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| **IRB#: 23321** | MED. REC. NO. \_\_\_\_\_  NAME \_\_\_\_\_  BIRTHDATE \_\_\_\_\_ |

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| **CLINICAL RESEARCH CONSENT AND AUTHORIZATION**  **SUMMARY OF KEY INFORMATION ABOUT THIS STUDY**  **TITLE**: Epilepsy Genetics Database  **PRINCIPAL INVESTIGATOR**: Jason Coryell, MD, MS *(503) 494-5856*  You are being asked to join a research study. This consent form contains important information to help you decide if you want to join the study or not.  **PURPOSE:**  The purpose of the study is to develop a centralized database for individuals with an identified genetic cause of their epilepsy. We are gathering information from genetic test results in which a definite or possible cause for epilepsy is identified. As many of these genetic disorders are individually rare, we are combining the results from many centers nationally. We are hoping to learn more about specific characteristics of rare genetic epilepsies, identify successful treatment patterns, and serve as a centralized recruitment pool for additional studies or trials that may be available to specific genetic causes of epilepsy.  **DURATION:**  Your participation in the study will consist of no additional visits to the regular care your child receives. We may ask to follow your child’s health through the use of an electronic survey for up to ten years.  **PROCEDURES:**  If you decide to take part in this study, there will be no procedures performed on your child, and there will be no specific treatment that your child is required to take. Your medical team will enter information from the genetic test(s) your child has received. They will also enter basic clinical information including seizure patterns, previous and current medications, and associated medical conditions. You may complete an annual form that updates this clinical information, including seizure frequency, quality of life, treatments, and other related health problems.  **RISKS:** There is no physical risk with this study. While private information remains encrypted to protect confidentiality, there is a small risk that private health information could be identified by someone other than your doctor/research team.  **BENEFITS:** You will not directly benefit from taking part in this research. Having greater information about rare genetic epilepsies, trends in treatment, and access to clinical studies may improve our ability to successfully treat seizures and related complications in the future.  **ALTERNATIVES:**  You may choose not to participate in this study, and may receive standard treatment or participate in another study if one is available.  This is a voluntary research study. You do not have to join the study. Even if you decide to join now, you can change your mind later. Please ask the Investigator if you have any questions about the study or about this consent form.  **END OF CONSENT SUMMARY** |
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| **IRB#: 23321** | MED. REC. NO. \_\_\_\_\_  NAME \_\_\_\_\_  BIRTHDATE \_\_\_\_\_ |

**Clinical Research Consent and Authorization Form**

**TITLE**: Pediatric Epilepsy Genetics Database

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| **PRINCIPAL INVESTIGATOR**: | Jason Coryell, MD, MS (503) 494-5856 |
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| **CO-INVESTIGATORS**: | Ittai Bushlin, MD, PhD (503) 494-5856 |
|  | Colin Roberts, MD (503) 494-5856 |
|  | Carter Wray, MD (503) 494-5856 |
|  | Holden Richards, BS (503) 494-5856 |
|  | Bryn McCarthy, RN (503) 494-5856  Beata Dyar, BS (503) 494-5856  Parvathi Sidigonde, MD (503) 494-5856 |
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**WHO IS PAYING FOR THE STUDY?**: No institutions or private entities is providing monetary support for this study.

**DO ANY OF THE RESEARCHERS HAVE A CONFLICT OF INTEREST WITH THIS STUDY?:** No investigators have a conflict of interest with this study.

**WHY IS THIS STUDY BEING DONE?:**

“You” means you or your child in this consent form.

You have been invited to be in this research study because your child has or may have a genetic cause for their epilepsy. The purpose of this study is to develop a national database for rare genetic epilepsies for the purpose of studying their characteristics and provide access to clinical trials or other studies.

Genes are the units of DNA--the chemical structure carrying your genetic information--that determine many human characteristics such as the color of your eyes, your height, and whether you are male or female.

Genetic information will be stored as part of the study. As this is a multi-center database, we anticipate identifying larger groups of people with rare genetic causes of epilepsy. You have the option of being contacted for future additional studies related to your condition; however, you have the right to opt-out of being contacted for any future studies. A box for opting out of being contacted for possible participation in other studies is included on the signature page.

Approximately 4000 participants are expected to enroll in this study nationally.

**WHAT EXAMS, TESTS AND PROCEDURES ARE INVOLVED IN THIS STUDY?**

No blood/tissue samples are collected or saved as a part of this study. Any genetic testing that you undergo is a part of routine clinical care. There is no specific treatment or medication provided or required. Your doctor will continue to treat using her/his best professional judgment.

Your medical record will be reviewed as part of this study including medical record number and date of birth. We will also review information related to your seizures such as type, frequency, as well as current and previous treatments. Personal health information (such as medical record number, date of birth, email) will only be visible to investigators at your hospital and the principal investigator. It is included to help the researchers at your institution identify you if you wish to be re-contacted for additional studies.

This study will not require ongoing participation. There is an option to receive an electronic form to complete annually for up to ten years. Examples of questions in this survey include seizure frequency, quality of life, treatments, and other related health problems. This takes between 5-15 minutes to complete. If you agree to this part of the study, we will collect your email address. This will only be used for sending surveys annually.

Genetic information from other family members will not be gathered for this study; however, if genetic records indicate whether a genetic variant is new or inherited, this information will be recorded.

**WILL I RECEIVE RESULTS FROM THIS STUDY?**

Information about your genetic test result should be discussed with your neurologist and/or geneticist; the research team will not provide further interpretation of the lab report. Further findings that stem from this research will not be provided to you. If you opt to be contacted for future studies, there is a possibility that you would learn more specific information from that study.

**WHAT RISKS CAN I EXPECT FROM TAKING PART IN THIS STUDY?**:

A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it

illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. Be aware that this federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination if you have already been diagnosed with the genetic disease being tested.

Although we have made efforts to protect your identity, there is a small risk of loss of confidentiality. If the results of these studies of your genetic makeup were to be accidentally released, it might be possible that the information we gather about you as part of this study could become available to an insurer or an employer, or a relative, or someone else outside the study. Even though there are certain genetic discrimination and confidentiality protections in both Oregon law and federal law, there is still a small chance that you could be harmed if a release occurred.

The annual survey contains questions related to quality of life, response to treatment, and SUDEP. Some of these questions may seem very personal or embarrassing. They may upset you. You may refuse to answer any of the questions that you do not wish to answer. If the questions make you very upset, we will help you to find a counselor.

**WHAT ARE MY CHOICES IF I DECIDE NOT TO TAKE PART IN THIS STUDY?**

You may choose not to be in this study. Your decision to participate or not participate will not change the care that your doctor provides you.

**WHO WILL SEE MY PERSONAL INFORMATION?**

We will take steps to keep your personal information confidential, but we cannot guarantee total privacy.

We will create and collect health information about you as described in the WHY IS THIS STUDY BEING DONE? and the WHAT EXAMS, TESTS AND PROCEDURES ARE INVOLVED IN THIS STUDY? sections of this form. Health information is private and is protected under federal law and Oregon law. By agreeing to be in this study, you are giving permission (also called authorization) for us to use and disclose your health information as described in this form.

The investigators, study staff, and others at Oregon Health & Sciences University (OHSU) may use the information we collect and create about you in order to conduct and oversee this research study. This will be entered into a RedCAP database maintained by researchers at OHSU. This is a secure database only available to participating researchers. An anonymous study number will be assigned to you. Only the investigators at your hospital will be authorized to link the study number to you.

This study is collaborative between participating US hospitals affiliated with the Pediatric Epilepsy Research Consortium (PERC). Information such as age, sex, and the genetic test result may be shared with co-investigators that participate in PERC, but it would be associated with the anonymous study number to maximize confidentiality. Identifiable information such as name,medical record number, and e-mail are not shared with investigators outside of the hospital where your child is seen. This information will not be shared with other organizations or posted in a public database, nor will it be sold to a third party. If there are additional studies that develop that may pertain to your child, researchers from your child’s hospital may contact you to participate. You may choose today whether you wish to be contacted for possible future studies (see final page). If you do not want to be contacted in the future, you may still participate in the current study.

We may release this information to others outside of OHSU who are involved in conducting or overseeing research, including:

* The Food and Drug Administration
* The Office for Human Research Protections, a federal agency that oversees research involving humans

Those listed above may also be permitted to review and copy your records, including your medical records.

We will not release information about you to others not listed above, unless required or permitted by law. We will not use your name or your identity for publication or publicity purposes, unless we have your special permission.

We may continue to use and disclose your information as described above indefinitely.

***WILL ANY OF MY INFORMATION OR SAMPLES FROM THIS STUDY BE USED FOR ANY COMMERCIAL PROFIT?***

Information about you or obtained from you in this research may be used for commercial purposes, such as making a discovery that could, in the future, be patented or licensed to a company, which could result in a possible financial benefit to that company, OHSU, and its researchers. There are no plans to pay you if this happens. You will not have any property rights or ownership or financial interest in or arising from products or data that may result from your participation in this study. Further, you will have no responsibility or liability for any use that may be made of your samples or information.

**WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?**

There will be no cost to you or your insurance company to participate in this study.

**WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?**:

If you believe you have been injured or harmed as a result of participating in this data collection, contact Principal Investigator, Jason Coryell, MD or other members of the study team at (503) 494-5856**.**

OHSU and the funder do not offer any financial compensation or payment for the cost of any injury or harm.  However, you are not prevented from seeking to collect compensation for injury related to negligence on the part of those involved in the research.  Oregon law (Oregon Tort Claims Act (ORS 30.260 through 30.300)) may limit the dollar amount that you may recover from OHSU or its caregivers and researchers for a claim relating to care or research at OHSU, and the time you have to bring a claim.

If you have questions on this subject, please call the OHSU Research Integrity Office at (503) 494-7887.

**WHERE CAN I GET MORE INFORMATION?**

If you have any questions, concerns, or complaints regarding this study now or in the future, contact the Principal Investigator, Jason Coryell, MD or other members of the study team at (503) 494-5856**.**

This research has been approved and is overseen by an Institutional Review Board (“IRB”), a committee that protects the rights and welfare of research participants. You may talk to the IRB at (503) 494-7887 or irb@ohsu.edu if:

• Your questions, concerns, or complaints are not being answered by the research team.

• You want to talk to someone besides the research team.

• You have questions about your rights as a research participant.

• You want to get more information or provide input about this research.

You may also submit a report to the OHSU Integrity Hotline online at <https://secure.ethicspoint.com/domain/media/en/gui/18915/index.html> or by calling toll-free (877) 733-8313 (anonymous and available 24 hours a day, 7 days a week).

**WHAT ARE MY RESPONSIBILITIES IN THIS STUDY?**

There are no further mandatory responsibilities beyond consent for researchers to collect clinical and genetic test information for the database. If you choose to provide ongoing data to the research team, there will be an annual survey sent electronically to your email address for up to 10 years.

**DO I HAVE TO TAKE PART IN THIS STUDY?**

Your participation in this study is voluntary. You do not have to join this or any research study. You do not have to allow the use and disclosure of your health information in the study, but if you do not, you cannot be in the study. Some parts of the study (the annual survey) are optional. You can choose not to participate in some or all of the optional parts but still participate in the rest of the study.

Your health care provider may be one of the investigators of this research study and, as an investigator, is interested in both your clinical welfare and in the conduct of this study. Before entering this study or at any time during the research, you may ask for a second opinion about your care from another doctor who is in no way involved in this project. You do not have to be in any research study offered by your physician.

**IF I DECIDE TO TAKE PART IN THIS STUDY, CAN I STOP LATER?**

If you do join the study and later change your mind, you have the right to quit at any time. This includes the right to withdraw your authorization to use and disclose your health information. If you choose not to join any or all parts of this study, or if you withdraw early from any or all parts of the study, there will be no penalty or loss of benefits to which you are otherwise entitled, including being able to receive health care services or insurance coverage for services. Talk to the investigator if you want to withdraw from the study.

If you no longer want your health information to be used and disclosed as described in this form, you must send a written request or email stating that you are revoking your authorization to:

Jason Coryell, MD

CDRC-P, 707 SW Gaines Rd

Portland, OR 97239

[pedsneuro@ohsu.edu](mailto:pedsneuro@ohsu.edu)

(If email, place Dr. Coryell’s name and ‘Epilepsy Genetics Database’ in the subject line)

Your request will be effective as of the date we receive it. However, health information collected before your request is received may continue to be used and disclosed to the extent that we have already acted based on your authorization.

If in the future you decide you no longer want to participate in this research, we will eliminate your study number and recorded data from the database. You will no longer receive annual surveys.

You may be removed from the study if the investigator stops the study. (ex: if investigator leaves and there is not a replacement for this research role). The information provided in the database may still be used by PERC collaborators, but this may limit the ability to be re-contacted for possible future studies.

We will give you any new information during the course of this research study that might change the way you feel about being in the study.

**SIGNATURES:**

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| ***OPT-IN FOR FUTURE STUDIES***  Future studies may develop for specific genetic conditions. You may give permission here to be contacted about future research opportunities.  \_\_\_\_\_ I want to be contacted by the study team if we are eligible to participate in a new study based on our genetic test results.  \_\_\_\_\_ I do not want to be contacted about future studies.  ***OPT-IN FOR ANNUAL SURVEY***  \_\_\_\_\_ I want to continue participation by completing an annual electronic survey (sent by email) that will take 5-15 minutes to complete.  \_\_\_\_\_ I do not want to receive annual electronic surveys.  **If yes for either, please provide e-mail:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

Your signature below indicates that you have read this entire form and that you agree to be in this study.

We will give you a copy of this signed form.

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| Participant Printed Name |  | Participant Signature |  | Date |
| Parent, Guardian, or Legally Authorized Representative Printed Name |  | Parent/Guardian/Representative Signature |  | Date |
| Person Obtaining Consent Printed Name |  | Person Obtaining Consent Signature |  | Date |
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| Use of an Interpreter: Complete if the participant is not fluent in English and an interpreter was used to obtain consent.  Participants who do not read or understand English must not sign this full consent form, but instead sign the short form translated into their native language.  This form should be signed by the investigator and interpreter only. If the interpreter is affiliated with the study team, the signature of an impartial witness is also required.  Print name of interpreter: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature of interpreter: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date: \_\_\_\_\_\_\_\_\_  An oral translation of this document was administered to the participant in \_\_\_\_\_\_\_\_\_\_\_\_\_ (state language) by an individual proficient in English and \_\_\_\_\_\_\_\_\_\_\_\_ (state language).  If applicable:  Print name of impartial witness: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature of impartial witness: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date: \_\_\_\_\_\_\_\_\_  See the attached short form for documentation. |