

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-AAAG0026

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	Principal Investigator	Telephone: 212-342-0488
Elisa Dicker	Assoc Research Scientist	Study Coordinator	Telephone: 212-342-0486

Research Purpose

You are 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.

You were selected as a possible participant in this study because you have a seizure disorder or you are related to somebody with a seizure disorder.

Information on Research

Study procedures

If you agree to 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 for a half hour to one hour to obtain a family tree called a pedigree, your medical history, a family history of seizure disorders, and the seizures you may have witnessed in your relatives. During this interview, some personal questions will be asked that could cause anxiety or stress. You 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, you will be asked to provide a sample of saliva in a special container designed for collecting saliva. If you are 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.

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 you 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.

Risks

There are no risks for providing a sample of saliva.

Your sample will have a unique code number assigned to you as soon as you agree to participate. The key to the coding will be kept in a separate locked file. Information obtained from this research will not be linked to you 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 yourself or your family members.

Participation in the study will NOT enable you to learn whether or not you 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

You 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 participate.

Compensation

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

You will not be paid for participating in this research.

Confidentiality

No information from this study that pertains to you will be provided to you. None of the information you 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 you or your relatives may have had, and about the existence of family members who may be unknown to you.

Your identity as a participant in this research study, and any information obtained during this study and identified with you 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 analyses, and for publication of any results from the study, you 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 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 privacy. This Certificate means that researchers cannot be forced to tell people who are not connected with the study about your 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 participation and results from this study will NOT be placed in your 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 information.

Additional Information

Genetic Research

Analysis of the saliva sample you donate 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 participate in this research study and, if you are asked, you should state that you have 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 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 you provide and your 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 you have 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 sample stored for future research and still be part of this research study. Also, you may agree to have your 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 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 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 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 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 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 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 donating an additional sample after 1 to 10 years.

Please initial: YES _____ NO _____

Any new findings which may affect your willingness to allow your samples 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 you are otherwise entitled. Likewise, if you elect to participate in this study, you may discontinue your participation at any time without penalty or loss of benefits to which you are otherwise entitled. Signing this form does not waive any of your legal rights.

If you have any questions about your 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 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 participant in the study.

Signature

Study Participant

Print Name _____ Signature _____ Date _____

Person Obtaining Consent

Print Name _____ Signature _____ Date _____