

Participant name:

DOB:

HSC #:

## Research Consent Form (Parent or Guardian on behalf of child)

### **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 a gene on chromosome 7 that causes infantile spasms or seizure disorders. We have already narrowed the location of such a gene to a small part of the 7th chromosome, and will now search for changes in genes from within this region, in children with infantile spasms or seizure disorders, that might be responsible for the spasms. We hope to identify the causative gene, so providing new knowledge about why some seizures happen. This may help with both diagnosis of infantile spasms and the design of new treatments.

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

- 1) Your child's medical records from SickKids, as well as any additional institutions, will be requested for review. These records will be used to tell us exactly the kind of seizures that your child has had.
- 2) Genetic studies: A small blood sample (20-30 cc or 1-2 tablespoons) will be taken from your child by a trained person. This blood sample will be taken while your child is already having blood drawn for clinical purposes at SickKids and a topical anaesthetic cream will be offered to help numb your child's skin. The blood sample will be used to provide genetic material (RNA and DNA) so that we can look for changes in genes to see whether they might be causing your child's seizures.

### **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 the 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 child's health care provider to discuss with you and your family.

If you apply for insurance and provide consent, information in your child's medical records, including the results of genetic testing will be available to the company. Your child's sample may also be used so that other research may be done, but only after all identifying information, like your child's name has been removed (see open consent only for this type of research).

**Potential Benefits:**

***To individual subjects:***

Your child will not benefit directly from participating in this study.

At the end of the study, if we identify a genetic alteration in your child that we believe is responsible for their seizures, we will issue a report detailing the findings. This report will be explained to your family by your child's neurologist. You may also have the chance to have our research findings independently confirmed by the Diagnostic laboratory at SickKids if you want to.

***To society:***

This study may not provide any direct benefit to your child, but it will increase our understanding of how changes in particular genes can cause infantile spasms and seizure disorders which may benefit other patients in the future.

**Confidentiality:**

We will respect your child's privacy. No information about who your child is 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 a child has been abused
- 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

Sick Kids Clinical Research Monitors or the regulator of the study may see your child's health record to check on the study. By signing this consent form, you agree to let these people look at your child's records. We will put a copy of this research consent form in your child's patient health record and give you a copy as well.

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 destroyed. Published study results will not reveal your child's identity.

The genetic information collected from your child will be kept strictly confidential. Your child's genetic material (blood or DNA sample) will be given a number code. The code will be kept in locked files and available only to Dr. Minassian and Dr. Osborne, or those working with them. No information that reveals your child's identity will be released or published without your consent. In addition, information regarding the results of this research may become part of your child's health record.

You can choose to have the genetic material isolated from your child's blood stored indefinitely with the number code, so that as new genes are discovered which are involved in infantile spasms, Drs. Minassian and Osborne and can include your child in their research (Open Consent). Alternatively, you can choose to have your child's genetic material used only for this study (Closed Consent). These choices are explained at the end of this form.

When your child has the maturity to understand these tests he/she may request the information and it will be made available to him/her.

**Reimbursement:**

None.

**Participation:**

If you choose to let your child take part in this study you can choose to take your child out of the study at any time. The care your child gets at Sick Kids will not be affected in any way by whether your child takes part in this study. You may choose at anytime to withdraw your child's genetic material (blood 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 let your child 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 your child 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 your child any of this money now or in the future because your child took part in this study.

Your child may be required to provide assent to participate in this study.

If your child becomes ill or is harmed because of study participation, we will treat your child 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 for 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 having my child take part in this study. I understand that I have the right to refuse to let my child take part in the study. I also have the right to take my child out of the study at any time. My decision about my child 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 have been told that my child’s medical records will be kept private except as described to me.
6. I understand that no information about my child will be given to anyone or be published without first asking my permission.
7. My child will provide a blood sample
8. My child’s 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.
9. I wish to be re-contacted with any new laboratory results that identify a specific genetic change in my child’s sample of DNA
10. My child’s sample may be stored indefinitely
11. 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.
12. Members of my family will be allowed access to my child’s stored DNA or tissue only if I give my written permission or without my permission after my death. I will continue to have access to my child’s DNA even in the event of my child’s death or until such time that my child has the maturity to make his or her own decisions relating to the stored genetic material.
13. On rare occasions samples obtained from my child may be used to develop commercial products for which I will receive no personal recognition or payment.

I agree, or consent, that my child \_\_\_\_\_ may take part in this study.

\_\_\_\_\_  
Printed Name of Parent/Legal Guardian

\_\_\_\_\_  
Parent/Legal Guardian’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 having my child take part in this study. I understand that I have the right to refuse to let my child take part in the study. I also have the right to take my child out of the study at any time. My decision about my child 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 have been told that my child’s medical records will be kept private except as described to me.
6. I understand that no information about my child will be given to anyone or be published without first asking my permission.
7. My child will provide a blood sample
8. Any blood or genetic material obtained from my child will be analyzed and then destroyed. Specifically, I give my consent for a blood 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 have another sample taken from my child.
9. On rare occasions samples obtained from my child may be used to develop commercial products for which I will receive no personal recognition or payment.

I agree, or consent, that my child \_\_\_\_\_ may take part in this study.”

\_\_\_\_\_  
Printed Name of Parent/Legal Guardian

\_\_\_\_\_  
Parent/Legal Guardian’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.”