CINCINNATI CHILDREN'S HOSPITAL MEDICAL CENTER
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

STUDY TITLE: The International Diffuse Intrinsic Pontine Glioma (DIPG) Registry and Repository

SPONSOR NAME: Maryam Fouladi, MD

INVESTIGATOR INFORMATION:

Maryam Fouladi, MD	(513) 636-4200 (ask for oncologist on call)
Principal Investigator Name	Telephone Number 24 hr Emergency Contact

Subject Name: _____ Date of Birth: _____/_____/____

When we say "you" in this consent form, we mean you or your child; "we" means the study staff.

INTRODUCTION:

You have been asked to participate in a research registry and repository study. It is important that you read and understand the following explanation of what will happen on this study. If you are unsure of what anything in this consent form means, please ask the study doctor. Participation in this registry and repository is completely voluntary and will not affect your treatment. Your doctors will take care of you in exactly the same way whether or not you decide to enroll in this registry and repository. Please take your time to make your decision about participating. You may discuss your decision with your friends, family, and health care team. If you have questions, you may ask your doctor.

WHO IS CONDUCTING THE RESEARCH STUDY?

This study is directed by Maryam Fouladi, MD, the researcher at Cincinnati Children's Hospital who is leading the International Diffuse Intrinsic Pontine Glioma Registry and Repository. Funds to conduct this study are provided by the supporting members of the DIPG Collaborative.

WHY IS THIS STUDY BEING DONE?

Doctors and other medical scientists want learn about the biology of DIPG and to develop better ways to diagnose and treat patients with DIPG. To do this, they need more information about the characteristics of DIPG tumors. Therefore, they want to establish a central location for clinical information and tumor tissue collected from DIPG patients.

The purposes of this study are:

- To enroll patients diagnosed with DIPG in the International DIPG Registry and Repository.

- To provide a central location for clinical information, scans, and tissue samples from patients with DIPG enrolled in the registry.

- To collect tissue samples in order to study how DIPG works on the molecular level. Researchers may use the tissue samples to study molecules such as proteins and DNA. Proteins are needed for the body to function properly and DNA is the molecule that carries our genetic information. Other researchers will be able to use the stored samples in the future to learn more about DIPG. The information researchers get from the research studies will be kept in the registry along with the clinical information.

- To help DIPG investigators around the world to work together to make more consistent diagnosis and better design of future research studies. We hope this will lead to better treatments for DIPG in the future.

To learn more about the DIPG Registry, please visit our website: http://dipgregistry.org/.

WHY HAVE YOU BEEN ASKED TO TAKE PART IN THIS RESEARCH STUDY?

You are being asked to take part in this research study because you have been diagnosed with diffuse intrinsic pontine glioma (DIPG), a type of brain tumor. There is currently little information available about patients with DIPG.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

There is no limit to how many people can participate in this study. This registry will enroll people from around the world, and about 150 people are expected to enroll per year.

WHAT IS INVOLVED IN THE STUDY?

Patients who agree to participate will have clinical information from their medical record stored in the DIPG Registry and Repository. For example, clinical information that will be stored includes; what symptoms you experienced when you were first diagnosed, what treatments you have for DIPG, and any side effects. No extra scans or procedures will be done just for this study. All medical information and tissue samples gathered for this study will be collected as part of your routine cancer care.

We will collect and review the results of radiologic scans (CT, PET and MRI scans) that were previously done to evaluate your tumor status and its response. We will also collect and review

scans performed anytime during and after your treatment.

If you had tumor tissue removed in the past or have tumor tissue removed at any time during or after treatment, any left-over tissue will be reviewed by a group of researchers who specialize in brain tumors. This group of researchers will also study your tissue to see how DIPG cells work and how they are different from normal brain cells. Information from this review will be kept in the registry. The left-over tissue will also be stored, so other researchers can use it in future studies to learn more about DIPG. No surgical procedures will be done for this study. We will only use left-over tissue from your initial diagnosis or any tissue collected before or after treatment. If you do not have tissue collected during or after treatment ask your doctor how you can donate tissue in the future.

Major centers for the DIPG registry and repository are located at Cincinnati Children's, and also in Canada, Europe and Australia. Your data/samples may be shared internationally.

If you have left-over tissue and you live in Canada, your tissue samples will be sent to The Hospital for Sick Children in Toronto, Canada, for storage in the repository.

HOW LONG WILL I BE ON THE STUDY?

The information obtained from you can be used indefinitely. Researchers will continue to collect information about you regarding any follow up scans, future treatment, and additional tissue samples (if you have surgery). We will continue to collect this information from your doctor, and we may also contact you with questions about how you are doing.

CAN I STOP BEING IN THE STUDY?

Yes. If you decide to participate, you have the right to remove yourself from this registry at any time. Just contact the study team at 1-877-349-8074, if you would like to stop.

WHAT ARE THE RISKS OF THE STUDY?

You will not need to undergo any new tests or other medical procedures to take part in this research study, therefore there are no medical risks.

The greatest risk to you is the release of information from your health records. Sometimes, health records have been used against patients and their families. For example, insurance companies may deny a patient insurance or employers may not hire someone with a certain illness (such as AIDS or cancer). Cincinnati Children's Hospital Medical Center will protect your (child's) health records so that your name, address, and phone number will be kept private. The chance that this information will be given to someone else is very small.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

There are no direct benefits to you from taking part in this study. We hope the information

collected and learned from the registry will benefit patients in the future.

WHAT OTHER OPTIONS ARE THERE?

You have the option not to participate in this study. If you do not participate, it will not affect your medical care.

WHAT ARE YOUR COSTS TO BE IN THIS STUDY?

Neither you nor your insurance company will be charged for participation in this study.

WILL YOU BE PAID TO PARTICIPATE IN THIS RESEARCH STUDY?

You will not be paid to participate in this research study. Tissues obtained in this research may result in the development of a product that could be patented or licensed. There are no plans to provide financial compensation to you should this occur.

WHO DO YOU CALL IF YOU HAVE QUESTIONS OR PROBLEMS?

For questions about this research study, you can contact the researcher Dr. Maryam Fouladi, at 513-803-1126 or the research coordinator at 1-877-349-8074 at Cincinnati Children's Hospital Medical Center.

If you have general questions about your rights as a research participant in this research study, you can call the Cincinnati Children's Hospital Medical Center Institutional Review Board at 513-636-8039.

HOW WILL INFORMATION ABOUT YOU BE KEPT PRIVATE?

Cincinnati Children's Hospital Medical Center and/or the Investigator will take the following precautionary measures to protect your privacy and confidentiality of your research and/or medical records:

- Your individual identifiers (name, address, date of birth, etc.) will not be used in any publications or reports. All your study records will be kept in secure areas with limited access.

- Medical scientists may request banked tissue and information for future research studies from the International DIPG Registry and Repository Committee. Your medical information and tissues will be labeled with a code number. Your individual identifiers will not be released with the banked information. Only the Cincinnati Children's research team will have the information that matches the code number to your identifying information.

A copy of this consent form will be included in your medical research record.

You will be registered in the Cincinnati Children's Hospital Medical Center's computer system as a research subject.

By signing this consent form, you are giving permission for representatives of Cincinnati Children's Hospital Medical Center ("CCHMC"), the Investigator and CCHMC employees involved with the research study including the Institutional Review Board and the Office for Research Compliance and Regulatory Affairs, and any sponsoring company or their appointed agent as well as representatives and staff of**:** the National Cancer Institute (NCI), the National Institutes of Health (NIH) and the Office for Human Research Protection (OHRP), the Federal Food and Drug Administration (FDA), the National Cancer Data Base (NCDB), the Ohio Department of Health (Cancer Registry), the International DIPG Registry and Repository, and referring institutions involved with the research study to be allowed to inspect and/or copy sections of your medical and research records related to this study.

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. GINA does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination based on an already-diagnosed genetic condition or disease.

The information from the research study may be published; however, you will not be identified in such publication. The publication will not contain information about you that would enable someone to determine your identity as a research participant without your authorization.

You can find more information about who can see your information and how it can be used in the following "HIPAA Authorization" section.

HIPAA AUTHORIZATION FOR USE/DISCLOSURE OF PROTECTED HEALTH INFORMATION FOR A RESEARCH STUDY

We understand that information about you and your health is personal and we are committed to protecting the privacy of that information. Because of our commitment to protect your privacy, we must obtain your written authorization (permission) before we may use or disclose (release) your "protected health information" (sometimes referred to as "PHI") related to the study described to you. This form provides that authorization and helps us make sure that you are properly informed of how this information will be used or disclosed. Please read the information below carefully before signing this form either for you, as the participant, or as the personal representative (parent, legal guardian, etc.) for the participant. Note that when we refer to "you" or "your" throughout this document, we are referring to the participant, even when this form is signed by the participant's personal representative.

USE AND DISCLOSURE COVERED BY THIS AUTHORIZATION

If you sign this document, you give permission to Cincinnati Children's Hospital Medical Center ("Cincinnati Children's") to use or disclose your medical and research information for the purpose of this study. Your PHI that will be used and disclosed in connection with this study consists of:

- Your medical records
- Your research record for this study
- Results of your laboratory tests
- Clinical and research observations made during your participation in the study
- In the event that your medical record contains such information, information concerning HIV testing or the treatment of AIDS or AIDS-related conditions, drug or alcohol abuse, drug-related conditions, alcoholism, and/or psychiatric/psychological conditions (but not psychotherapy notes).

Who will disclose, receive and/or use the information?

This form authorizes the following to disclose, use and receive your PHI:

- Every research site of the study (including Cincinnati Children's and each site's research staff and medical staff)
- Every health care provider who provides services to you in connection with the study
- Any laboratories and other individuals and organizations that analyze your PHI in connection with the study
- The Sponsor and the people and companies they use to oversee, administer and/or conduct the study
- Federal regulatory agencies, other foreign regulatory agencies, and others as required by law
- The members of the Cincinnati Children's Institutional Review Board and staff of the Office of Research Compliance and Regulatory Affairs
- The Principal Investigator and members of the study's research team
- Data Safety Monitoring Board (if applicable)

By signing this document, you are authorizing Cincinnati Children's to use and/or disclose your PHI for this study. The purpose for the uses and disclosures is to conduct the study explained to you during the informed consent process and to ensure that information relating to the study is available to all parties who may need it for research purposes.

Those persons who receive your information may not be required by Federal privacy laws (such as the Health Insurance Portability and Accountability Act, also known as "HIPAA") to protect it and may share the information with others without your permission, if permitted by laws governing them.

You may revoke (choose to withdraw) this authorization at any time after you have signed it by providing the Principal Investigator (listed on the first page of the informed consent

document) with a written statement that you wish to revoke it. Your revocation will be effective immediately and your PHI can no longer be used or disclosed for this study by Cincinnati Children's and the other persons or organizations that are identified above, except to the extent that Cincinnati Children's and/or the other persons or organizations identified above have already acted in reliance on the Authorization. In addition, the information may continue to be used and/or disclosed to preserve the integrity of the study.
Unless you notify us in writing of your decision to withdraw this authorization to use and disclose your PHI, it will expire at the end of the study. If the study involves the creation or maintenance of a research database repository, this authorization will not expire.

If you refuse to sign this authorization, you may not be able to receive research-related procedures and may not be able to continue in this study. However, your rights concerning treatment not related to this study, payment for services, enrollment in a health plan or eligibility of benefits will not be affected.

For further information about your rights, please see the Cincinnati Children's Notice of Privacy Practices on our website at http://www.cincinnatichildrens.org/about/corporate/hipaa.

SIGNATURES

I have read the information given above. The investigator or his/her designee have personally discussed with me the research study and have answered my questions. I am aware that, like in any research, the investigators cannot always predict what may happen or possibly go wrong. I have been given sufficient time to consider if I (or my child) should participate in this study. I hereby give my consent for myself (or my child) to take part in this study as a research study subject. I will receive a copy of this signed form for my records.

_____ _____
Signature of Subject Date

_____ _____
Signature of Subject's Parent or Legally Authorized Representative* Date

*** If signed by a legally authorized representative, a description of such representative's authority must be provided**

_____ _____
Signature of individual obtaining consent Date