

GCO # 07-0916 _____

PART I: RESEARCH PARTICIPANT INFORMATION SHEET

TITLE OF PROJECT:

Search For Genes Influencing Childhood Absence Epilepsy

A. PURPOSE OF THE STUDY:

You/your child are being asked to participate in a research study. The purpose of this study is to investigate whether different forms of epilepsy and certain patterns in the EEG (electroencephalogram or pictures of brain waves) are passed down from one family member to another, and if so, how does this occur. You/your child qualify for participation in this study because you/your child or somebody in your family has Childhood Absence Epilepsy, also called "Petit Mal" epilepsy.

B. DESCRIPTION OF THE RESEARCH:

Results of this research may enable researchers to understand the cause of these staring spells and maybe also other kinds of seizures.

Study Procedures:

If you/your child take part in this study, you/your child will partake in the following:

Interview: You will be interviewed to obtain a family tree (called a pedigree), a family history of seizure disorders and your/your child's medical history. The interview will take about half an hour. You may also be asked to contact your relatives to ask if they would also participate in this study. Your relatives may contact us directly.

DNA Sample: We will ask you/your child to provide us with either saliva (spit) in a specially designed container (2ml or 0.07 oz), which we will provide to you/your child, or a sample of blood [ages 4-6: 15ml (0.5 oz), ages 6-10: 20ml (0.7 oz), ages 10 and over: 30ml (1 oz)].

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The DNA sample will be banked for an indefinite period of time. The sample will get a unique identifier code without any personal identifiers. No personal identifying information will be given out.

We would like to store a sample of your blood or tissue that will be obtained from you during this current research study. We need to ask your permission to store this sample, and we would like to know how we might use it in future approved research studies. It is possible that products may someday be developed from the [bodily fluids, substances, or tissues] that you are providing. There are no plans to share any profits from such products with you.

(1) Do you give us permission to store and label your sample in a way that it will be **possible to link** the sample back to you?

Yes _____ No _____

(2) If YES to #1, do you give us permission to **re-contact you** in the future to obtain additional information or for possible participation in another research project?

: Yes _____ No _____

(3) Do you give us permission to store and label your sample in a way that it will be **impossible to link** the sample back to you?

Yes _____ No _____

Note: If you agree to have the sample and information stored without any way of identifying you, then you will not be able to change your mind and ask for the blood/tissue to be destroyed at a future date.

(4) Do you give us permission to store the sample indefinitely and use the sample in future **studies that are directly related** to the current study?

Yes _____ No _____

(5) Do you give us permission to store the sample indefinitely and use the sample in future **studies that are unrelated** to the current study?

Yes _____ No _____

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(a) If the future unrelated research can be done with the samples and associated information without having to know the specific source, we will do so.

(b) If the future unrelated research requires that we know who the specific samples and associated information came from, then we will do one of the following:

(i) *If you allow us to contact you in the future, we will be able to explain to you why we wish to use your blood/tissue and your associated information in future research, and we will tell you what we will do with the sample and the information about you. We will then ask your permission to use your blood or tissue in that research project.*

May we have your permission to contact you in the future?

Yes _____ No _____

(ii) If you do not give us permission to contact you in the future, or if we find that contacting you is not practical, for example because you have moved, we may still use your blood and tissue. Either we will use it after we have removed all links to you and your identifiable health information, or will ask the Institutional Review Board for permission to use the identified sample and associated health information. The Institutional Review Board (IRB) is a committee of doctors and scientists. There are also non-scientists on the committee that are not associated with this hospital or medical school. The IRB can give permission to the researcher to use and share your identified health information and the associated blood/tissue, but only if it determines that doing this will not be more than a minimal risk to you or your privacy.

(6) Do you give us permission to have portions of the stored sample **distributed to other investigators** at MSSM or other institutions for use in research that is either related or unrelated to the purpose of this study?

Yes _____ No _____

(7) If you change your mind you are free to discontinue participation in the study any time. In order to do this you must send a letter stating that you no longer wish to participate in the research study, and you withdraw authorization for us to use your DNA specimens, to Dr. M. Durner at Mount Sinai School of Medicine, One Gustave L. Levy Place, Box 1230, New York, NY 10029. Your data will then be deleted and your sample will be destroyed.

EEG: For those who do not have epilepsy but have family members affected with seizures and are under the age of 20, a well trained technologist may record an EEG for approximately an hour. For the EEG, some wires will be pasted on to your/your child's

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head and connected to a recording machine. The paste is water based and washes off. During the EEG recording a flickering light will be shined in front of your/your child's eyes in short intervals for a total of less than 3 minutes. This is called photic stimulation. We will also ask you/your child to breathe heavily for 5 minutes. This is called hyperventilation. These procedures can be terminated at any time at your/your child's request. Findings that need further clarification will be communicated to your/your child's treating physician or primary care physician.

Duration: If you/your child agree to take part, you/your child's participation will last for about 1/2-2 hours in total during one or two visits only.

Discontinuation: The study doctor may take you/your child out of the study if there is a reason.

Once children who are study participants turn 18 years of age they will be re-consented and given the opportunity to withdraw their samples/data or, if they cannot be contacted, all identifying information will be removed and the data will be made anonymous.

Because the possible significance of any results of this genetic research is not known, the results of these studies will not be given to you/your child. You should be aware that insurance companies sometimes use information from genetic testing to deny coverage. This study involves research in genetics that could be used by others to develop such genetic testing in the future. At present, any information obtained from this research cannot be considered to provide any meaningful information about the health of the participant. It is not a genetic test. The purpose of this study is to use genetic tools to find the causes of CAE. If you/your child are asked, you/your child should state that you/your child have not had a genetic test.

C. COSTS/REIMBURSEMENTS:

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

You/your child will not be paid for participating in this research. However, you/your child will be reimbursed for provided receipts for transportation expenses.

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D. POTENTIAL RISKS AND DISCOMFORTS:

During the interview some personal questions may be asked that could cause anxiety or stress. You/your child may refuse to answer any or all of the questions.

Providing saliva (spit) has no known associated risks.

Drawing blood samples may produce fainting, pain, swelling, bruising, and possible infection at the place where the blood is drawn.

The EEG is a routine procedure involving very small risks. The paste used to stick on the EEG electrodes may produce occasional allergic reactions, i.e. rash, itching. There is also a small chance only in persons who are sensitive to flickering light of triggering a seizure. However, we will monitor the EEG during this procedure and will turn off the flickering light as soon as first traces of such a response in this EEG are observed.

E. POTENTIAL BENEFITS:

You/your child will not receive any direct 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. This may also lead to better and new diagnoses and treatment, which may be more effective and with fewer side effects.

F. ALTERNATIVES TO PARTICIPATION:

The alternative is not to participate.

G. CONFIDENTIALITY:

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Your identity as a participant in this research study will be kept confidential in any publication of the results of this study. The information obtained during this research (Research Record) will be kept confidential to the extent permitted by law. However, this Research Record and your personal Medical Record (if any and if relevant to the study) may be reviewed by government agencies (such as the Food and Drug Administration or the Department of Health and Human Services), the agency or company sponsoring this research, individuals who are involved in, or authorized to monitor or audit, the research, or the Institutional Review Board (the committee that oversees all research in humans at Mount Sinai School of Medicine) if required by applicable laws or regulations.

H. COMPENSATION/TREATMENT:

If you/your child believe that you/your child have suffered an injury related to this research as a participant in this study, you should contact Dr. Martina Durner at telephone number: 212-6598816.

I. VOLUNTARY PARTICIPATION:

Participation in this study is voluntary. If you/your child decide not to participate, this will not affect your/your child's ability to receive medical care at Mount Sinai or to receive any benefits to which you/your child are otherwise entitled.

Any new information that develops during this study, which might affect your decision to participate, will be given to you immediately.

A signed copy of this consent form will be given to you.

J. TERMINATION OF PARTICIPATION :

You/your child may discontinue participation in the study at any time without penalty or loss of benefits to which you/your child are otherwise entitled.

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If you/your child decide to participate, you/your child are free to withdraw your consent without effect to you/your child or effect on your/your child's medical care.

Some of the reasons the doctor may take you/your child out of the study include:

- You/your child cannot meet all the requirements of the study
- You/your child no longer want to participate

K. CONTACT PERSON(S):

If you/your child have any questions, at any time, about this research, or want to discuss any possible study-related injuries please contact Dr. Martina Durner, at telephone number: 212-6598816. If you still have questions regarding the study or your/your child's rights as a participant in the study you may discuss them with an administrator of the Institutional Review Board at Mount Sinai School of Medicine at telephone number (212)659-8980.

L. DISCLOSURE OF FINANCIAL INTERESTS:

None

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AUTHORIZATION TO PARTICIPATE IN RESEARCH

The participant/surrogate and the investigator/delegate must each SIGN, DATE and TIME this two page authorization form.

Research Subject's Name (printed): _____

1. I hereby volunteer to participate in a research program under the supervision of Dr. Martina Durner and her associates at Mount Sinai School of Medicine.
2. I acknowledge that I have read, or had explained to me in a language I understand, the attached consent document and that _____ has explained to me the nature and purpose of these studies. This explanation included a description of the parts of the study that are experimental, the possible discomforts, symptoms, side effects and risks that I might reasonably expect, and the possible complications, if any, that I might reasonably experience from both known and unknown causes as a result of my participation in these studies. I have had the opportunity to ask questions I had about the study and all of the questions I asked were answered to my satisfaction.
3. I understand that I am free to withdraw this authorization and to discontinue my participation in these studies any time. The consequences and risks, if any, of withdrawing
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from the study while it is ongoing have been explained to me. I understand that such withdrawal will not affect my ability to receive medical care to which I might otherwise be entitled.

4. I confirm that I have read, or had read to me, this entire authorization and that all blanks or statements that require completion were in fact, properly completed before I signed this authorization.

Research Subject/Surrogate: _____
Signature

Name: _____
Print Name

Relationship: _____
If signed by surrogate

Date: _____ Time: _____

Subject/Surrogate Initials _____

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For subjects who are not able to read this consent document themselves, the following must be completed:

I confirm that I have accurately translated and/or read the information to the subject:

Name: _____
Signature

Name: _____
Print Name

Address: _____
Number and Street City State Zip Code

Date: _____ Time: _____

I confirm that the consent document was translated and/or read to the subject:

Name of Witness: _____
Signature

Name of Witness: _____
Print Name

Date: _____ Time: _____

AUTHORIZATION TO PARTICIPATE IN RESEARCH (continued)

I have fully explained to the above volunteer/patient/relative/guardian the nature and purpose of the foregoing drugs, devices or procedures, possible alternative methods of treatment which might be advantageous, the benefits reasonably to be expected, the attendant discomforts and risks involved, the possibility that complications may arise as a result thereof and the consequences and risks, if any, which might be involved in the event the volunteer/patient/relative/guardian hereafter decides to discontinue such treatment. I believe that the above volunteer/patient/relative/guardian understands the nature, purposes, benefits, and risks of participation in this research. I have also offered to answer any questions the above volunteer/patient/relative/guardian might have with respect to such drugs, devices or procedures and have fully and completely answered all such questions.

Signature of Principal Investigator/Delegate (person who obtained consent)

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From: _____ To: _____

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Print Name of person who obtained consent

Title

Date: _____

Time: _____

Subject/Surrogate Initials _____

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