

Columbia University Medical Center Consent Form

Attached to Protocol: IRB-AAAA6217

**Principal Investigator: David Greenberg
(dag2005)**

**IRB Protocol Title: A MULTICENTER STUDY OF IDIOPATHIC GENERALIZED
EPILEPSY
Phenotypes, Drug Response & Genetic Epidemiology of IGE**

Consent Number: CF-AAAG0028

Participation Duration: 2 hours

Anticipated Number of Subjects: 1500

Contact

<u>Contact</u>	<u>Title</u>	<u>Contact Type</u>	<u>Numbers</u>
David Greenberg	Professor Clin		Telephone: 212-342-0488
Elisa Dicker	Assoc Research Scientist		Telephone: 212-342-0486

Research Purpose

Your child is invited to participate in a research study on epilepsy. The purpose of this research project is to investigate how different forms of epilepsy are inherited.

Results of this study may enable researcher to understand what causes certain forms of epilepsy that often start during adolescence or childhood.

This study includes all patients and their families who are willing to participate regardless of sex, social status or ethnic background. All patients will have a diagnosis of epilepsy. Family members of the patient may be healthy or have a seizure disorder.

Your child was selected as a possible participant in this study because your child has a seizure disorder, or your child is related to somebody with a seizure disorder

Information on Research

Genetic Material

Saliva will be used to extract deoxyribonucleic acid (DNA) to study genetic information on epilepsy and also possibly to investigate the basic workings of DNA. Due to unforeseen circumstances, it is possible that the available sample of saliva is insufficient for DNA extraction in which case we may need to ask your child for another sample.

The DNA extracted from the saliva will be stored indefinitely in the laboratory of Dr. David A. Greenberg at the Columbia University Mailman School of Public Health.

Study procedures

If you agree to have your child participate you will be contacted by telephone to speak with one of our study coordinators. The entire participating procedure will not take more than 2 hours.



Dr. David A. Greenberg or an authorized member of the research team will interview you your child for a half hour to one hour to obtain your child's health history. During this interview, some personal questions will be asked that could cause anxiety or stress. Your child may refuse to answer any or all questions.

In order to find the genes involved in these epilepsies, we need to have the participation of other members of the family whether they have symptoms or not. For this reason you will be asked if you are willing to inform other family members about this study and whether they would also like to participate. If interested, your relatives may contact Dr. Greenberg or a member of his staff. Alternatively, your relatives may give permission to be contacted by Dr. Greenberg or an authorized member of his staff. All information regarding participation of family members will be kept private by the investigator.

In addition to the interview, your child will be asked to provide a sample of saliva in a special container designed for collecting saliva. If your child is not interviewed in person, this special container will be sent to you via express mail and we will provide a pre-paid, return envelope for you to send it back to us.

Risks

There are no risks for providing a sample of saliva.

Your child's sample will have a unique code number assigned to your child as soon as you agree to have your child participate. The key to the coding will be kept in a separate locked file. Information obtained from this research will not be linked to your child in any way.

There are no psychological risks from this genetic research because genetic information that may be obtained from this study does not have clinical diagnostic value. You will not receive any medical or genetic information about your child or your family members.

Participation in the study will NOT enable you to learn whether or not your child or your family members carry a gene that raises risk for epilepsy. This is because most of the study's results will pertain to all of the families analyzed as a group, rather than to specific families or individuals. In addition any results from the study that may be relevant to specific families or individuals would have to be confirmed and validated in a subsequent study before their clinical significance would be known.

Benefits

Your child will not receive any specific benefit for participation in this study. Findings derived from this study might benefit epilepsy patients in general and contribute to our understanding of the causes of epilepsy.

Alternative Procedures

There are not alternatives available for this study. The alternative is not to have your child participate.

Compensation

All procedures performed exclusively for this study will be done at no cost to you or to your child's insurance carrier.

Your child will not be paid for participating in this research.

Confidentiality

No information from this study that pertains to your child will be provided to you. None of the information your child provide will be released to anyone, including members of your family, without your permission. Similarly, none of the information your relatives provide will be released to you without their permission. This includes information about medical conditions your child or your relatives may have had, and about the existence of family members who may be unknown to you.

Your child's identity as a participant in this research study, and any information obtained during this study and identified with your child will remain confidential. Specific genotype information might be shared with other researchers for purposes of determining the epilepsy genes but no identifying information will be disclosed. For laboratory and statistical analysis, and for publication of any results from the study, your child will be assigned a coded number and no personal information will be used. Identifying information and records will be kept in locked files at this institution. All information and data will be entered into a computer and stored using encrypted files. Data will be organized and managed using the data base management system MySQL. Access to the data-base is restricted to study personnel only.

All records connected with this study will be kept confidential to the extent permitted by law. Your child medical record in connection with this study is subject to review by the CUMC IRB, the OHRP and agents of the National Institute of Health (NIH), the sponsor of this research in accordance with applicable laws and regulations.

It is particularly important for you to know that we have been granted a Certificate of confidentiality from the National Institute of Neurological Disorders and Stroke for this study to make sure we can protect your child's privacy. This Certificate means that researchers cannot be forced to tell people who are not connected with the study about your child's participation. This includes courts and the police. However, if under certain circumstances, you choose to voluntarily request disclosure, the researchers will release information.

Information about your child's participation and results from this study will NOT be placed in your child's medical records. Your insurance company or your employer or potential employer will NOT have access to any of your information. No insurance company or any other person will have access to your child's information.

Additional Information

Genetic Research

Analysis of the saliva sample your child donates for this study might reveal sensitive information

about relationships in your family (for example, adoptions or non-paternity). If this should occur, neither you nor any of your family members would be informed about it.

At present, the possible significance of any results of this genetic research is not known. It cannot provide meaningful information about the health of a study participant. Therefore, if you decide to have your child participate in this research study and, if you are asked, you should state that your child has NOT had a genetic test. It is possible, that in the future, this research could be used to develop genetic testing. The results of these studies will not be given to you.

I agree to have my child's saliva used for genetic research as described above

Please initial: YES _____ NO _____

Future research

No tests other than those authorized by you shall be performed on the sample your child provides and your child's sample shall be destroyed at the end of the research study unless you provide permission for additional testing as stated below.

While we do not have any further specific research plans at this time, we may want to use the sample your child has provided for future studies on genetic information on epilepsy and also possible to investigate the basic workings of DNA.

You may choose not to have your child's sample stored for future research and still be part of this research study. Also, you may agree to have your child's sample stored and later decide that you want to withdraw it from storage. If you make that decision, you should call Dr. David A. Greenberg at 212-342-0488 and ask that your child's sample be discarded.

Please read the following statements and indicate your choices by placing your initials on the desired line. If you do not initial either YES or NO, we will assume that you intended your answer to be NO.

The DNA sample will be banked for an indefinite period of time. The sample will get a unique identifier code. Please understand that no personal identification will ever be given out.

Please initial: YES _____ NO _____

I agree to have my child's DNA sample stored for Dr. David A. Greenberg to use in future studies that he conducts that are related to this research study.

Please initial: YES _____ NO _____

I agree to have my child's DNA sample stored for Dr. David A. Greenberg to use in future studies that he conducts that are not related to this research study.

Please initial: YES _____ NO _____

I agree that Dr. David A. Greenberg can share my child's sample of saliva/DNA for use in studies conducted by other investigators who are related to this research study. I understand that no personal information will be given to other researchers.

Please initial: YES _____ NO _____

I agree that Dr. David A. Greenberg can share my child's sample of saliva/DNA for use in studies conducted by other investigators who are not related to this research study. I understand that no personal information will be given to other researchers.

Please initial: YES _____ NO _____

At any time these samples will be destroyed at your request.

We may need to contact you again in the future for research purposes if we run out of your child's sample before the end of the study. Please initial the appropriate statement to indicate whether or not you give permission for future contact.

I give permission to be contacted in the future for research purposes

Please initial: YES _____ NO _____

I give permission to be contacted about having my child donate an additional sample after 1 to 10 years.

Please initial: YES _____ NO _____

Any new findings which may affect your willingness to allow your child's sample to be used in this study for ongoing or future research will be communicated to you. However, all information obtained up to this point in time may be retained by the investigator.

Voluntary Participation

Participation in this study is voluntary. Refusal to participate will involve no penalty or loss of benefits to which your child is otherwise entitled. Likewise, if you elect to have your child participate in this study, you may discontinue your child's participation at any time without penalty or loss of benefits to which your child is otherwise entitled. Signing this form does not waive any of your child's legal rights.

If you have any questions about your child's rights as a subject, you may contact:

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. If you have questions in the future, you can reach Dr. David A. Greenberg at: 212-342-0488.

Statement of Consent

I voluntarily consent to have my child 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 have my child participate in the study or to withdraw at any time. My decision to have my child not to participate or to withdraw from the study will not affect my child 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 my child would have if my child were not a participant in the study.

Signature

Parent/Guardian

Print Name _____ Signature _____ Date _____

Person Obtaining Consent

Print Name _____ Signature _____ Date _____

Child

Print Name _____