurocognitive testing at month 36.
- MRI of the brain every 3 months through month 24, then every 6 months through month 60. Selected MRI sequences may be performed during the standard of care brain MRI.

Research tests and procedures done after radiation therapy include:

- FDG PET and MET PET every 12 months through month 36.
- Neuropsychological and neurocognitive testing every 12 months through month 60, except 36 month.
- Quality of life questionnaires every 3 months through month 24, then every 6 months through month 60.
- Actigraphy every 12 months through month 60.
- Cytokines every 12 months through month 60.
- Physical function testing to evaluate your overall physical abilities such as strength, flexibility, balance, coordination, and cardiac fitness, including cardiopulmonary fitness evaluations and electrocardiogram.

RERTEP Study Calendar

		Months after Radiation Treatment Start															
	0	**3**	**6**	**9**	**12**	**15**	**18**	**21**	**24**	**27****	**30**	**33****	**36**	**42**	**48**	**54**	**60**
MRI of Brain (standard and research)	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
MRI of Spine[1]	X				X				X				X		X		X
PET and MET PET Scans[7, 8]	X				X				X				X				
X-rays, QCT/DEXA Scan[3 5]	X																
Radiation Oncology Clinic	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Blood tests (Standard)	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Blood tests (Cytokines)[6, 8]	X				X				X				X		X		X
Blood tests (Endocrine)	X				X[2]				X[2]								
Blood tests (Genomics)	X																
Lumbar puncture[4]	X																
Endocrine Clinic[3]	X				X				X				X		X		X
Neurology Clinic[3]	X				X				X				X		X		X
Psychology tests	X				X				X				X		X		X
Eye tests[3]	X				X				X				X		X		X
Hearing tests[3]	X				X				X				X		X		X
Actigraphy (wrist watch)	X				X				X				X		X		X
QOL and Sleep/Fatigue Questionnaires	X	X	X	X	X	X	X	X	X		X		X	X	X	X	X
Physical Performance	X				X				X				X		X		X

[1]May be repeated more times for patients age 3-21 years and who has metastatic disease (the cancer has spread from the place where it first started to another place in the body)
[2]Endocrine blood tests may not be performed if you recently stopped steroid medication or you are taking growth hormone or adrenal insufficiency medication. Every attempt will be made to draw all blood tests at the same time.
[3]May be repeated more times if you are having medical problems or at your doctor's discretion.
[4]Lumbar puncture may be waived if deemed unsafe.
[5]Must be at least 3 years of age.
[6]For patients enrolled before August 30, 2019
[7]Must be done without sedation
[8]MET PET scans and cytokines will not be collected after July 1, 2020
[**]Optional follow-up visits at the discretion of the treating doctor

4. What are my other choices if I do not take part in this study?

You can choose not to take part in this study or you might choose one of these options:

- Getting treatment or care for your cancer without being in a research study. This might include only surgery, only radiation therapy, only chemotherapy or other combinations, agents or forms of therapy not planned for this study. Please feel free to discuss these options with your study doctor.
- Take part in another research study, if available.
- No further treatment and comfort care only. You could choose to have no further therapy. In such a case, you may continue to receive supportive medical care, such as narcotics for pain and transfusions for anemia, and other treatments to reduce your pain or other symptoms as much as possible. It is important that you talk with your doctor about the benefits and risks of the research treatment and other options, such as comfort care. Should you decide to accept no further treatment; the cancer will probably get worse.

The researcher in charge of the study can tell you about the disease and the benefits of other treatment options. Please feel free to ask the researcher about the disease and its outcomes.

5. How many people will take part in this study?

About 99 children and young people will take part in this study at St. Jude Children's Research Hospital.

6. How long will I be in the study?

You may be in the study for up to 5 years after starting radiation therapy.

7. What risks can I expect from taking part in this study?

Side effects may occur with all forms of radiation therapy. These depend on the age of the patient and the location and size of the tumor. Some side effects appear during treatment (short-term effects) and others appear months to years later (long-term effects). The chance of having side effects can be increased by other treatments including surgery or specific medications. There may be side effects that we do not know about yet. You will be watched carefully for any side effects. You should talk to your study doctor about any side effects that you have while taking part in the study. The possible side effect of radiation therapy administered a second time may be the same as standard radiation treatment. The list below includes possible side effects.

Short-term Side Effects:

- Skin changes such as irritation, dryness, redness or peeling of the skin
- Fatigue (tiredness)

- Pain due to radiation
- Nausea and vomiting
- Loss of appetite
- Hair loss
- Swelling of the brain and inflammation that may cause headaches or make existing neurological symptoms worse. This swelling is less common in patients who have had most of their tumor removed during surgery.
- In response to treatment, the tumor may enlarge, which can cause a variety of neurological symptoms including loss of vision, weakness, loss of coordination and severe pain. Measures may be required during and following treatment to manage tumor enlargement including brain surgery to remove part of the tumor.
- In the event that you require anesthesia during radiation therapy, the short term side effects of treatment listed above may be slightly worse.
- There is a risk of exposure to a small dose of ionizing radiation from the MET PET, PET and X-ray scans. MRI, CT, X-ray and nuclear medicine scans are common standard imaging tests used in the diagnosis and monitoring of many diseases. The most common discomfort is the length of time a person must lay still and flat while the scan is being done. Rarely, some people may have an allergic reaction to dyes injected for some of these tests. Uncommon allergic reactions may result in rash, difficulty breathing, low blood pressure or other complications. Please let your doctor or nurse know if you have previously had an allergic reaction.
- The fitness tests will require you to exert physical effort that may result in momentary discomfort associated with muscle tightness in the thigh, shin or hand, or temporary shortness of breath. In addition, the mask used during the exercise test could be uncomfortable for some people. If you feel uncomfortable, you can stop the test at any point. The tests will be administered and monitored by a certified clinical exercise specialist. A medical doctor from the research team is available during the assessment if you or the study team has concerns or issues with testing.
- The most common risks related to drawing blood from your arm are brief pain and possibly a bruise.
- A common side effect of a spinal tap is a headache that can be treated by lying flat for long periods of time, drinking fluids, and/or taking pain medicine.
- Some of the questions asked on the Quality of Life Questionnaires may be sensitive topics and you may experience some emotional distress.
- While wearing the actigraphy watch, you might experience slight discomfort.

Long-term Side Effects:
The occurrence and severity of long-term side effects from radiation therapy depend on age at the time of treatment, the area of the brain that requires treatment and complications that arise from the tumor or treatments before or after radiation therapy. Possible long-term side effects include:

- Decreased cognition. This includes negative effects on general intelligence,

learning difficulties, problems with memory, attention and behavior. This may lead to decreased performance in reading, spelling and math. The risk of cognitive effects cannot be predicted but we do know that young children, and those who have extensive surgery before radiation to the brain, will have the most problems.

- Hormone deficiencies and abnormalities in growth and development. Radiation to the brain may result in growth hormone, thyroid hormone, stress (adrenal) hormone and pubertal hormone deficiencies and obesity.
- Dental problems from radiation therapy are rare but may happen depending on the dose to the teeth and salivary glands.
- Depending on tumor location, there is a risk of hearing loss.
- Damage to part of the brain close to the tissue that is being treated with radiation (this damage is called necrosis).
- Damage to blood vessels that would result in stroke or stroke-like symptoms.
- With any type of radiation therapy there is always the rare risk that another tumor might form in tissue that is in the path of the radiation beam. This includes the growth of new tumors that have no chance of cure.
- Delayed wound healing in any region that has been irradiated.
- Death

Reproductive Risks: Female participants must not be pregnant or breastfeeding a baby when entering the study and must not get pregnant during the study. The radiation in this study can be harmful to an unborn baby. You must use effective birth control while on this study. The researcher can tell you about the best methods to use during this study. Some methods might not be approved for use in this study. If you think you have become pregnant during the study, you must notify the researcher immediately. If you become pregnant, you will be taken out of the study. Male participants who are able to father a child must use an effective form of birth control while on this study. Effective forms of birth control include oral contraceptives, condoms and abstinence. Birth control methods should be continued for 6 months after treatment to avoid pregnancy.

Sedation/Anesthesia Risks: Another risk could be related to possible side effects from anesthesia. If sedation is required to help you hold still during any procedure or scan, a member of the sedation team will explain the possible side effects and you will be asked to sign a separate consent form. We will try to perform any procedure or scan that requires sedation at the same time you have other procedures that require sedation. However, this is not always possible. Sometimes you may need to have these procedures or scans separated from each other, which may require you to have additional sedation.

Receiving additional anesthesia for research purposes could have additional risks. It is possible that anesthesia medicines given to children for a long time or at higher total doses could have a negative effect on how the brain develops, especially in young children. Recent information suggests this could include learning, memory, or behavior problems. Higher total doses of anesthesia and longer total times sedated with anesthesia medications

appears to increase these risks. By consenting to the optional research tests you may have about 6 **total hours** of **additional** **anesthesia time**, if you require sedation to complete the research only portion of the imaging test. These additional pictures are to help researchers and are not expected to change your medical care (benefit you) in any way.

The short term side effects from anesthesia/sedation include vomiting, sore throat, headache, backache, muscle pains, shivering, sleepiness, confusion and/or problems urinating.

With any anesthetic/sedation procedure, there may be serious risks or problems that cannot be prevented, and are not known ahead of time. These may be allergic reaction, nerve damage, low blood pressure, spasms in the throat, voice box or breathing tubes, problems breathing, slow breathing, heart attack, brain damage, numbness that does not go away, loss of movement, seizures, unusual reactions, or rarely, death.

Some anesthetics require medical devices around or in the mouth and nose. There may be soreness and bruising in the mouth, nose and throat. Sometimes, but not often, teeth my get knocked loose, chipped or damaged.

Anesthesia risks following the use of sedation and/or anesthetic drugs involve primarily the respiratory system. These include a brief halt in breathing, decreased oxygen saturation, airway obstruction, and possible use of airway devices. Other possible adverse effects include low blood pressure, slowed heart rate, fast heart rate, low body temperature, and possibly delayed awakening.

Gadolinium Risk: Gadolinium based contrast agents (GBCA), are used for MRI tests to help see the images better. Small amounts of GBCA can stay in the body for months to years and can be deposited in the brain and other tissues. The risk of GBCA staying in the body is increased in children. At this time the full effects of GBCA retention in the body are unclear, additional safety studies are ongoing. You could potentially receive more of a GBCA by participating in this study than you would if only receiving standard of care imaging tests.

Surgery Risks: If the study doctor determines that surgery is needed to remove the tumor, you will be asked by the surgeon to sign a separate consent form at the time of that surgery. The surgeon will discuss the procedure and risks with you at that time.

Genomics Risks: The most common risks related to drawing blood from your arm are brief pain and possibly a bruise.

a) There is a risk that someone could get access to the personal information in your medical records or other information researchers have stored about you.
b) There is a risk that someone could trace the information in a central database back to you. Even without your name or other identifiers, your genetic information is unique to you. The researchers believe the chance that someone will identify you is very small, but the risk may change in the future as people come up with new

ways of tracing information.

c) In some cases, this information could be used to make it harder for you to get or keep a job or insurance. There are laws against the misuse of genetic information, but they may not give full protection. There can also be a risk in knowing genetic information. New health information about inherited traits that might affect you or your blood relatives could be found during a study. The researchers believe the chance these things will happen is very small, but cannot promise that they will not occur.

8. What are the possible benefits of the study?

You may benefit from the treatment you receive for your recurrent ependymoma. Taking part in this study may or may not help you personally. However, a possible benefit of this study is that your condition will be monitored more often than during usual clinical care. This means that if a condition arises, it may be identified sooner than it normally would. The information gained in this study may help researchers develop better treatments for children and adolescents in the future.

9. Can I stop taking part in this study?

You can choose to stop the study at any time. Your taking part in the study is voluntary. Tell the study doctor if you are thinking about stopping or decide to stop. He will tell you how to stop safely. It is important to tell the study doctor if you are thinking about stopping so any risks from the radiation can be evaluated by your doctor. Another reason to tell your doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful for you.

10. Can I be taken out of the study without my consent?

You may be taken out of the study without your consent for the following reasons:

- Your doctor decides that continuing in the study would be harmful for you
- You are unable to keep appointments or take therapy as instructed
- You need a treatment not allowed on this study
- Your condition gets worse
- New information is learned that a better treatment is available, or that the study is not in your best interest
- You become pregnant prior to or during radiation therapy

11. Will I be paid for my time or expenses?

At yearly visits when you return the actigraph to the Nursing Research Department, you will receive a $25 gift card from St. Jude to reimburse for your time and inconvenience in taking part in the sleep study. You will not receive reimbursement or compensation for your participation in other parts of the study. Also, any costs related to medical care that you receive at home will not be paid for by St. Jude.

12. How will new findings from this research study be shared with me?

We will tell you anything we learn during the study that might cause you to change your mind about staying in the study. If you are interested in learning more about when and how to get the results of this research study, please contact Dr. Thomas Merchant at 901-595- 3300.

13. How will I find out the results of this study?

The researcher will give you information about the overall results of this study. St. Jude researchers share information with research participants in many ways, including:

- articles on www.StJude.org
- in newsletters
- in medical or scientific journals
- in the media

Published research results will only describe groups of participants. Information that identifies individuals will not appear in research journals or other reports.

14. Who will see my research records and medical information?

We will keep your medical records private to the degree allowed by law. We will not give information from your medical records to anyone outside the hospital unless we are required by law to do so. We will not identify you personally in any publication about this study. No information other than what is needed for the study is recorded.

The study results will be kept in your research record for at least 6 years after the study is finished. At that time, the research data that has not been put in your medical record will be kept for an unknown length of time. Any research data that has been put into your medical record will also be kept for an unknown length of time.

Breach of confidentiality: Very rarely, data might be accidentally released from your records that could embarrass you or affect your ability to get insurance. We take several steps to prevent this from happening, including:

- Storing names or other personal information separately from research records
- Limiting access to members of the research team
- Storing electronic data only on password-protected computers
- Reporting study results on the whole group and never identifying individuals in any reports

OPTIONAL TREATMENT PLAN

1. Pathologists at St. Jude will perform clinical studies on your tumor sample

that was collected at surgery to confirm the diagnosis and to learn more about the biology of recurrent ependymoma tumors. A variety of tests will be done to learn more about your tumor's specific chromosomes. Chromosomes are a part of a cell that contains genetic information. If the doctors find your tumor is specific for a special chromosome abnormality called 1q gain (extra copies of genetic material on chromosome 1) and your tumor came back in the original tumor site (has not spread to other parts of your body) and are over the age of 3 years old, you may choose to have craniospinal irradiation treatment in place of focal irradiation (treatment to tumor and its borders). Tumors that show 1q gain tend to have a higher risk of the tumor coming back in other locations of the brain and spine.

Circle choice of "yes" or

"no". YES NO

2. I agree to the additional time added to the clinical scans to perform research only tests.

   Circle choice of "yes" or "no" or "not eligible"

   YES NO Not eligible less than 3 years old

3. If not requiring sedation, I agree to participate in the research only FDG PET, MET PET, and PET scans.

   Circle choice of "yes" or "no" or "N/A".

   YES NO N/A

SUMMARY OF RESEARCH AND PRIVACY RIGHTS

The following statement describes your rights as a research participant in this study:

1) You may refuse to be in this research study or stop at any time. This decision will not affect your care or your relationship with your doctor or St. Jude. If available, you may receive routine medical care at St. Jude Children's Research Hospital.

2) If you have insurance, TennCare or Medicaid, or other health care coverage such as an employer-sponsored benefit plan, they will be billed for many of the services we provide. However, we do not bill patients or their families for the cost of medical care not covered by their health plans. This includes research costs.

3) Your samples and information may be used to develop a new product or medical test, which may be sold. If this happens, you will not receive any payments for these new products.

4) If you have any questions about this study or if you are injured as a result of this study, contact Dr. Merchant**,** at 901-595-3300 immediately. If you are injured from being in this research study, St. Jude will provide reasonable and necessary care for that injury. If you need more care than St. Jude can provide, we will help you find medical care somewhere else. It is not the hospital's policy to provide payment if you are injured from being in this study; however, you are not giving up any of your rights by signing this consent form.

5) 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.

6) A decision to take part in this research means that you agree to let the research team use and share with other researchers your health information also called protected health information (PHI) for the study explained above. This information will be kept indefinitely. You have the right to see, copy, and ask for changes to your protected health information that will be used or given out. However, research information may not be seen until the end of the study.

7) When you first registered at St. Jude, you received a copy of the St. Jude Notice of Privacy Practices. It tells how your PHI may be used or given to someone outside the hospital. You have the right to read the Notice of Privacy Practices before you sign this form. It may have changed since you first registered at St. Jude. You can find it at the bottom of every page on the St. Jude Internet website: *www.stjude.org*.

8) Federal agencies such as the Food and Drug Administration (FDA), the Office of Human Research Protections (OHRP), the National Institutes of Health (NIH), and St. Jude Children's Research Hospital Institutional Review Board (IRB), your insurance company or other health benefits plan (if charges are billed to these plans), as well as other regulatory agencies, committees, or persons involved in overseeing research studies may review your research and medical record.

9) Information about you that may be given out includes your complete medical records, including details about diagnosis, illness, treatment, and information that may be recorded about past diagnosis or treatment and information taken as a part of this research study as explained in this informed consent.

10) After your records are given to or used by others, St. Jude Children's Research Hospital cannot promise that information will not be given out again. Also, the information given out may no longer be protected by federal privacy laws.

11) St. Jude uses reasonable safeguards and means to protect your private information. However, St. Jude cannot guarantee the security and confidentiality of e-mail, text messages, fax communications or mail.

12) Researchers and study staff are required by law to report suspected child abuse, threat of harm to self or others, and certain diseases that spread from person to person.

13) Your permission to use and give out your child's protected health information will end when your child turns 18 years of age. At that time, we may contact your child for his or her permission to continue using it.

14) You may take back permission for your records to be used or given out at any time, for any reason, except when that information has already been given out or used for the study based on your permission. To take back your permission, please fill out a form called a Revocation of Release of Authorization. You may ask for this form by calling the St. Jude Privacy Officer at 901-595-6141. You must mail the form or hand it to:

    HIPAA Privacy Officer
    St. Jude Children's Research Hospital
    262 Danny Thomas Place, Mail Stop 280
    Memphis, TN 38105

15) You can get more details about your rights as a research participant by calling the St. Jude Institutional Review Board at 901-595-4357 or the Research Participant Advocate at 901-595-4644. If you are outside of the Memphis area, please call toll-free 1-866-583-3472 (1-866-JUDE IRB).

16) The St. Jude Research Participant Advocate is an individual who is not part of the research study team and is available to you to discuss problems, concerns, and questions. The Advocate can help you obtain information and can relay any input you may have concerning the research to the research study team. You can reach the Advocate by calling 901-595-4644, or if you are outside of the Memphis area, call toll free at 1-866-583-3472 (1-866-JUDE-IRB).

17) You will be given a copy of this signed consent form.

PARENT/GUARDIAN STATEMENT (Required for participants younger than 18 years):
I have read this document or it was read to me. I have been encouraged to ask questions and all my questions have been answered. I give permission for my child to be in this research study. Both parents must sign if Option 2 is circled Yes.

Parent/Legal Guardian Signature	Date	Time AM/PM (circle one)
Parent/Legal Guardian Signature	Date	Time AM/PM (circle one)

ASSENT DISCUSSION (Required for participants 7–13 years old)

☐ The research was explained to the minor participant in age-appropriate terms and the minor verbally agreed to take part in the study.

☐ Minor declined to take part in the study. The minor declined for the following reason(s):

_____

☐ An assent discussion was not initiated with the minor for the following reason(s):
- ☐ Minor is under 7 years of age.
- ☐ Minor is incapacitated.
- ☐ Minor refused to take part in the discussion.
- ☐ Other_____

RESEARCH PARTICIPANT STATEMENT (14–17 years old and Adult Participants 18 years and older):
I have read this document or it was read to me. I have been encouraged to ask questions and all my questions were answered. I agree to take part in this research study.

Research Participant Signature	Date	Time AM/PM (circle one)

RESEARCHER/DESIGNEE STATEMENT: I have explained the research to the participant and his/her parent(s) or legal guardian(s). The research participant and parent(s)/guardian(s) were encouraged to ask questions and all questions were answered to their satisfaction. A copy of this form has been given to the participant or his/her representative.

Researcher/Designee Signature	Date	Time AM/PM (circle one)

_____
Print Name

RESEARCH PARTICIPANT ADVOCATE STATEMENT

(A research participant advocate or ombudsperson serves as a witness. For non-English speaking participants, the interpreter may also serve as the witness/advocate.)

I observed the informed consent process. The research study, intervention/observation, risks, benefits, and alternatives were presented to the research participant and/or legal guardian(s). They were encouraged to ask questions, and research team members answered all their questions.

The participant /parent(s) indicated that they: 1) understood the information presented; and 2) voluntarily consented /agreed to take part in the research.

_____	_____	_____
Research Participant Advocate	*Date*	*Time* *AM/PM (circle one)*

_____	_____	_____
Interpreter (if needed)	*Date*	*Time* *AM/PM (circle one)*

PLEASE FAX CONSENT FORM TO PROTOCOL OFFICE #6265