

# Columbia University Medical Center Consent Form

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**Attached to Protocol: IRB-AAAA8505**

**Principal Investigator: Jeffrey Bruce (jnb2)**

**IRB Protocol Title: Genetic and Radiographic Analysis of Pilomyxoid Astrocytoma**

**Consent Number: CF-AAAC0789**

Participation Duration: 15

Anticipated Number of Subjects: 50

## Contact

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<u>Contact</u>	<u>Title</u>	<u>Contact Type</u>	<u>Numbers</u>
Richard Anderson	Assistant Professor of Neurosurgery	Co-Investigator	Telephone: 2123058101
Jeffrey Bruce	Professor	Principal Investigator	Telephone: 212-305-7346
Ricardo Komotar	Resident, Neurosurgery	Co-Investigator	Telephone: 212-305-4679
Ruchey Sharma	Departmental Administrator	Administrative	Telephone: 212-305-7056

## Research Purpose

The purpose of this study is to examine the genetic mutations in Pilomyxoid Astrocytoma to better understand the molecular events that underly its aggressive clinical course and evaluate this tumors radiographic presentation.

## Information on Research

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This study involves research into the gene mutations and MRI characteristics of Pilomyxoid Astrocytoma (PMA). The purpose of our project is to uncover genetic mutations in PMA to better understand underlying molecular events which account for its aggressive clinical course, and evaluate MRI scans to learn more about its radiographic presentation. The brain tumor you/your child has is a rare pediatric neoplasm that has not yet been genetically studied. You/your child will be asked to sign a consent form, a HIPAA waiver, and a brief questionnaire. The expected time required for participation is fifteen minutes. The questionnaire will provide us with the data necessary to retrieve tissue samples and MRI scans from you/your child's treating physician. These samples and scans will be used in our investigations. Tumor tissue will be studied that has already been stored and is not needed for clinical care. Neither you nor your child will be required to complete any further



procedures.

### **Risks**

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There are no risks to participation in this study.

### **Benefits**

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There is no direct benefit to participation in this study. Discovery of genetic mutations in pilomyxoid astrocytoma, however, has the potential to improve diagnosis and treatment of this pediatric tumor. Furthermore, information gained from this study has more global applications in the understanding of the biologic process in all pediatric brain tumors.

### **Alternative Procedures**

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There are no alternative procedures.

### **Compensation**

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There is no compensation for this study.

### **Additional Costs**

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There are no additional costs associated with this study.

### **Research Related Injuries**

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There are no risks for research related injuries.

### **Confidentiality**

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Misuse of genetic information could adversely affect insurability and employability. This study involves research in genetics that could be used to develop such genetic testing in the future. At present, any information obtained from this research cannot be considered to provide meaningful information about the health of a study participant. Therefore, if you decide to participate in this research study and agree to genetic research, and if you are asked, you should state that you have not had a genetic test. For logistical reasons, our proposal cannot maintain strict anonymity, since there is identifying information that is collected with the pathological specimen in order to properly match genetic information with a given individual. However, we will deidentify the data after it has been collected. Deidentification involves the replacement of direct patient identifier from biological specimens or data sets with a linking code by which the data remain identifiable. For linking purposes, we use study specific codes, rather than medical record numbers, social security numbers, or other easily decoded combinations of initials and birth dates. Access to the linking files will be restricted to the PI, coinvestigator and the research team at Columbia University, and only given on an as needed basis. More specifically, all clinical data and followup information will be locked in a secure metal file cabinet with only the PI and coinvestigator having keys. Digital files will be maintained on the primary investigators computer with password protection. All patient identifiers are removed from the pathological specimens before sending them for genetic analysis. All patient identifiers are removed from the MRI scans as well. The results of the genetic analysis will not be released to any individual.



Applicable Institutional Review Boards ("IRBs") that independently review the study to assure, adequate protection of research participants, as required by federal regulations. The investigator, regulatory authorities, and IRB may keep the research records indefinitely. If the results of the study are published or presented at a medical or scientific meeting, you will not be identified.

### **Voluntary Participation**

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Participation is voluntary. If you/your child do not want to take part in this study, you/your child's physician under the normal standard of care will follow you. Refusal to participate will not influence your medical care. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. You/your child may chose not to be in the study or, if you/your child agree to be in the study, you/ your child may withdraw from the study at any time. You/your child may also withdraw you/your child authorization for us to use your data, but must do this in writing. You/your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you/your child are entitled, and will not affect your access to health care.

We will provide you/your child with any information that becomes available during the study that might affect you/your child's decision to stay in the study.

### **Additional Information**

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If you have any question or concerns about the study, you may contact the Principal Investigator, Dr. Jeffrey N. Bruce (212-305-7346) or the coinvestigator, Dr. Ricardo J. Komotar (212-305-4679) listed on this consent form.

If you have any question about the patient's rights as a subject, you may contact:

Health Sciences Institutional Review Board  
Columbia University Health Sciences  
722 West 168th Street, 4th Floor  
New York, NY 10032  
Telephone: (212) 305-5883

An Institutional Review Board is a committee organized to protect the rights and welfare of human subjects involved in research.

### **Statement of Consent:**

I voluntarily consent to participate in the study. I have thoroughly read this consent form and understand the nature and the purpose of the study. I have fully discussed the study with the investigator or study staff, have had the opportunity to ask questions and have received satisfactory answers. The explanation I have been given has mentioned both the possible risks and benefits to participating in the study and the alternatives to participation. I understand that I am free to not participate in the study or to withdraw at any time. My decision to not participate or to withdraw from the study will not affect my future care or status with this investigator. I understand that I will receive



and may keep a copy of this signed and dated consent form. By signing and dating this consent form, I have not waived any of the legal rights that I would have if I were not a participation in the study.

## Signature

*Study Coordinator*

Print Name \_\_\_\_\_ Signature \_\_\_\_\_ Date & Time \_\_\_\_\_

*Study Subject*

Print Name \_\_\_\_\_ Signature \_\_\_\_\_ Date & Time \_\_\_\_\_

*Principal Investigator*

Print Name \_\_\_\_\_ Signature \_\_\_\_\_ Date & Time \_\_\_\_\_

