RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE:	Molecular-guided therapy for the treatment of patients with relapsed and refractory childhood cancers
PROTOCOL NO.:	NMTRC009 WIRB® Protocol #20140562
SPONSOR:	Giselle Sholler, MD
INVESTIGATOR:	Name Address City, State Zip Country
SITE(S):	Name Address City, State Zip Country
STUDY-RELATED PHONE NUMBER(S):	Name 24 Hour Telephone Number Required

In this consent form, "you" always refer to the subject. If you are a legally authorized representative, parent or guardian, please remember that "you" refers to the study subject.

You are being invited to participate in a research study conducted by the Neuroblastoma and Medulloblastoma Translational Research Consortium (NMTRC). The NMTRC is a collaboration of academic medical centers and other organizations around the country. Helen DeVos Children's Hospital, a member of Spectrum Health Hospitals, serves as the lead organization of the NMTRC.

This study is a clinical trial (a research study involving subjects). Research studies include only subjects who choose to take part. Your participation in this study is entirely voluntary. Please read the consent form carefully. This consent form may contain words that you do not understand. Please ask the study doctor or study staff to explain any words or information that you do not clearly understand. You will be given a copy of it to keep if you decide to participate in this study. You will be given a copy of this consent form to take home and you may discuss your decision with your friends and family if you would like.

You are being invited to participate in this study because you have recurrent or unresponsive neuroblastoma, brain, or a rare tumor.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to test the feasibility (ability to be done) of an experimental test to help plan your cancer treatment. This study plan is not studying the effectiveness of the proposed combinations of therapy for your cancer that you may receive after the experimental testing.

This study will look at an experimental technology to determine a tumor's molecular makeup (gene expression profile) and mutations. This technology, called the "Pediatric Gene Analysis Platform," is based on genetic testing done at Ashion Analytics, LLC (Ashion), which is a clinical laboratory developed by the Translational Genomics Institute (TGen) in Phoenix, Arizona and methods of genetic analysis created by NMTRC and TGen. The Pediatric Gene Analysis Platform being used to discover new ways to understand pediatric cancers and potentially predict the best treatments for patients with cancer in the future. This experimental technology has not been approved by the U.S. Food and Drug Administration.

Pediatric Gene Analysis will be done using the Hi Seq 2500 Sequencer.

This study is for research purposes only. If you agree to participate in this study, a current specimen obtained from your tumor during a regular (standard of care) surgical biopsy or bone marrow procedure along with a blood sample will be sent to Ashion and the Sholler/NMTRC laboratory at Spectrum Health. Researchers will attempt to identify the molecular makeup within the specimen. If you choose to be in the optional portion of this study researchers will also evaluate additional blood and bone marrow samples. This additional testing is different than the routine tests currently performed at the hospital for the evaluation of cancer. If we are unable to obtain enough tumor cells for molecular makeup identification you will be unable to continue in the study.

After your tumor has been analyzed, the researchers will use your tumor's genetic information to generate a report. The report will provide information that predicts which drugs your specific tumor may be most sensitive to. Your personalized research report will be reviewed by a committee made up of at least three oncologists and one pharmacist to decide which combination of drugs might work best against your tumor (the "treatment recommendation board"), and they will recommend a personalized treatment plan for you. Your referring/primary oncologist will be invited to attend the treatment recommendation board meeting. After the board creates your recommended treatment plan, your study doctor will review this plan and any other possible standard treatment options with you (and your referring/primary oncologist, if applicable) before starting any treatment.

The goals of this part of the study are:

- To determine feasibility (ability to be done) and safety of using tumor samples and the experimental technology to guide therapy decisions in relapsed and refractory childhood cancers.
- To determine if our treatment recommendation board (at minimum a panel of 3 oncologists and 1 pharmacist) can use your bone marrow or tumor samples to make real-time treatment recommendations using your specific genetic information and predicted therapies identified in your personalized genetic report.

- To deliver therapy based on molecular guided predictions.
- To determine the activity of treatments chosen based on:
  - How each subject responds to treatment
  - How long a subject lives without their disease progressing

HOW MANY SUBJECTS WILL TAKE PART IN THE STUDY?

We plan to enroll approximately 200 to 220 subjects in this study nationwide over the next two years.

WHAT WILL HAPPEN IF I TAKE PART IN THIS RESEARCH STUDY?

You will need to have the following exams, tests and procedures to find out if you can be in the study. Depending on the results of these studies, they may show that you are not eligible to take part in this study. Most of these exams, tests and procedures are part of regular cancer care and may be done even if you do not join the study. If you have had some of them recently, they may not need to be repeated. This will be up to your study doctor.

- Medical history
- Physical exam
- Vital signs (blood pressure, pulse, temperature)
- Blood tests
- Urine tests
- MRI (use of a magnetic field to produce an image) or CT scan (test that produces a picture of your body using radiation) of the tumor(s)
- Any other imaging studies or tests deemed necessary for assessing your tumor by your treating physician

Additional Tests for Some Subjects

- MIBG scan (unless your tumor is pre-determined to not show up on an MIBG scan) or PET scan (An MIBG scan involves injecting a radioisotope into the blood on the first day, and then scanning the whole body on the second day to see where the isotope was absorbed)

Additional Tests for Neuroblastoma Subjects and any Subject with suspected Bone Marrow Disease Involvement:

- Bone marrow examination (this involves using a needle to extract a small amount of your bone marrow from both of your hips usually under anesthesia)

You will need the following tests and procedures that will be evaluated in this study.

- Analysis of your tumor sample and generation of a personalized genetic report
- Review of personalized genetic report with the study doctor
- If you are eligible, you will then be offered and placed on a treatment plan.

As a part of your regular (standard of care) treatment you may have a surgical operation to remove as much of the tumor as possible. You will be asked by the pediatric surgeon to sign a separate consent form at the time of that surgery, which will review the risks and benefits of that surgical procedure. If tumor is obtained by surgery, you will be asked if some of the tumor can be saved for special research testing. There is a separate consent section for this at the end of this consent form.

Methods for Giving Drugs

The study doctor will discuss with you the method of giving drug or drug combinations after the treatment plan is determined.

Study Plan:

If the exams, tests and procedures show that you can be in the study, and you choose to take part, a portion of your tumor tissue (either bone marrow biopsy or tissue) along with a blood sample will be sent to the Ashion for testing. This testing will generate a personalized genetic report. The personalized genetic report will provide information that predicts which of the drugs your specific tumor may be most sensitive to. These reports will be used by the treatment recommendation board to recommend a specific treatment plan for your tumor. Your treating physician will know these recommendations when planning your treatment. Some of the factors that will be taken into account in choosing your treatment may include the safety, mechanism (how the drug works), availability, and cost of the drugs predicted. Once you have completed the pre-study procedures and the treatment recommendation board has made a treatment recommendation based on the testing results obtained from a portion of your tumor tissue (either bone marrow or tissue), your physician will review your treatment options with you, and you will be asked to begin a treatment.

Please read the section regarding drug risks for important information relating to this study.

One of the major goals of this study is to identify biologic treatment targets unique to your individual tumor. Therefore the specific treatment plan developed may recommend drugs or combinations of drugs with which there is little or no prior experience in children.

There will be specific testing done while you are on study to monitor your progress and health.

You may participate in this part of the study without agreeing to specific treatment therapy. Deciding not to be in the study or leaving the study will not result in any penalty or loss of benefits to which you are entitled.

You will need tests and procedures that are part of regular cancer care. They may be done more often because you are in this study.

If you have another tumor removal as part of your standard course of care during the time you are on this study, you may be offered the opportunity to have the tumor tested again and to repeat the treatment recommendation board. At this time a new treatment recommendation may be

made depending on the results of the repeat test. If this occurs and you agree to the new treatment plan you will start over on the study.

Testing Requirements for Study:

Procedure	Pre-Study	Cycle 1 Day 1	Cycle 1 Day 8	Cycle 1 Day 15	Cycle 1 Day 22 (if applicable)	Subsequent Cycles Day 1	Off Therapy
Informed consent	X						
Medical history	X	X	X	X	X	X	
Physical exam	X	X	X	X	X	X	X
Vital signs	X	X	X	X	X	X	X
Height	X	X					X
Weight	X	X				X	X
Blood Tests	X	X	X	X	X	X	X
Urine Tests	X	X				X	X
Surgical resection &/or diagnostic biopsy	X						
MRI or CT	X	Radiologic measurements will be performed after Cycle 2 and then should be performed every 8 weeks or every other cycle (whichever occurs first) through Cycle 6, after which they may be performed as per institutional standard.					
MIBG	X						
Bone Marrow (for any subject with suspected BM disease)	X	Should be repeated after Cycle 2 and then should be performed every 8 weeks or every other cycle (whichever occurs first) if positive at study entry through Cycle 6, after which they may be performed as per institutional standard.					
B-HCG (pregnancy test)	X						
EKG (as indicated)		X					

All required scans (MIBG's and MRI/CT's) must be done at your study institution unless otherwise approved by the sponsor.

HOW LONG WILL I BE IN THE STUDY?

As a subject in this study you will remain in this study for as long as you have no disease progression or until you need to come off study.

WHAT SIDE EFFECTS OR RISKS CAN I EXPECT FROM BEING IN THE STUDY?

Genetic testing:

Some of the risks associated with genetic testing include:

- Inaccurate results
- Unknown meaning of results
- Misuse of results by others

Testing may give incorrect answers. This could mean a falsely positive result that you have the gene, when you do not. Or it could mean a falsely negative result that the gene is absent, when

you actually do have the gene. Either way, a false result would mean that your genetic test information would be incorrect.

There are risks associated with a loss of confidentiality of your health information and genetic testing results. Information about genetic test results may affect your employment, insurance, or family relationships. The sponsor cannot be certain that your genetic test results could never be linked to you.

Drug Risks:

Your study doctor will provide you a more detailed list of the risks of the drugs involved in your specific treatment plan. Attached to the end of this consent form is a list of the possible drug therapies. Your study doctor will discuss your personalized plan with you.

The following information is general information about chemotherapy risks.

All people who receive cancer treatment are at risk of having side effects. In addition to killing tumor cells, cancer chemotherapy can damage normal tissue and produce side effects. Side effects are usually reversible when the medication is stopped but occasionally persist and cause serious complications. A person can die from these and other complications.

Common side effects include nausea, vomiting, hair loss, and fatigue. Drugs may be given to prevent or decrease nausea and vomiting. Hair loss is usually temporary, but on very rare occasions it may be permanent. Some chemotherapy may lead to sterility. Sterility is the inability to have children. There is also the possibility that a second cancer may develop years later as a result of the chemotherapy.

The most common serious side effect from cancer treatment is lowering of the number of blood cells resulting in anemia, and increased chance of infection.

Allergic and infusion reactions have been reported. Symptoms of a reaction may include headache, rash, itching, flushing, swelling, and shortness of breath. Severe reactions, such as Stevens-Johnson Syndrome (SJS), Toxic epidermal necrolysis (TEN) or and Drug Reaction with Eosinophillia and Systemic Symptoms (DRESS), could be life threatening. If you have symptoms of a reaction, you should contact the study doctor or his/her study staff immediately.

Organ dysfunction, such as skin, liver or lung problems. These could be mild, such as abnormal blood tests without symptoms, or could be life-threatening.

Abnormal blood clotting, either too much or too little. This could result in excessive bleeding or clots in blood vessels, and could be life-threatening.

There also may be other side effects that we cannot predict.

There is a risk that the treatment plan will not get rid of the cancer for as long as possible or that the cancer can go away after the treatment and then come back at a later date.

You may be prescribed drugs in a combination that has not been used before or has limited use together. Side effects can be increased when chemotherapy drugs are combined. Information about how these drugs may interact could be based on theoretical knowledge that may not have been tested before. There may be unknown interactions of using these drugs together. These drug combinations may have serious side effects that we may not know about which could occur immediately or at a later time after you have stopped taking the medication. Your study doctor will discuss this with you at the time of your treatment decision.

If you do have side effects, we may recommend medicine or treatments to try to control them and make you comfortable.

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

Device Risks:

The "Pediatric Gene Analysis Platform" test is an experimental technology (not FDA-approved) that will be used to help identify a drug, or combination of drugs for your treatment, based on the molecular makeup of your tumor. No test is perfectly accurate and there is a risk that results from this test may incorrectly identify/fail to identify the molecular makeup of your tumor. An incorrect test result (indicating that your tumor has a particular molecular makeup, when it does not) could result in your receiving a study drug, or combination of drugs that may have no benefit to you, and which may have side effects and cause harm.

Bone marrow examination risks:

The test may be painful. There is also a small risk of infection or bleeding. The pain normally lessens within minutes to hours.

Risks of 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.

Reproductive Risks:

Because the drugs used in cancer treatment can affect an unborn baby, you should not become pregnant or father a baby while on this study. You should not nurse your baby while on this study. Both men and women should use one of the more effective birth control methods during treatment and for six months after treatment is stopped. These methods include

- total abstinence (no sex),
- oral contraceptives ("the pill"),
- an intrauterine device (IUD),

- levonorgestrol implants (Norplant), or
- medroxyprogesterone acetate injections (Depo-provera shots).

If one of these cannot be used, contraceptive foam with a condom is recommended.

The study doctor must be notified if pregnancy occurs during the course of the study.

A possible effect of drugs used to treat your tumor is the possibility of sterility (inability to have children).

WHAT IF THERE ARE NEW FINDINGS?

We will tell you if we learn any new information that may affect your health, welfare, or decision to stay in this study. You may be asked to sign a revised consent form if this occurs.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

Because there is not much information about molecular guided therapy in your tumor type, we do not know if you will experience personal benefit from taking part in this study. Information learned from this study may help future children with cancer.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

Taking part in this study may lead to added costs to you or your insurance company. You will be charged for the standard medical treatment you receive while in this study.

You will not have to pay for the blood and tumor sample testing done at Ashion or at the Sholler/NMTRC laboratory at Spectrum Health.

You will not have to pay for the review conducted by the treatment recommendation board.

Please ask to speak to a financial counselor if you have any questions about the costs of being in this study.

- For more information on clinical studies and insurance coverage, you can visit the National Cancer Institute's Web site at
- http://www.cancer.gov/clinicaltrials/learningabout/payingfor/how-insurance-companies-decide You can print 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.

WILL YOU BE PAID FOR TAKING PART IN THIS STUDY?

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

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

You do not have to participate in this study to have a genetic analysis of your tumor. One choice is to not be in this study and to receive your cancer treatment in the usual way.

If you decide that you don't want any more active treatment, one of your options is called "comfort care." Comfort care includes pain medication and other support. It aims to maintain your comfort and dignity rather than cure disease. Usually this care can be provided at home.

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

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.

Each subject in this trial will be identified by a unique identifier that will be used on all report forms and any other material submitted to the NMTRC. Report Forms for this study will be both paper and electronic. Electronic data will be stored in a secure data center that is housed by a third party. Your medical records are available to those caring for you at this hospital. Other people or groups who may see or copy your medical record and other health information because you are participating in this study include:

- The Neuroblastoma and Medulloblastoma Translational Research Consortium (NMTRC), affiliates of the NMTRC, and the NMTRC009 study committee
- Spectrum Health and its affiliates
- Ashion Analytics, LLC at TGen
- The U.S. Food and Drug Administration
- The Western Institutional Review Board® (WIRB®)
- The Spectrum Health Institutional Review Board
- Department of Health and Human Services (DHHS) agencies

Otherwise your name will not be released without your written permission, unless required by law. If results of this study are published, your identity will remain confidential.

Please refer to the separate authorization form that explains more specifically how your personal health information will be used.

Part of this study will be looking at genetic information collected from the samples you provide. Your genetic information may be shared with and seen by individuals working at Ashion, TGen, Dell Inc., and other organizations that are collaborating with NMTRC or funding this study. While your genetic information, by itself, may not directly identify you, you should be aware that certain other laws and regulations may provide additional protections for that information.

Specifically, 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.

GINA does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA does not prohibit discrimination on the basis of an already manifest genetic disease or disorder.

A description of this clinical trial will be available on 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.

WHAT HAPPENS IF I AM INJURED?

Participating in research may result in an injury or illness. Medical treatment related to this injury or illness will be available at your treating institution, but such treatment may not be free of charge. No funding has been set aside to pay for the costs of treating an injury or illness that results from this study. Your medical insurance may pay for such treatment, but you may ultimately be billed for payment.

Ask the study doctor for more information about this. We also encourage you to determine your health insurer's policy about paying for treatment in a research study.

By signing this consent form, you are not giving up any legal rights.

WHO WILL PROVIDE FUNDING?

Funding for this research study will be provided by the Neuroblastoma and Medulloblastoma Translational Research Consortium (NMTRC) and Dell, Inc.

CAN I WITHDRAW OR BE WITHDRAWN FROM THE STUDY?

Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled.

Tell your study doctor if you are thinking about stopping or decide to stop. He or she will tell you how to stop safely. It is important to tell the study doctor if you are thinking about stopping so any risks from treatment can be evaluated by your study doctor. Another reason to tell your

study doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful for you.

Your study doctor or sponsor may decide to take you off study at any time without your consent if any of the following occur:

- You do not meet the requirements to take part in the study (for example, there is not enough sample of tumor cells to perform the analysis needed for the personalized genetic reports.)
- You need a treatment that is not allowed on this study
- Your tumor worsens
- The study doctor believes it is in your best interest
- New information becomes available that would suggest that continuing in this study would not be in your best interest
- The study is stopped
- You do not consent to continue in the study after being told of changes in the research that may affect you
- Or for any other reason.

CONTACT INFORMATION

Contact [INSERT INSTITUTION PI NAME] at [INSERT INSTITUTION PI CONTACT NUMBER] for any of the following reasons:

- if you have any questions about your participation in this study,
- if at any time you feel you have had a research-related injury, or
- if you have questions, concerns or complaints about the research.

If you have questions about your rights as a research subject or if you have questions, concerns, input or complaints about the research, you may contact:

Western Institutional Review Board® (WIRB®)
1019 39th Avenue SE Suite 120
Puyallup, Washington 98374-2115
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com

WIRB is a group of people who perform independent review of research.

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

WHERE CAN I GET MORE INFORMATION ABOUT CANCER AND CLINICAL STUDIES?

You may call the National Cancer Institute's Cancer Information Service at: 1-800-4-CANCER (1-800-422-6237) or. You may also visit the NCI Web site at http://cancer.gov/

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

If you agree to be in this study, you will receive a signed and dated copy of this consent form. You will be given a copy of the protocol (full study plan) upon request. If you want more information about this study, ask your study doctor.

Additional optional tumor biology consent

If you agree to allow your samples to be stored for future research, your tumor samples, blood, and/or bone marrow will be stored in a safe and confidential laboratory indefinitely. Your name will not be used to identify your sample when it is stored in the lab. The samples will be identified only by a de-identified code. Samples will be frozen and stored in a carefully controlled deep freezer.

You have the option to remove the samples from the laboratory at any time because a link will remain between your samples and you. If in future, you ask that your stored samples be destroyed, it is important to know that any research that has already been done on the samples cannot be changed. No matter what you decide to do, it will not affect the care that you will get.

There is no way to predict exactly what tests will be performed with your stored samples. Because any future, additional tests are for research only, usually your study doctor or you will not know the results. It is very unlikely that the research testing might find important information about your current or future health. If this unlikely event happens, the researchers may contact your study doctor about what the research test results might mean. Only your study doctor will be notified and the information will not become part of your medical record. Your study doctor may discuss this unexpected finding with you, and may recommend that you see a genetic counselor and/or repeat testing in a clinical (not research) laboratory if needed. It is possible that your study doctor may decide that no action is needed.

Please initial your choice on the line below:

1. Additional tumor samples may be taken and sent to an NMTRC laboratory for additional tests.

   #1: Yes_____ No_____ _____ / _____
   Initials Date

2. Additional blood samples may be taken and sent to an NMTRC laboratory for additional tests.

#2: Yes_____ No_____ _____ / _____
Initials Date

3. If I have a bone marrow sample done as part of my regular care, extra bone marrow samples may be taken and sent to an NMTRC laboratory for additional studies.

#3: Yes_____ No_____ _____ / _____
Initials Date

4. I agree to let researchers store material (eg, leftover cells or genetic material that is taken at the time of a procedure) for future use to learn about, prevent, or treat cancer.

#4: Yes_____ No_____ _____ / _____
Initials Date

Statement of Consent

I have been given and have read a summary of this research study. I have been able to ask questions and my questions have been answered to my satisfaction. Should I have any further questions about the research, I may contact the person conducting the study at the address and telephone number given on page one of this consent form. My participation is voluntary and I may refuse to participate or withdraw at any time without penalty or prejudice to my present and/or future care. I agree to participate in this study.

I authorize the release of my medical records for research or regulatory purposes to the sponsor, the FDA, DHHS agencies, governmental agencies in other countries, [Site Specific] and WIRB®.

By signing this consent form, I have not given up any of my legal rights.

Consent and Assent Instructions:

Consent: *Subjects 18 years and older who can provide consent must sign on the subject line below*
Consent is provided by the Legally Authorized Representative for adult subjects unable to consent
Competent subjects who become adults during the study must provide written consent using the subject line below
For subjects under 18, consent is provided by the parent or guardian

Assent: *Is not required for subjects 17 years and younger*
Written assent is required for adult subjects where possible using the assent section below

Name of Subject Printed

CONSENT SIGNATURE:

Signature of Subject Date

Signature of Legal Guardian or Legally Authorized Representative Date
(applicable for children and subjects unable to provide consent)

Name of Legal Guardian or Legally Authorized Representative Printed

Authority of Subject's Legally Authorized Representative or Relationship to Subject

Signature of Person Conducting Informed Consent Discussion Date

Name of Person Conducting Informed Consent Discussion

Signature of Principal Investigator or Designee (if different from above) Date

Name of Principal Investigator or Designee Printed (if different from above)

ASSENT SIGNATURES, For Adult Subjects with a Legally Authorized Representative:

Assent:

For adult subjects who have a legally authorized representative, I confirm that:

- I have explained the study to the extent compatible with the subject's understanding, and the subject has agreed to be in the study.

OR

- The subject is not able to assent due to lack of mental capacity.

Signature of Person Conducting Assent Discussion Date

---------- Use this witness section only if applicable ----------

If this consent form is read to the subject because the subject is unable to read the form, an impartial witness not affiliated with the research or investigator must be present for the consent and sign the following statement:

I confirm that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject. The subject freely consented to be in the research study.

Signature of Impartial Witness Date

Note: This signature block cannot be used for translations into another language. A translated consent form is necessary for enrolling subjects who do not speak English.

HIPAA AUTHORIZATION FORM FOR USE & DISCLOSURE OF HEALTH INFORMATION FOR RESEARCH PURPOSES (TEMPLATE)

The information we are asking to use and disclose (share) for this research study may include your Protected Health Information (PHI). This information is protected by a federal law called the Health Insurance Portability and Accountability Act (HIPAA). In general, we cannot use or share your health information for research without your permission.

What will be done with my information?

Each subject in this trial will be identified by a unique identifier that will be used on all report forms and any other material submitted to the NMTRC. Report Forms for this study will be both paper and electronic. Electronic data will be stored in a secure data center housed at a third party. Your health information will be collected and entered in this password-secure database along with the information from other people taking part in this study, and will only be accessible to the people involved in conducting this research.

Why am I being asked to give permission for the use and disclosure of my information?

Your health information will be used to evaluate the feasibility (ability to be done) of an experimental test to help plan your cancer treatment. To evaluate this test, we need to see and use your health information, including your genetic information.

What information will be used and shared for this study?

To complete this research study, we will need to collect and share (disclose) information about you. This information may include:

- Your date of birth, name, contact information, medical record number, and insurance information.
- Genetic information about you and your cancer.
- Existing medical records and medical history.
- New health information collected for purposes of this study.
- Copies of medical records you have with other health care providers.

With whom will my information be shared (disclosed)?

- Dr. Giselle Sholler, the Neuroblastoma and Medulloblastoma Translational Research Consortium (NMTRC), affiliates of the NMTRC, and the NMTRC009 study committee
- Your study doctor and his/her research staff
- Spectrum Health Hospitals staff or its agents
- Ashion Analytics, LLC at Tgen
- The Western Institutional Review Board® (WIRB®)
- The Spectrum Health Institutional Review Board (IRB) and its staff
- The Food and Drug Administration (FDA) and other government agencies who regulate this study

Once your protected health information has been shared (disclosed), it is possible that anyone who receives that information may re-disclose it. Because some of these individuals who receive your protected health information may not be required by law to keep your information confidential, we cannot guarantee that your information will not be released or made available to another party once it leaves your treating institution. Therefore, we share your information only if necessary and we use all reasonable efforts to request that those individuals who receive your information take steps to protect your privacy.

How long will my health information be used and shared?

This authorization has no expiration date.

Can I stop my protected health information from being collected and shared?

You can tell us to stop collecting your health information at any time. We will stop using and sharing your information, except in very limited cases if needed to comply with law, protect your

safety, or make sure the research was done properly. If you have any questions about this please ask.

If you want us to stop using and sharing your health information, you must tell us in writing. Send your written request to:

[insert study doctor contact information]

What happens if I do not want you to use and share my health information?

If you decide not to give permission for us to use and share your health information, you will not be able to participate in this study. Your decision will in no way affect your medical care or cause you to lose any benefits to which you are entitled.

When will my information be destroyed?

We do not know when your information will no longer be used. Unless you tell us to stop using and sharing your information, it will be kept for an indefinite length of time.

[If the HIPAA authorization form will be a document separate from the consent form, appropriate signatures blocks need to be inserted here].