

## PARTICIPANT ASSENT FORM

### The International Pyridoxine-Dependent Epilepsy Registry

#### **Invitation:**

I am invited to participate in this research study because I have a condition called Pyridoxine dependent epilepsy (PDE). No one will make me to be a part of the study. Even if I agree now to be part of the study, I can change my mind later. No one will be mad at me if I choose not to be part of this study.

#### **Why the doctors are doing this study?**

The disease that I have is very rare. It is important to get information from many people with PDE to better understand this condition. This will help to develop new treatments in the future that will help people with these diseases. The study will be going for 10 years or longer.

#### **What will happen during the study?**

The study will collect information about my disease. The information will be provided by my doctor and I will not be asked to do anything other than allowing the doctor to answer the questions about my health.

#### **Will I get better if I am in the study?**

The study doctors do not know if good things will happen to me by being in this study. I may have no benefit from this study.

#### **What if I have any questions?**

I can ask questions at any time, now or later. If I have any questions about this study, I can ask my parents or guardians or call **Dr. Clara van Karnebeek** at **604-875-2628**. If I want to talk to someone outside of the study I can call the Research Participant Complaint Line at the University of British Columbia Office of Research Ethics at **604-822-8598**.

#### **Who will know about what I did in the study?**

The doctor and other study person will be the only people who know that I took part in this study. My name will not be given to anyone who is not helping with this study.

#### **Can I quit?**

I don't have to be in this study. No one will be mad at me if I don't want to do this. I can say "yes" now and change my mind later. My doctors will still take care of me even if I do not want to be in this study.

#### **My choice**

I have had time to think about this study and ask any questions. I understand what will happen to me if I am in the study. I agree that the doctor can use a story about my health. I agree to be in the



study. I know that I can quit the study at any time. I will be given a copy of this paper to take home with me.



**I agree to participate in the study**

\_\_\_\_\_  
Name of Subject

\_\_\_\_\_  
Signature of Subject

\_\_\_\_\_  
Date

**ASSENT STATEMENT**

I confirm that I have explained the nature and purpose of the study, potential benefits, and possible risks associated with the study to the minor subject. I have answered any questions that have been raised, and have witnessed the above signature. I am qualified to perform this role.

Signature of Investigator or Authorized Individual: \_\_\_\_\_

Printed Name of Investigator or Authorized Individual: \_\_\_\_\_

Date: \_\_\_\_\_

**Note to Physician: After assent, can you please write the PDE Registry REDCap® web-page generated patient data code here: \_\_\_\_\_**