

## **Research Consent Form – Parent or Guardian Consent Form (Brain Tumor Project)**

If you have questions about the study or the consent form at any time, please contact us at 651-229-3480 or [info@braintumorproject.org](mailto:info@braintumorproject.org).

### **RESEARCH CONSENT FORM (Brain Tumor Project) KEY POINTS**

“The Brain Tumor Project” is a patient-driven movement that empowers brain tumor patients to directly transform research and treatment of disease by sharing copies of their medical records and tissue and/or blood samples with researchers in order to accelerate the pace of discovery. Because we are enrolling participants across the country regardless of where they are being treated, this study will allow many more patients to contribute to research than has previously been possible.

#### **1. What is the purpose of this study?**

We want to understand brain tumors better so that we can develop more effective therapies. By partnering directly with patients, we are able to study many more aspects of cancer than would otherwise be possible.

#### **2. What will I/my child have to do if we agree to participate in this study?**

Participation requires little effort. With your permission, we may ask that you send a sample of your child’s saliva to us in a pre-stamped package that we will provide. We may also ask for your child’s medical records. If so, we will take care of obtaining copies of your child’s medical records from the hospitals or centers where your child receives their medical care. If needed, we may contact you to ask if you would be willing to sign an additional release form for your child’s medical records to be shared with us. If you elect to share your child’s tissue with us, we may also obtain small amounts of your child’s stored tumor tissues from hospitals or centers where your child receives their care. If you elect to share your child’s blood with us, we may ask to have a sample of blood (1 tube or 2 teaspoons) drawn at your child’s physician’s office, local clinic, or nearby lab facility – we will provide detailed instructions on how to do this.

#### **3. Does my child have to participate in this study?**

No. Taking part in this study is voluntary. Even if you decide to have your child participate, you can always change your mind and leave the study.

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#### **4. Will my child benefit from participating?**

While taking part in this study may not improve your child's health, the information we collect will aid in our research efforts to provide better cancer treatment and prevention options to future patients. We will provide updates about key research discoveries made possible by your participation on our website.

#### **5. What are the risks of taking part in this research?**

If you elect to share a sample of your child's blood, there are small risks associated with obtaining a sample of blood. Your child may experience slight pain and swelling at the site of the blood draw. These complications are rare and should resolve within a few days. If they do not, you should contact your child's doctor.

There may be a risk that your child's information (which includes your child's genetic information and information from your child's medical records) could be seen by unauthorized individuals. However, we have procedures and security measures in place designed to minimize this risk and protect the confidentiality of your child's information.

In the unlikely event of an unauthorized disclosure, there is a Federal law, known as the Genetic Information Nondiscrimination Act (GINA), which protects your child from genetic discrimination. GINA generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against your child based on your child's genetic information. However, this law does not protect your child against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. If your child already has or have had cancer, any unauthorized disclosure of genetic results is unlikely to change an insurer's view of your child's risk.

#### **6. Will it cost me/my child anything to participate in this study?**

No.

#### **7. Who will use my child's samples and see my child's information?**

Your child's samples and health information will be available to researchers at the Broad Institute of MIT and Harvard, a not-for-profit biomedical research institute. After removing your child's name and other readily identifiable information, we will share results obtained from their participation with the greater research community as well as central data banks at the National Institutes of Health.

#### **8. Can my child stop taking part in this research study?**

Yes, you can withdraw your child from this research study at any time, although any of your child's information that has already been entered into our system cannot be withdrawn. Your child's information would be removed from future studies.

## 9. What if my child or I have questions?

If you or your child have any questions, please send an email to [info@braintumorproject.org](mailto:info@braintumorproject.org) or call 651-229-3480 and ask to speak with a member of the study staff about this study.

## FULL RESEARCH CONSENT FORM

### The Brain Tumor Project

#### A. Introduction

You are being invited to enroll your child in a research study that will collect and analyze samples and health information of patients with brain tumors. This study will help doctors and researchers better understand why brain tumors occur and develop ways to better treat and prevent them.

Cancers occur when the molecules that control normal cell growth (genes and proteins) are altered. Changes in the genes of tumor cells and normal tissues are called “alterations”. Several alterations that occur in certain types of cancers have already been identified and have led to the development of new drugs that specifically target those alterations. However, the vast majority of tumors from patients have not been studied, which means there is a tremendous amount of information still left to be discovered. Our goal is to discover more alterations, and to better understand those that have been previously described. We think this could lead to the development of additional therapies and cures.

Genes are composed of DNA “letters,” which contain the instructions that tell the cells in our bodies how to grow and work. We would like to use your child’s DNA to look for alterations in cancer cell genes using a technology called “sequencing.”

Gene sequencing is a way of reading the DNA to identify alterations in genes that may contribute to the behavior of cells. Some changes in genes occur only in cancer cells. Others occur in normal cells as well, in the genes that may have been passed from parent to child. This research study will examine both kinds of genes.

You are being asked to have your child participate in the study because your child has a brain tumor. Other than providing your child’s saliva samples and, if you elect to, your child’s blood sample(s) (1 tube or 2 teaspoons per sample), participating in the study involves no additional tests or procedures.

This form explains why this research study is being done, what is involved in participating, the possible risks and benefits of the study, alternatives to participation, and your child’s rights as a participant. The decision is yours. We encourage you to ask questions about the study now or in the future.

#### B. Why is this research study being done?

We want to understand cancer better so that we can develop more effective therapies. By partnering directly with patients, we will be able to study many more aspects of cancer than has previously been possible. In addition, because we are enrolling participants across the country regardless of where they are being treated, this study will allow many more patients to directly contribute to research than might otherwise be feasible.

### **C. What other options are there?**

Taking part in this research study is voluntary – you may choose to not have your child participate. Your decision to not have your child participate will not affect your child's medical care in any way or result in any penalty or loss of benefits.

### **D. What is involved in the research study?**

With your consent, we may obtain copies of your child's medical records and ask that you collect a sample of your child's saliva at home—we will provide detailed instructions on how to do this. We may contact you to ask if you would be willing to sign an additional release form for your child's medical records to be shared with us. You may also choose to send your child's medical records directly to us. If you elect to share your child's tissue samples with us, we may request a portion of your child's tumor tissues through already stored biopsies or surgical specimens in hospitals or centers where your child received medical care in the past.

If you elect to share a sample of your child's blood with us as well, we may ask you to have a sample of blood (1 tube or 2 teaspoons) drawn at your child's physician's office, local clinic, or nearby lab facility. We'll ask you to send any blood and/or saliva sample(s) to us in pre-stamped packages that we will provide. We may ask your child to provide blood at multiple different time points. We will contact you before sending the blood kit. If you do not want your child to participate in the blood draw at that time, please just inform one of the study staff members.

We will analyze the genes in your child's cancer cells (obtained from their tissue or blood sample) and your child's normal cells (obtained from your child's blood sample or from your child's saliva sample). No additional procedures will be required. The results of this analysis will be used to try to develop better ways to treat and prevent cancers.

We will link the results of the gene tests on your child's cancer cells and normal cells with medical information that has been generated during the course of your child's treatment. We are asking your permission to obtain a copy of your child's medical record from places where your child has received care for their cancer.

In some cases, a research doctor may contact you to find out if you would be interested in having your child participate in a different or future research study based on information that may have been found in your child's samples or medical information.

To allow sharing of information with other researchers, the National Institutes of Health (NIH) and other organizations have developed central data (information) banks that analyze information and collect the results of certain types of genetic studies. These central banks will store your child's genetic and medical information and provide the information to qualified researchers to do more studies. We will also store your child's genetic and medical information at the Broad Institute of MIT and Harvard and share your child's information with other qualified researchers. Therefore, we are asking your permission to share your child's results with these special banks and other researchers, and have your child's information used for future research studies, including studies that

have not yet been designed, studies involving diseases other than cancer, and/or studies that may be for commercial purposes (such as the development or approval of new drugs). Your child's information will be sent to central banks and other researchers only with a code number attached. Your child's name, social security number, and other information that could readily identify your child will not be shared with central banks or other researchers. We will never sell your child's readily identifiable information to anyone under any circumstances.

#### **E. How long will my child be in this research study?**

Your child may be asked to give samples of blood, tissue, and/or saliva after you and your child consent to enrolling in this study. You may also be asked to complete additional questionnaires about your child's experience with a brain tumor. We will keep your child's blood, tissue, and saliva samples and medical records indefinitely until this study is finished, unless you inform us that you no longer wish to have your child participate. You may do this at any time. More information about how to stop being in the study is below.

Once the study is finished, any left over blood and saliva samples and your child's medical records will be destroyed. Any tissue samples that we have will be returned to the pathology department at the hospital or other place where your child received treatment.

#### **F. What kind of information could be found in this study and will I be able to see it?**

The gene tests in this study are being done to add to our knowledge of how genes and other factors affect cancer. This information will be kept confidential and while you will not receive information about your child's personal results obtained from studying your child's blood, saliva, or tissue samples, we will provide general results and major discoveries to all participants. We will do this by regularly updating the website that you used to enroll in this study. Furthermore, we will publish important discoveries found through these studies in the scientific literature so that the entire research community can work together to better understand cancer. Your child's individual data will not be published in a way in which your child could be readily identified. Abstracts, which are plain language summaries of the published reports, will be available to you and the general public.

#### **G. What are the risks or discomforts of the research study?**

If you elect to share a sample of your child's blood, there are small risks associated with obtaining the tube of blood. Your child may experience slight pain and swelling at the site of the blood draw. These complications are rare and should resolve within a few days. If they do not, you should contact your child's doctor.

There is a small risk that by participating in this study, the gene test results, including the identification of genetic changes in your child's cancer or normal cells, could be seen

by unauthorized individuals. We have tried to minimize this risk by carefully limiting access to the computers that would house your child's information to the staff of this research study.

In the unlikely event of an unauthorized disclosure, there is a Federal law, known as the Genetic Information Nondiscrimination Act (GINA), which protects your child from genetic discrimination. GINA generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against your child based on your child's genetic information. However, this law does not protect your child against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. If your child already has or have had cancer, any unauthorized disclosure of genetic results is unlikely to change an insurer's view of your child's risk.

There is a small but real risk that if your child's samples are used for this research study, they might not be available for clinical care in the future. However, we have attempted to minimize this risk in the following way: the pathologists in the department of pathology where your child's specimens are kept will not release your child's specimen unless they believe that the material remaining after the research test is performed is sufficient for any future clinical needs.

#### **H. What are the benefits of the research study?**

Taking part in this research study may not directly benefit your child. By joining this study, your child will help us and other researchers understand how to use gene tests to improve the care of patients with cancer in the future. We will provide study participants updates on our project website about key research discoveries made possible by your participation.

#### **I. Can my child stop being in the research study and what are my child's rights?**

Your child can stop being in the research study at any time. We will not be able to withdraw all the information that already has been used for research. If you tell us that you/your child wants to stop being in the study, we will return any remaining tumor samples from where we obtained them, and destroy any remaining blood, saliva samples, or DNA samples we have. We will not perform any additional tests on the samples. Additionally, we will not collect any additional medical records and we will destroy the medical records we already have. However, we will keep the results from the tests we did before your child stopped being in the study. We will also keep the information we learned from reviewing your child's medical records before your child stopped being in the study. We will not be able to take back the information that already has been used or shared with other researchers, central data banks, or that has been used to carry out related activities such as oversight, or that is needed to ensure quality of the study.

To withdraw your permission, you must do so in writing by contacting the researcher listed below in the section: "Whom do I contact if my child or I have questions about the research study?" If you/your child choose to not participate, or if your child is not eligible



to participate, or if your child withdraws from this research study, this will not affect your child's present or future care and will not cause any penalty or loss of benefits to which your child are otherwise entitled.

**J. Will my child be paid to take part in this research study?**

There is no financial compensation for participation in this study.

**K. What are the costs?**

There are no costs to you or your child to participate in this study.

**L. What happens if my child is injured or sick because they took part in this research study?**

There is little risk that your child will become injured or sick by taking part in this study. There are no plans for this project to pay you/your child or give you/your child other compensation for any injury. You and your child do not give up your legal rights by signing this form. If you/your child think your child has been injured as a result of taking part in this research study, please tell the person in charge of this research study as soon as possible. The research doctor's contact information is listed in this consent form.

**M. What about confidentiality?**

We will take rigorous measures to protect the confidentiality and security of all your child's information, but we are unable to guarantee complete confidentiality. Information shared with the research team through email, or information accessible from a link in an email, is only protected by the security measures in place for you/your child's email account. Information from your child's medical records and genomics tests will be protected in a HIPAA compliant database.

When we receive any of your child's samples, your child's name, social security number, and other information that could be used to readily identify your child will be removed and replaced by a code. If we send your child's samples to our collaborators for gene testing, the samples will be identified using only this code. The medical records that we receive will be reviewed by our research team to confirm that your child is eligible for the study and to obtain information about your child's medical condition and treatment.

We will store all of your child's identifiable information related to the study (including your child's medical records) in locked file cabinets and in password-protected computer files or secure databases at the Broad Institute and we will limit access to such files. We may share your child's identifiable information or coded information, as necessary, with regulatory or oversight authorities (such as the Office for Human Research Protections), ethics committees reviewing the conduct of the study, or as otherwise required by law.



When we send the results of the gene tests and your child's medical information to central data banks or other researchers, they will not contain your child's name, social security number, or other information that could be used to readily identify your child.

The results of this research study or future research studies using the information from this study may be published in research papers or included in presentations that will become part of the scientific literature. Your child will not be identified in publications or presentations.

#### **N. Whom do I contact if my child or I have questions about the research study?**

If you or your child have questions about the study, please contact the research doctor or study staff listed below by emailing [info@braintumorproject.org](mailto:info@braintumorproject.org) or calling 651-229-3480:

- Nikhil Wagle, MD
- Corrie Painter, PhD

For questions about your child's rights as a patient, please contact a representative of the Office for Human Research Studies at (617)-632-3029. This can include questions about your child's participation in the study, concerns about the study, a research related injury, or if your child feel/felt under pressure to enroll in this research study or to continue to participate in this research study. Please keep a copy of this document in case you want to read it again.

#### **O. Authorization to use your child's health information for research purposes**

Because information about your child's health is personal and private, it generally cannot be used in this research study without your written authorization. Federal law requires that your child's health care providers and healthcare institutions (hospitals, clinics, doctor's offices) protect the privacy of information that identifies your child and relates to your child's past, present, and future physical and mental health conditions.

If you sign this form, it will provide your child's health care providers and healthcare institutions the authorization to disclose your child's protected health information to the Broad Institute for use in this research study. The form is intended to inform you about how your child's health information will be used or disclosed in the study. Your child's information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

##### **1. What personal information about my child will be used or shared with others during this research?**

- Health information created from study-related tests and/or questionnaires
- Your child's medical records

- Your child's saliva sample

If elected (at the end of this form):

- Your child's blood sample(s)
- Your child's tissue samples relevant to this research study and related records

## **2. Why will protected information about my child be used or shared with others?**

The main reasons include the following:

- To conduct and oversee the research described earlier in this form;
- To ensure the research meets legal, institutional, and accreditation requirements;
- To conduct public health activities (including reporting of adverse events or situations where you or others may be at risk of harm);
- To better understand the diseases being studied and to improve the design of future studies

## **3. Who will use or share protected health information about my child?**

The Broad Institute and its researchers and affiliated research staff will use and/or share your child's personal health information in connection with this research study.

## **4. With whom outside of the Broad Institute may my child's personal health information be shared?**

While all reasonable efforts will be made to protect the confidentiality of your child's protected health information, it may also be shared with the following entities:

- Federal and state agencies (for example, the Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, and/or the Office for Human Research Protections), or other domestic or foreign government bodies if required by law and/or necessary for oversight purposes. A qualified representative of the FDA and the National Cancer Institute may review your medical records.
- Outside individuals or entities that have a need to access this information to perform functions relating to the conduct of this research such as data storage companies.

Some who may receive your child's personal health information may not have to satisfy the privacy rules and requirements. They, in fact, may share your child's information with others without your permission.

## **5. For how long will protected health information about my child be used or shared with others?**

There is no scheduled date at which your child's protected health information that is

being used or shared for this research will be destroyed, because research is an ongoing process.

#### **6. Statement of privacy rights:**

- You have the right to withdraw your permission for the doctors and researchers to use or share your child's protected health information. We will not be able to withdraw all the information that already has been used or shared with others to carry out related activities such as oversight, or that is needed to ensure quality of the study. To withdraw your permission, you must do so in writing by contacting the researcher listed above in the section: "Whom do I contact if I have questions about the research study?"
- You have the right to request access to your child's personal health information that is used or shared during this research and that is related to your child's treatment or payment for your child's treatment. To request this information, please contact your child's doctor who will request this information from the study directors.

#### **P. Participation Information**

If you decide to sign this consent form, we may ask you for information about contacting your child's physicians and the hospitals that your child was treated at for their cancer. We will not disclose details about the results of your child's participation in this study with any of the individuals that we contact, but rather ask them to provide us with your child's medical history and your child's tissue samples.

#### **Q. Documentation of Consent**

##### **This is what I agree to:**

- You can work with me to arrange a sample of my child's blood to be drawn at my child's physician's office, local clinic, or nearby lab facility.

Yes          No

- You can request my child's stored tissue samples from my child's physicians and the hospitals and other places where my child received care, perform (or collaborate with others to perform) gene tests on the samples, and store the samples until this research study is complete.

Yes          No

##### **In addition, I agree to all of the following:**

- You can request my child's medical records from my child's physicians and the hospitals and other places where my child received and/or continue to receive treatment and link results of the gene tests you perform on my child's saliva and, if I elect on this

form, blood and tissue samples with my child's medical information from my child's medical records.

- You can analyze my child's saliva sample that I will send you, link the results to my child's medical information and other specimens, and store the specimen to use it for future research.
- You can perform (or collaborate with others to perform) gene tests on the blood and saliva samples from my child that I will send you and store the samples until this research study is complete.
- You can use the results of the gene tests and my child's medical information for future research studies, including studies that have not yet been designed, studies for diseases other than cancer, and/or studies that may be for commercial purposes.
- You can share the results of the gene tests and my child's medical information with established public databases (e.g., the NIH, cBioPortal, Tumor Portal, The Exome Aggregation Consortium (ExAC)/Genome Aggregation Database (gnomAD)) and with other qualified researchers in a manner that does not include my child's name, social security number, or any other information that could be used to readily identify my child, to be used by other qualified researchers to perform future research studies, including studies that have not yet been designed, studies for diseases other than cancer, and studies that may be for commercial purposes.
- You can contact me in the future for reasons related to this research study, for example to ask if I would be willing to sign any additional documents that my child's hospital(s) may require in order to share my child's medical records, or to ask for my child's contact information when they are approaching the age of consenting for themselves.
- You can collect my child's medical information until my child is able to consent for themselves (age of majority; between 18 and 21 years old depending on location). The data collection and generation may occur after my child reaches age of majority, but will only be done with information from when my child was a minor.
- If my child remains in the study when they reach the age of consenting for themselves, you can contact them to re-consent to the study. You can contact me to get my child's contact information. After re-consenting, the project team will continue to request medical records and tissue samples from any point in my child's brain tumor treatment.
- When my child reaches the age of majority, they will also be given the option to keep or remove my access to their forms and data related to this study.

**My full name below indicates:**

I have had enough time to read the consent and think about agreeing to participate in this study;

I have had all of our questions answered to our satisfaction;

I am willing to have my child participate in this research study;

I have been told that my child's participation is voluntary and if I decide not to have my child participate it will have no impact on my child's medical care;

I have been told that if I decide to have my child participate now, I can decide to withdraw my child from the study at any time.

I acknowledge that a copy of the signed consent form will be sent to my email address

**Your Child's First Name:**

**Your Child's Last Name:**

**Your child's Date of Birth (mm/dd/yyyy):**

**Your First Name:**

**Your Last Name:**

**Relationship to child (Parent/Guardian)**

**Date:**

**Your Signature (Full Name):**