Joseph G. Gleeson, MD and his associates are conducting a research study to find out more why some children have brain diseases such as seizures and mental retardation. This research project studies the genes from children with brain diseases and their parents, in order to pinpoint which genes are responsible for brain diseases. You are asked to participate because someone in your family either has mental retardation or convulsions or may be at risk for developing these sorts of problems. There will be approximately 800 new participants joining this study every year. To date there have been over 2700 individuals participating in this project.

If you agree to be in this study, the following will happen to you:

1. A blood sample (approximately 3 tablespoons) will be drawn from a vein in your arm, or if you are having surgery, from the IV line that is placed for anesthesia, or a saliva sample (approximately 2 tablespoons) will be collected from you and sent to Dr. Gleeson's laboratory.
2. If you are having surgery, the surgeon will save a small piece of tissue that would have been thrown away otherwise.
3. Medical records from each member of your family will be forwarded to Dr. Gleeson for review.
4. After drawing your blood or saliva, and surgical tissue if applicable, Dr. Gleeson will be responsible for deciding how it will be used. The blood sample may be used for additional research carried out in Dr. Gleeson’s lab. A small amount of your DNA sample will be sent to a DNA bank and it may be used by Dr. William Dobyns at the University of Chicago; Dr. Elliot Sherr at the University of California, San Francisco; Dr. Charles Schwartz at Greenwood Genetic Center, and other future researchers collaborating on this project. The sample will not include your name or any other identifying information, but it will be sent with the name of the disease that we are studying in your family. Your sample may be used to validate new genetic mutations or to identify additional mutations in new genes. You consent to such uses. If you later decide you do not want your blood used for research, you can tell Dr. Gleeson and we will do our best to destroy your blood sample.
5. You will not receive compensation for participating in this study, though you may be reimbursed for your travel expenses. Additionally, the necessary phlebotomy procedures or doctor visits will be of no cost to you.

Participation in this study may involve some added risks and discomforts. These include:

1. The blood draw may hurt slightly. Risks include possible pain, discomfort, and bruising at the needle site, possible dizziness and fainting and possible infection. Any associated bleeding will be treated with pressure and the area may bruise temporarily. If infection occurs, it will require treatment.
2. There is a chance that participation in this study could cause psychological distress. Some people involved in genetic studies have felt anxious about the possibility of having a gene that places them at risk or that can be passed on to children. If you experience these feelings during the study, have your parents contact us and we will arrange for you to speak with a genetic counselor.

3. There is a possibility that participation in the study could cause social harm, which can be associated with the gathering of genetic information. We will do our best to keep all information confidential. However, the testing may find a gene, which puts you at risk for developing a genetic disease at some point in the future. This information, if given to the wrong source, may adversely affect you socially and cause you to be stigmatized. We will not make this information available to anyone unless your parents ask us to do so. All of the information we collect during the study will be kept locked and secured. None of it will be released unless your parents ask us to do so. In the course of collection of the clinical information we may need to review your medical records such as MRI scans, pathology reports, laboratory or progress reports etc. This information as well, will be kept confidential and not shared with anyone outside this project. We will not release this information to insurance companies, family members, work places or any other institutions. Even though, the risk of losing confidentiality via medical records cannot be fully eradicated, we take all the precautions to protect this information.

4. In order to help advance future patient screening strategies, a new condition in our research study might require that your DNA sequence, diagnosis, and de-identified pedigree data be deposited into the NIH’s (National Institute of Health) dbGAP database. Your personally identifiable information (PII) will not be shared on this database. Your PII will remain confidential. Only de-identified genetic data would be deposited into the dbGaP database.

Dr. Gleeson and/or __________________________ have told you about the study and have answered all your questions.

Your other option is not to participate in this study. You do not have to be in this study if you don’t want to be. You can stop any time you want and no one will be upset or angry with you.

You agree to be in this study:

_________________________________________  __________________________
Adolescent’s Signature                      Date

_________________________________________  __________________________
Witness                                    Date