

Columbia University Medical Center Assent 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-AAAG0027

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. People with epilepsy have different kinds of seizures. Some people have staring spells. Other people may fall down and shake all over. In other people one arm or one leg shakes, and in others everything may look or sound strange for a few moments. We want to find why and how people get epilepsy and why it happens in some families and not in others.

The reason you were selected as a possible participant in this study is that you or somebody in your family has epilepsy

Information on Research

If you and your parent/s or guardian/s agree that you participate, we are going to ask you some questions in the presence of your parent/s or guardian/s. You don't have to answer any questions you do not like.

We will ask you to give us a sample of saliva. You can do that by spitting into a container we will give you.

The DNA that we will extract from your saliva will be used to do genetic research. However, the results of the study will not tell us anything about your health. Maybe some time in the future we can develop a test to know more about your health. For now, if anybody asks if you had genetic testing you should say that you did NOT have it.

Risks

Giving a sample of saliva does not hurt and it is not dangerous.

Benefits

You yourself will not benefit from this study but with your help we will be able to learn more about what causes epilepsy. This work will hopefully benefit other children and grown-ups in the future.

Alternative Procedures

The alternative is not to take part in this research study.

Compensation

You will not be paid for participating in this study.

All costs for this study will be paid by the investigator's funds.

Your parent/s or guardian/s will be reimbursed for transportation expenses.

Voluntary Participation

Your participation in this study is completely up to you. You can refuse to participate or stop participating at any time.

If you have any questions, please ask, and we will do our best to answer them.

If you have more questions in the future, you or your parent/s or guardian/s can reach Dr. David A. Greenberg at 212-342-0488.

If you/your parent/s or guardian/s have any questions about your rights as a subject, you/your parent/s or guardian/s 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.

Assent to Participate

It is up to you if you want to be in this study. If you don't want to do this, just tell me and I will not ask you any questions. No one will be upset with you if you do not want to participate or even if you change your mind later and want to stop participating.

You can ask any questions that you have about the study. If you have a question later that you didn't think of now, you can ask it later.

If you want to be in this study, please sign your name to this paper. You and your parent(s) will be given a copy of this form after you sign it.

I have talked about this study with my parent/s or guardian/s and Dr. David A. Greenberg or an authorized member of the research team. I understand what I have to do and I want to participate.

I understand that my participation is up to me and that I can change my mind at any time without people feeling angry with me.

I have read the above and it has been explained to me, and I agree to enter this research study.

Signing this form does not waive any of my legal rights.

Signature

Assent

Print Name _____ Signature _____ Date _____

Person Obtaining Consent

Print Name _____ Signature _____ Date _____