The KCNT1 Epilepsy Foundation Registry: For the Collection of Information to Facilitate and Advance Better Care and Research

KCNT001

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INTRODUCTORY PARAGRAPH

We invite you to participate in this research study. This research will involve administration of health and quality of life surveys. The goal is to better understand KCNT1-related disorders, engage patients in a patient-centered drug discovery process, and help identify patients who may qualify for drug trials. The specific aims of this research are to: 1) understand disease and symptom progression, 2) study and improve quality-of-life for families, and 3) understand natural history and long-term outcomes. There may also be Sub-studies developed periodically to understand more specific issues that may involve additional consents.

Taking part in this study is entirely voluntary. Please discuss questions about this study with our staff members. Talk to your family and friends about it and take your time to make your decision. If you decide to participate, please accept this consent as confirmation.

KEY INFORMATION

- You will voluntarily complete multiple surveys throughout the year covering the topics of symptom management and health behaviors related to KCNT1-related epilepsy and disorders.
- The time to complete each survey varies. A survey can take anywhere from 4 to 30 minutes.
- No information that connects your identity with your responses will be collected.
- You may receive a gift card after completion of the study.
- Your information will help advance research for KCNT1-related disorders.

Section 1. WHY IS THIS RESEARCH STUDY IMPORTANT?

This study will contribute to the growing body of knowledge about KCNT1-related disorders.

Your participation helps educate clinicians, researchers, drug developers and regulatory agencies about the unmet needs of the community. Ultimately, this supports the development of new treatments.

Section 2. WHAT WILL I BE DOING IF I DECIDE TO PARTICIPATE?

If you wish to participate, you will respond to a series of surveys. Depending on the topic, surveys may be sent out just once, on an annual basis or more frequently. Participation in these surveys is entirely voluntary. You are welcome to answer any surveys and contribute any data you are comfortable sharing. You can leave out or choose not to contribute anything if you are uncomfortable.

When you respond to these surveys, you will be providing basic demographic information (like age, gender, etc.) and more detailed information about health history, symptoms and quality-of-life.

Off-Label Drug Repurposing Sub-Studies

There will also be sub-studies that involve additional surveys, clinical data collection from your doctor, and extra time spent. You will only participate in this research if your doctor determines that you are a good candidate for the use of these off-label medications. Participation is entirely voluntary. Your treatment plan will not change if you do not take part in the research.

Section 3. HOW LONG DOES IT TAKE TO COMPLETE THE STUDY?

Because KCNT1-related disorders affect people for the duration of their lifetimes, there is no set end date for the registry. We hope to follow patients for a long time and measure long-term outcomes and quality-of-life.

You will be invited to participate in studies throughout the year, but you are not required to complete any surveys within a specific time frame. You are free to start any survey and return later at a more convenient time. You may contact the study coordinator at any time to take action in accordance with your data privacy rights, such as to delete your data.

Section 4. ARE THEIR ANY DISCOMFORTS AND RISKS?

One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure. Some of the tools we will use include:

- Data encryption of all your research data (at collection, storage and analysis levels)
- Authentication processes (to prove you are you)
- Strong internal policies
- Required training for all study team members (ensuring qualifications)

- Regular security audits
- Policies will follow all relevant regulatory standards, including Good Clinical Practice and similar legislation such as the Health Insurance Portability & Accountability Act (HIPAA)

  Additionally, answering medical questions may cause anxiety or other psychological distress to you while completing a questionnaire. To reduce these risks, you have the opportunity to discuss any questions with study team members. Responses to all questions are optional. You will not be required to answer any questions that make you feel uncomfortable.

Section 5. WHAT ARE THE BENEFITS OF MY PARTICIPATION? Possible Benefits to Self

You may not benefit directly from participating in this study.

Possible Benefits to Others

The results of this research may provide insights into other related diseases including genetic epilepsies, traumatic brain injury, and other diseases that intersect with the KCNT1 gene or the associated symptoms.

Section 6. WHAT WILL YOU DO WITH MY INFORMATION AND HOW WILL IT BE PROTECTED?
All information taken from this study will be coded to protect your identity. No names or other identifying information will be used when discussing or reporting data. The investigator(s) will safely keep all files and data collected in a secure database, accessible only by qualified study team members on study-approved and password-protected devices. Once the data has been fully analyzed it will be destroyed.

Your data are reviewed, stored, and analyzed in the secure database. Any hard copies of your data that are collected (via any paper surveys administered to you) will be transferred to this database by study team members. Hard copies of these surveys will be maintained in secure

locations in locked file cabinets, accessible only to key personnel (qualified study team members). We will tell you if there is a data breach.

No identifiable information will ever be publicly available. Some deidentified data may be shared with researchers who want to analyze the data in aggregate to learn more about KCNT1-related disorders and epilepsy. All researchers inquiring about this data will be required to obtain Institutional Review Board approval before they are provided this deidentified information. This is to further ensure you have adequate privacy and confidentiality.

Section 7. DOES IT COST ME ANYTHING TO PARTICIPATE?

There are no known risks of injury from participation in this study, and there are no situations envisioned in which costs would be incurred by you that would require reimbursement, including medical care.

You will not lose any legal rights by signing this form.

Section 8. WILL I BE PAID TO PARTICIPATE?

There is no compensation associated with participation in this study.

Section 9. HOW IS THIS STUDY FUNDED?

This study is entirely funded by the KCNT1 Epilepsy Foundation. There are no conflicts of interest.

Section 10. WHAT IF I DO NOT WANT TO PARTICIPATE?

Taking part in this study is voluntary. You can withdraw or terminate participation at any time. Please contact Sarah Drislane (sarah@kcnt1epilepsy.org) to initiate the process to withdraw or terminate.

Section 11. WHAT IF I HAVE QUESTIONS?

You have the right to ask any questions about this study and research. If you have questions, complaints, or concerns or believe you may have developed an injury related to this research, contact Sarah Drislane (sarah@kcnt1epilepsy.org) and the Genetic Alliance IRB at irbadmin@geneticalliance.org.

END CONSENT

Collection of the participant response and decision as to whether or not to proceed and participate in this study will utilize the parameters in IRB-approved protocol# PEER001 that describe the consent process and tools for all consents.