UNIVERSITY OF WASHINGTON
ADULT CONSENT FORM/PARENTAL PERMISSION FORM
HCN1 Registry

Researcher: Nicholas Poolos, MD, PhD, Professor and Vice Chair for Research, Department of Neurology, University of Washington (206) 744-3576 npoolos@uw.edu
http://depts.washington.edu/nplab

Before you agree to participate in the HCNI Registry, it is important that you understand what is involved and what will be done with the information you provide. This form contains answers to some of the questions you might have to help you decide whether or not to join this research registry. Being in this registry is voluntary. Please read this carefully. At the end of the form there is a section for you to sign to confirm that you agree to participate. If you have any questions after reading this form, please contact us before signing the form.

What is the purpose of this registry?

This registry has been created to collect information about patients diagnosed and currently living with the HCN1 mutation and their biological parents. Data registries like this one compile data on patients with a condition to help improve research and clinical care. This registry will help researchers study the HCN1 mutation. For example, researchers might use this data to study how HCN1 mutations cause epilepsy and developmental delay in affected patients, and to predict the clinical course associated with the mutations. A second purpose of the HCN1 registry is to keep names and contact information of individuals who are interested in being contacted in the future for other research studies.

Who should complete this form?

We are asking the parent or guardian of a patient to complete this form and authorize access to medical records for this registry. If you are also a biological parent of a HCN1 patient, you also have the option to join this registry as a participant.

What will happen if I agree to participation in this registry?

If you agree to take part in the HCN1 registry, the following will happen:

#1. Collection of self-reported information

- We may first ask you some questions by phone about the patient. If you are a biological parent also consenting for your own participation, we will also ask questions about you. We will collect demographics (such as age, gender, race), and information you might have about genetic testing results, developmental history, and other related clinical information. This phone call may last up to 30 minutes.

#2. Collection of medical records

- **For the HCN1 patient**, we will request medical records that contain information about the genetic testing, diagnosis, clinical characteristics, other testing, and outcomes. This includes information about the following:
    - Genetic testing results for the HCN1 mutation (we are requesting only genetic information that is limited to the nature of the HCN1 mutation). If we receive testing from a targeted genetic panel, we will keep this information in the registry. We are not requesting broad genetic testing information.
    - Developmental history
    - Results of neuroimaging, EEG testing, and other testing that relates to the patient's diagnosis
    - Information related to epilepsy diagnosis
    - Information about drug exposure and response
    - Demographic information such as gender, date of birth, race, etc.
- **For biological parents** who also participate in this registry, we will need to request the following information from your medical record:
    - Results of similar genetic testing
    - Developmental history
    - Information related to epilepsy diagnosis
    - Information about drug exposure and response
    - Demographic information such as gender, date of birth, race, etc.

#3. Follow-up information

To make sure the data in the registry is correct and up to date, it is important that we update it regularly.

- To do this, we will contact you by phone, email, or mail about once a year to see if there is any new information about completed genetic testing and developmental information. It may take up to 15 minutes to provide additional information.
- There may be new information in the patient or biological parent's medical records that we will collect over time and store in the registry. How much data and how frequent data is collected from the medical record is dependent on the individual participant.

#4. Contact for Future Research:

One goal of this registry is to store names and contact information of individuals interested in participating in future research opportunities related to the HCN1 mutation. This is an optional part of the registry. If you give your permission for future contact, the following will happen:

- You will tick "yes" to question #3 of informed consent on page 5 of this form, indicating you would like to be contacted about future studies.

- The registry team will store your name and contact information in the registry.
- Only the registry team at the University of Washington will have access to personal identifiers and contact information to contact individuals for future research. In the case a study is designed in the future, the UW team may contact you to see if you or the patient or parent might be suitable for the new study. The UW registry team will not give names or any personal information to other researchers. If you decide to take part in a future study, you will need to review and sign a separate consent form.

How will medical records be shared?

The HCN1 registry team will need to gain access to your medical records to obtain information necessary for the project. You may send copies of medical records directly to the registry team, or we can obtain the records on your behalf.

We will ask you to sign a HIPAA authorization form and a Release of Information form so the registry team may request these medical records.

Are there risks to participating in this registry?

The risks related to participating in this registry include risks of invasion of privacy and breach in confidentiality. We will collect the minimum information necessary for this registry. We have explained how we will store and share information from this registry with others, and how the data will be confidential below.

Are there benefits to participating in this registry?

This registry is intended as a public service for the benefit of future patients diagnosed with the HCN1 mutation. This information may help us better understand how HCN1 mutations cause epilepsy and developmental disability, and better predict the clinical outcomes of children affected by HCN1 mutations.

The results of research facilitated by the registry may be patentable or may have commercial potential. However, you will not receive patent rights and will not receive financial benefits from future commercial development.

We will inform you (if you agree), if you might be suitable for a future study.

We will publish some general statistical information from the registry and from our registry and other registries on our website, so you will be able to find out information about how many other patients have been diagnosed with the HCN1 mutation.

Will I receive any individual results?

There are no plans to release information to participants. This registry will not generate individual results that will benefit patients or biological parents. Specifically, researchers are not

using this registry to look at the data to generate new diagnoses or risk categories (e.g. determine if you are at risk of Alzheimer's disease).

Will registry data be kept confidential?

The information you provide will be kept for an indefinite period at the University of Washington, under the responsibility of Nicholas Poolos, MD, PhD.

Identifiers will be stored separate from other information about participants.

Only the registry team at the University of Washington will have access to personal identifiers and contact information to contact individuals for future research.

We have a Certificate of Confidentiality from the federal National Institutes of Health. This helps us protect your privacy. The Certificate means that we do not have to give out identifying information about you even if we are asked to by a court of law. We will use the Certificate to resist any demands for identifying information.

We can't use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. Also, you or a member of your family can share information about yourself or your part in this research if you wish.

There are some limits to this protection. We will voluntarily provide the information to:

- a member of the federal government who needs it in order to audit or evaluate the research;
- individuals at the University of Washington, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly;
- the federal Food and Drug Administration (FDA), if required by the FDA;
- state or local authorities, if we learn of child abuse, elder abuse, or the intent to harm yourself or others.

Government or university staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm.

If we publish any research or other documents based on data from this registry, research will never identify a participant by name.

How will data I share be used in future research?

One goal of this registry is to collect information about patients and biological parents affected by the HCN1 mutation to facilitate sharing of data for future research. For this reason, the information that we obtain will be shared with researchers for future undefined studies. We will remove anything that might identify a participant from the information, so that information may

then be used for future research studies or given to another investigator without getting additional permission from you.

When data is shared, it will be identified by a code and not by identifiers. This means that when researchers receive data from the HCN1 Registry, they will not be able to find out personal information (name, address etc.), but only the information they need about the mutation to accomplish their research study.

Researchers who study data from this registry may share back results of their analysis and we will store this information in the registry.

It is also possible that in the future we may want to use or share study information that might identify you. If we do, a review board will decide whether or not we need to get additional permission from you.

I want to be involved in future clinical research. If I register, is this guaranteed? Although one of the goals of this registry is to make it easier for patients to be recruited for research studies, there is no guarantee that registering your details will ensure you will be involved in a future study.

I don't want to be involved in a clinical trial. Should I still register? If you do not want to be contacted about future research studies, you do not need to consent for this portion of the registry. If you do not want to receive any information about future studies that you might be eligible for, please tick "no" in question 3 of the informed consent section on page 5 of this form.

Do I have to participate in the registry, and can I withdraw if I change my mind? Your participation in this project is completely voluntary. If you wish to withdraw information from the registry you will be free to do so without having to provide any explanation. Please note, that if we have already shared information about you to other researchers, we will be unable to withdraw that data. If you wish to withdraw, you should get in touch with the staff in charge of the HCN1 registry. Contact details are provided below.

Who should I contact if I have any questions? If you would like any additional information or need to tell us about any change in your data, or if you wish to withdraw your data from the registry, please contact Nicholas Poolos, MD, PhD via email: npoolos@uw.edu or phone: 206-744-3576.

Subject's statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, or if I have been harmed by participating in this study, I can contact one of the researchers listed on the first page of this consent form. If I have questions about my rights as a research subject, I can call the Human Subjects Division at (206) 543-0098 or call collect at (206) 221-5940. I give permission to the researchers to use my medical records as described in this consent form. I will receive a copy of this consent form.

(1) Do you agree for the patient diagnosed with the HCN1 mutation to participate in this registry?

□ NO □ YES

(2) If you are a biological parent, do you agree to participate for yourself in this registry?

□ NO □ YES

(3) If we receive information about a future study which you might be eligible for, would you like to be informed about this?

□ NO □ YES

Printed name of subject	Signature of subject	Date

When subject is a minor:

Printed name of parent	Signature of parent	Date

When subject is not able to provide informed consent:

Printed name of representative	Signature of representative	Date

Relationship of representative to subject

Copies to: Researcher
Subject