

Participant name:

DOB:

HSC #:

## Research Consent Form (Parent for self)

### **Title of Research Project:**

Analysis of Candidate Genes on Chromosome 7 in Infantile Spasm and Seizure Disorders

### **Investigator(s):**

BERGE MINASSIAN; (416 813 6291)  
LUCY OSBORNE; (416 946 5804)

### **Purpose of the Research:**

We hope to use this study to find genes on chromosome 7 that cause infantile spasms or seizure disorders. We have already narrowed the location of such a gene to a small part of the 7<sup>th</sup> chromosome, and have searched for changes in a gene from within this region in children with infantile spasms or seizure disorders. Your child's DNA has been tested for changes in this gene and we have found an alteration that requires follow-up genetic studies. These studies will help determine whether the genetic change is contributing to the infantile spasms in your child.

### **Description of the Research:**

1) Genetic studies: we ask you to donate a saliva sample. We will take the genetic material (DNA) from your saliva sample so that we can check for the same genetic change on chromosome 7 that we identified in your child.

### **Potential Harms:**

#### ***Potential Discomforts or Inconvenience:***

The interpretation of the genetic information will depend in part on the family information that you have provided. If the results of genetic tests do not fit with the information that you have given about your family, it may be that the test is faulty, or that the family information that you gave is wrong. For example, this might happen if parents do not mention that their child was adopted, or that the father is different from the apparent father (this is known as non-paternity).

Although genetic testing is usually accurate, as with all testing some inaccuracies may occur. Also genetic testing is ongoing and new research may mean that the interpretation of the test results may change over time. On occasion, in the process of testing for one genetic condition, another genetic alteration may be identified. Such findings would be reported to your health care provider to discuss with you and your family.

**Potential Benefits:*****To individual subjects:***

You will not benefit directly from participating in this study.

At the end of the study we will issue a report detailing the findings. This report will be explained to you by your child's neurologist. You will also have the chance to have our research findings independently confirmed by the Diagnostic laboratory at SickKids if you wish to.

***To society:***

This study may not provide any direct benefit to you or your child, but it will increase our understanding of the genetic basis of infantile spasms and seizure disorders and may benefit patients in the future.

**Confidentiality:**

We will respect your privacy. No information about who you are will be given to anyone or be published without your permission, unless required by law. For example, the law could make us give information about you

- If you have an illness that could spread to others
- If you or someone else talks about suicide (killing themselves), or
- If the court orders us to give them the study papers

The Investigators will keep a copy of this signed consent, and will provide you with a copy. Sick Kids Clinical Research Monitors or the regulator of the study may see your signed consent to check on the study.

The information produced from this study will be stored in a secure, locked location. Only members of the research team (and maybe those individuals described above) will have access to this information. This could include research team members who are not at SickKids or the University of Toronto. When the research study is finished the information will be kept as long as required then destroyed. Published study results will not reveal your identity.

The genetic information collected from you will be kept strictly confidential. Confidentiality will be maintained at all times by assigning number codes rather than names to genetic material (saliva and DNA sample). The codes will be kept in locked files and available only to Drs. Minassian and Osborne, or those working with them. No information that reveals your identity will be released or published without your consent.

The genetic material isolated from your saliva will be stored indefinitely (unless you choose to remove your sample from the study, as described in the Participation section) with the number code, so that as new genes are discovered which are involved in infantile spasms, Drs. Minassian and Osborne and can include you in their research.

**Reimbursement:**

None.

**Participation:**

If you choose to take part in this study you can choose to take yourself out of the study at any time. The care your child gets at Sick Kids will not be affected in any way by whether you take part in this study.

You may choose at anytime to withdraw your genetic material (saliva DNA sample) from the study, in which case the genetic material will be destroyed.

New information that we get while we are doing this study may affect your decision to take part in this study. If this happens, we will tell you about this new information. And we will ask you again if you still want to be in the study.

During this study we may create new tests, new medicines, or other things that may be worth some money. Although we may make money from these findings, we cannot give you any of this money now or in the future because you took part in this study.

If you become ill or are harmed because of study participation, we will treat you for free. Your signing this consent form does not interfere with your legal rights in any way. The staff of the study, any people who gave money for the study, or the hospital are still responsible, legally and professionally, for what they do.

**Sponsorship:**

The sponsor/funder of this research is the Canadian Institutes of Health Research

**Conflict of Interest:**

I, and the other research team members have no conflict of interest to declare.

**Open Consent:**

By signing this form, I agree that:

- 1 You have explained this study to me. You have answered all my questions.
- 2 You have explained the possible harms and benefits (if any) of this study.
- 3 I know what I could do instead of taking part in this study. I understand that I have the right to refuse to take part in the study. I also have the right to take myself out of the study at any time. My decision about taking part in the study will not affect my child’s health care at SickKids.
- 4 I am free now, and in the future, to ask questions about the study.
- 5 I understand that no information about me will be given to anyone or be published without first asking my permission.
- 6 I will provide a saliva sample
- 7. My sample will be used in research relating to Infantile Spasms and Seizure Disorders; this testing will be undertaken in an accredited clinical service laboratory and/or a research laboratory.
- 8. My sample may be stored indefinitely
- 9. Samples may be used in this laboratory for research on other genetic conditions after all the identifying information has been removed; I understand that any sample held at SickKids without identifying information cannot be retrieved.
- 10. Members of my family will be allowed access to my stored DNA or tissue only if I give my written permission or without my permission after my death.
- 13. On rare occasions samples obtained from me may be used to develop commercial products for which I will receive no personal recognition or payment.

I \_\_\_\_\_ agree, or consent, to take part in this study  
Printed Name of Parent

\_\_\_\_\_  
Parent’s signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name of person who explained consent

\_\_\_\_\_  
Signature of Person who explained consent & date

\_\_\_\_\_  
Printed Witness’ name (if the parent/legal guardian does not read English)

\_\_\_\_\_  
Witness’ signature & date

OR

**Closed Consent:**

By signing this form, I agree that:

1. You have explained this study to me. You have answered all my questions.
2. You have explained the possible harms and benefits (if any) of this study.
3. I know what I could do instead of taking part in this study. I understand that I have the right to refuse to take part in the study. I also have the right to take myself out of the study at any time. My decision about taking part in the study will not affect my child's health care at Sick Kids.
4. I am free now, and in the future, to ask questions about the study.
5. I understand that no information about me will be given to anyone or be published without first asking my permission.
6. I will provide a saliva sample
7. Any saliva or genetic material obtained from me will be analyzed and then destroyed. Specifically, I give my consent for a saliva sample to be taken for testing related only to Infantile Spasms and Seizure Disorders; this testing will be undertaken in an accredited clinical service laboratory and/or a research laboratory and that the sample and any genetic material extracted from it will be destroyed once the results of the testing are available. I also understand that if I want any further genetic testing to be done in the future, I will need to provide another sample.
8. On rare occasions samples obtained from me may be used to develop commercial products for which I will receive no personal recognition or payment.

I \_\_\_\_\_ agree, or consent, to take part in this study  
Printed Name of Parent

\_\_\_\_\_  
Parent's signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name of person who explained consent

\_\_\_\_\_  
Signature of Person who explained consent & date

\_\_\_\_\_  
Printed Witness' name (if the parent/legal guardian does not read English)

\_\_\_\_\_  
Witness' signature & date

If you have any questions about this study, please call Dr. Berge Minassian at 416 813 6291

If you have questions about your rights as a subject in a study or injuries during a study, please call the Research Ethics Manager at 416-813-5718.”