are contacted with results, you should talk to your regular doctor about what the test results may mean to you.

B. Protecting your Privacy and Keeping your Information Confidential

We will work very hard to keep your information confidential.

If you volunteer to be part of the project, this signed consent form will either be stored in a locked file (if you are signing a paper consent) or in a secured computer system (if you are signing an online consent).

When results of this research project are reported in medical journals or at scientific meetings, the people who volunteered their samples and information will not be named.

B1. Removing your identity from your tissue samples and medical information

Your tissues and information will be de-identified, which means that all of your obvious identifiers (like name, medical record number, address, and phone) will be stripped away. Your samples and information will only be labeled with a random number code.

If a model derived from your tumor is created, the link between the model and your identifiable information will be permanently broken after the model is successfully created and a given set of information has been collected. This will occur prior to the storage of the model in the repository. From then on, only the random code will be attached to the tissue samples, models, and your information and it will not be possible to link you back to those models.

C. Your Tissue Samples and Information

C1. Collection of your samples and medical information

Your biopsy or surgery is part of a medical treatment that you agreed upon with your doctor. That biopsy or surgery is not part of this research project. During the procedure, the cancer tissue will be (or was) removed. Many times, there is more tissue than is needed for your diagnosis, which is normally thrown away. After the pathology department takes the tissue they need for your medical care, we are asking your permission to get some of that extra cancer tissue.

To understand the genetic changes in your cancer tissue, we need to compare these changes to your normal cells. To do this, we will analyze a blood sample that will have already been collected as part of your routine care. Many times more blood is collected than is needed for your clinical care, and this is usually thrown away. We are asking your permission to use some of that extra blood for genetic analysis.

In some cases, it may be necessary to collect an additional tube of blood, so we are also asking your permission to draw four tablespoons of blood from a vein in your arm. If you object to having blood drawn, we can collect some normal cells by swabbing cells from the inside of your cheeks.

We are also asking to collect information from your medical records, including your age, ethnic background, diagnosis, disease history, medical treatments, and response to treatments.

You are not expected to need any time to recover from participating in this biobank.

C2. What we do with your samples and medical information

Tissue will be used directly from surgery to attempt to create models. These models will take several months to develop. The remaining tissue will be preserved and stored for later use at our biobank at the Children's Hospital of Pennsylvania.

If a model is successfully created, it will be made available to other researchers, as will the genetic sequence information.

Researchers who obtain these models from the repository will not have access to any identifiable information about you such as your name, address, or date of birth, and they must agree not to attempt to identify you. The genetic information from your tumor sample(s) and from the cancer model will be obtained by a method called sequencing. Sequencing allows researchers to read the codes of instructions that are spelled out in your DNA and help them identify genetic changes that result due to the cancer process.

Information from sequencing of your samples, the models, and your clinical information will be put into a central database, along with information from the other people who volunteer for this project.

To access the database, any researcher and their institution will have to:

- Agree to use the data only for research projects
- Agree to never use the data to identify the donors of the materials
- Apply for access and receive approval from the NIH's Data Access Committee, which has responsibility for enforcing the donor protection rules

D. Potential Risks of Participating in this Project

There are some risks if you decide to participate in this research project.

If the staff learn any new information that might change your mind about continuing in the project, they will tell you about it.

D1. Blood draw risks

In the event that an additional tube of blood needs to be drawn, there are possible side effects from drawing a blood sample, which include mild pain, bleeding, or bruising. Sometimes an infection can happen at the site of the needle insertion. Fainting or light-headedness can sometimes occur, but usually lasts only a few minutes.

D2. Risks if information about you is accidentally released

Keeping your information confidential is very important to us, and we use many safety measures to protect that information. However, some of this information may still be traceable to you and we cannot guarantee that your identity will never become known. It is possible, for example, that there could be violations to the security of the computer systems used to store the link between the random number code and your name or other identifiers. It is also possible that, in the future, someone could compare information in our databases with information from you (or a relative) in another database and be able to identify you (or your relative).

While we believe the risks to you and your family of disclosure of your private information are low, we are unable to tell you exactly what all of the risks are.

There are some laws that protect you against genetic discrimination by employers or insurance companies. In 2008, the Federal government passed the Genetic Information Nondiscrimination Act (GINA), a law that prohibits genetic discrimination in employment and health insurance. It is important to note that while this law protects you from certain kinds of genetic discrimination, there are exceptions. For example, GINA does not apply to employers with fewer than 15 employees. Additionally, this law does not protect you from genetic discrimination in life, disability, or long-term care insurance.

If your identity became known, here are some of the possible risks:

- There could be psychological or social risks associated with loss of privacy. For example, your genetic information could potentially be used in ways that could cause you or your family distress by revealing that you (or a relative) carry a genetic disease. This could lead to the denial of life insurance for you (or a relative).
- There is the possibility that your genetic information may be used to identify you and your family members since relatives share genetic information. Patterns of genetic variation also can be used by law enforcement agencies to identify you or your relatives.
- There may also be other privacy risks that we have not foreseen.

E. Voluntary Participation

The choice to participate in this research is completely up to you. No matter what you decide, it will not affect your medical care.

E1. Benefits of participating in this project

You will not personally benefit from this project because the research is still in its early stages.

The main reason you may want to participate is to help researchers and health professionals around the world to better understand the causes of oligodendroglioma and other cancers so that they can try and find better ways to prevent, detect, treat, and cure them in the future.

E2. Costs and payments to you

It will not cost you anything to participate in this project.

You will not be paid to participate in this project.

Your medical information, tissue samples, and any models that are made will only be used for research. However, it is possible that some of the research using your samples could eventually lead to invention of new diagnostic tests, new drugs, or other products that could be sold by companies. If this happens, you will not get any part of the profits from these products.

E3. Withdrawing from the project

You may choose to stop being part of this research project for any reason. What your withdrawal will mean will depend on certain criteria as described below.

We cannot precisely anticipate how long it will take to work with your samples to successfully make a model. If you withdraw while researchers are still working with your sample in the laboratory, we will stop working with your tissue samples and stop trying to make models, and we will stop collecting any of your medical information for research purposes. Your information will be deleted and your tissue will be thrown away.

If you withdraw after we have created a model and collected necessary information, and if that model has been deposited into a public repository, it will no longer be possible to discard your samples or the models or remove your information. This means that, if you agree to let us use your tissues and information, and if cancer models are successfully grown from your samples, the models and your associated information could be used forever.

If you choose not to participate or to withdraw from the project later, it will not affect your present or future care, and it will not cause any penalty or loss of benefits to which you are otherwise entitled.

To withdraw from this project, please contact the research staff at the phone number on page 1 of this form.

<u>For adults considering whether to be in the biobank</u>:

<u>What if I work for the study center or sponsor? What if I am a family member of someone who works for the study center or sponsor?</u>

Study center/sponsor employees and their family members do not have to be in this biobank. An employee's or his/her family member's decision to be in the biobank, or to leave the biobank early, will not affect the employee's job or job benefits.

<u>For parents/guardians who are considering whether to allow their child to be in the biobank</u>:

<u>What if I work for the study center or sponsor? What if I am a family member of someone who works for the study center or sponsor?</u>

Study center/sponsor employees and their family members do not have to let their children be in this biobank. An employee's or his/her family member's decision to allow a child to be in this biobank, or to have the child leave the biobank early, will not affect the employee's job or job benefits.

F. Agreeing to Participate in the Project

Please keep a copy of this form in case you want to read it again or contact the people running this project.

F1. Contact information and questions

If you have any questions or concerns about this project, please contact the principal investigator at the phone number listed on page 1 of this form. This can include questions about your participation in the project, concerns or complaints about the project, a research-related injury, or if you feel/felt under pressure to enroll in this research project or to continue to participate in this research project.

Quorum Review reviewed this biobank. Quorum Review is a group of people who review research studies to protect the rights and welfare of research participants. Review by Quorum Review does not mean that biobank participation is without risks. If you have questions about your rights as a biobank participant, if you are not able to resolve your concerns, if you have a complaint, or if you have general questions about what it means to participate in a biobank for research, you can call Quorum Review or visit the Quorum Review website at www.QuorumReview.com.

Quorum Review is located in Seattle, Washington.
Office hours are 8:00 AM to 5:00 PM Pacific Time, Monday through Friday.
Ask to speak with a Research Participant Liaison at 888-776-9115 (toll free).

DOCUMENTATION OF CONSENT

My signature below indicates:

- I have had enough time to read the consent form and think about participating in this project
- I have had all of my questions answered to my satisfaction
- I am willing to participate in this biobank
- I have been told that my participation is voluntary and I can withdraw at any time
- I am willing to be contacted in the future for follow-up health information or to learn about new research opportunities

By signing this form, I do not give up any of my legal rights. I will get a signed copy of this consent form.

_____
Printed Name of Participant

_____ _____
Signature of Participant (If an Adult) Date

If participant does not have the legal capacity to consent to their participation:

I am the parent/guardian or legally authorized representative of the participant named above and I consent to his/her participation in this biobank.

_____
Printed Name of Parent/Guardian
or Legally Authorized Representative

_____ _____
Signature of Parent/Guardian Date
or Legally Authorized Representative

I attest that the individual providing consent had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to participation in this biobank.

_____

Printed Name of Person Explaining Consent

_____ _____

Signature of Person Explaining Consent Date