ORPHAN DISEASE CENTER
UNIVERSITY OF PENNSYLVANIA, PERELMAN SCHOOL OF MEDICINE
INFORMED CONSENT FORM

Protocol Title: Orphan Disease Center CDKL5 Deficiency Disorder International Patient Registry

Principal Investigator: Dan Lavery, PhD
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Understanding Your Participation

Introduction:
Thank you for your interest in the Orphan Disease Center CDKL5 Deficiency Disorder International Patient Registry ("**Registry**"). The purpose of this online registry is to collect personal, medical, and other information about patients with CDKL5 Deficiency Disorder (CDD) in order to improve understanding of this rare disease and future care for patients. Researchers will also use this registry to design and conduct research, as well as to identify patients who may be eligible for participation in research studies.

Please read this information carefully.
To help you decide if you want to take part in this study, you should know:

- Taking part in this study is completely voluntary.
- You can choose not to participate.
- You are free to change your mind at any time if you choose to participate.
- Your decision won't cause any penalties or loss of benefits to which you/ your child is otherwise entitled.
- Your decision won't change the access to medical care you/ your child receives, now or in the future, if you choose not to participate or discontinue your participation.
- You can take your time to decide if you want to participate. You can return to this form at a later time, and you can ask questions at any time by emailing or calling the Orphan Disease Center:

Email: ODCRegistry@pennmedicine.upenn.edu ***Phone: 215-746-2704**

(*To ask a question in a language other than English, please contact the Orphan Disease Center by email.)

For the purpose of this form "the patient" will refer to the person diagnosed with CDD. "You" will refer to the person entering the information. This may be the patient or the patient's legal guardian (parent or caregiver).

What is a patient registry?
A patient registry is a place to store detailed information about patients with a specific disease or syndrome. Establishing a registry addresses two important needs.

- First, scientists studying rare diseases need accurate information directly from patients or caregivers to understand how rare diseases affect people.
- Second, scientists who are ready to start studies to learn more about rare diseases, including investigating potential treatment options, need to find people to participate in these studies.

Who can participate in this Registry?
Patients, and/or the legal guardians of patients with either:

- a clinician-confirmed diagnosis of CDD, or
- a clinician-confirmed clinical pre-disposition to CDD

may participate in this Registry.

Who can sign the consent form?

- Patients who are over the legal age, per local regulations, and who understand the consent form are eligible to join the Registry on their own.
- Otherwise, the legal guardian of the patient must sign the consent in order to enter data on behalf of the patient.
    - When the patient turns the legal age, per local regulations, if the patient is able to provide informed consent, he or she will be contacted to do so. If the patient no longer wishes to participate in the Registry, the patient may choose not to consent, and they will be withdrawn from the Registry at that time.
    - Legal guardians cannot continue to enter data on behalf of an adult patient, unless the patient is either 1) not capable of understanding and providing informed consent, or 2) capable of understanding and providing consent but unable to enter data due to physical limitations (in which case he or she must authorize the individual who will enter data on their behalf).

If you are a legal guardian consenting on behalf of a patient who is under the legal age, per local regulations, but who is capable of understanding information about the study, please use the script below to explain to the patient what is involved if you choose to participate :

"This is a research study that collects information about people with a rare disease called CDKL5 Deficiency Disorder. By participating in this study, information about you and your guardian(s) will be entered into a computer database called a registry. The registry is connected to the web, but is locked so that only the research team can see the information. The registry will ask about your disease, your family, medical information, your past doctor visits, how you feel, how your disease changes over time, and other questions. Some questions might make you uncomfortable or be hard to answer. There are some questions that require an answer, but, for the most part, you do not have to answer any questions you don't want to answer. Your personal information will be kept private by the research team, but once your name and other personal information have been removed, your other information may be shared both within and outside of the registry. Participating in this research study might help researchers find new treatments for CDKL5 Deficiency Disorder. You can also learn about other studies that you might be able to participate in. We expect this registry to last at least 5 years. If you do not want to be in this study, you do not have to participate. Being in this study is up to you, and no one will be upset if you do not want to participate, or even if you change your mind later and want to stop. You do not have to decide if you want to participate right now – you can think about it and decide later. You or your guardian can also ask any questions that you have about this study at any time by contacting the research team."

What will happen if you choose to participate in the Registry?

- You are reading this form because you have provided basic contact information in order to create a username and password to access the online Registry.
- Upon reading the "Understanding Your Participation" section of this form, you will indicate that you agree to participate in the Registry by signing the Informed Consent portion of the form.
- You will be asked to keep a copy of the form for yourself (either printed or saved electronically).

- When you log into the Registry, you will be asked to complete questionnaires. These questionnaires include some basic health information as well as CDD-specific questions about clinical information, diagnoses, and experiences of the patient.
- The time to complete the questionnaires will be different for each person. You can complete the questionnaires at your preferred pace. You can save what you have completed and return to complete questions at a later time.
- If more than one family member has the same diagnosis, you will need to create a different account and complete the informed consent process for each affected person. For example, if you have a son and a daughter with CDD, then your son will have a profile just about him, and your daughter will have a completely separate profile just about her. You will be able to log in to both profiles with the same username and password.
    - Adult patients participating in the Registry cannot provide consent on behalf of their adult family members diagnosed with CDD. Each family member participating in the Registry will need to provide separate consent for their participation.

Will I be expected to provide the Registry with additional information in the future?
Yes. The Registry is most valuable for scientific research when it is kept up-to-date. Therefore, you will be asked to update your/ your child's profile and information at least once per year.

- The Orphan Disease Center research team will send out notifications through your Registry profile or to the email address you provide in the Registry at least annually to remind you to log-in and complete the questionnaires.
- The Orphan Disease Center research team may also contact you to request that you fax or upload your/ your child's genetic test results and any other relevant reports or testing results.

What will my participation in this Registry involve?
Participation in the Registry involves the following:

- Contributing information about you and/or your child to an international data registry for CDD, called the Orphan Disease Center CDKL5 Deficiency Disorder International Patient Registry. The following personal information may be collected from you (meaning the patient and/or legal guardian) and used over the course of your involvement in the Registry:
    - Name
    - Address
    - Email address
    - Telephone number
    - Date of birth
    - Internet IP Address
    - Past, current, and future information from personal and family medical history,
    - Results and information from physical examinations, tests and/or procedures, including dates
    - Allergies and medications
    - Answers to survey questions about the patient, as well as the patient's legal guardian, if applicable
    - Medical information entered by your clinician following routine/standard of care visits, if you provide consent to collect this information
- Participation in online surveys at least once per year and agreement to receive reminders to update your/ your child's information and complete new surveys to get an idea as to how you/ your child is feeling .
- Option to allow the ODC to contact the clinician whose information you provide in the portal, to allow for this clinician to enter information about you/ your child in the Registry including information from your/ your child's medical record, and to allow for this clinician to view information that you have entered.
- Option to be contacted in the future for clinical trials or research studies
- Consent for the transfer of your/ your child's personal health information, **without** direct identifiers, to other entities, such as qualified researchers, health authorities, and other third

parties, without violating confidentiality to the extent permitted by the applicable law(s) or regulations
- Uploading documents to the Registry where required; these may include medical records, genetic reports, and other relevant documents (e.g. CAT scans, MRIs).

As mentioned above, your participation involves allowing the data you enter to be shared for research purposes, including the transfer of your/ your child's data to other entities, such as qualified researchers, health authorities, and other third parties, without violating confidentiality, to the extent permitted by the applicable law(s) or regulations. Your/ Your child's data may also be combined with information from other participants in the Registry to create averages and summaries (for example, average age at diagnosis) to be shared publically, including within the Registry for all participants to view. These summaries will not include any identifiable information about individual participants.

Who may use and share information about me?
The following individuals may use or share your/ your child's information for this research study:
- The Principal Investigator, Dan Lavery
- The research team at the Orphan Disease Center
- Authorized personnel from the University of Pennsylvania Institutional Review Boards (the committees charged with overseeing research on human subjects), The Food and Drug Administration, Office of Regulatory Affairs, Office of Human Research (the office that monitors research studies), European Medicines Agency, and other regulatory agencies
- Personnel from Pulse Infoframe (the software company hosting the Registry), who may see identifiable information in the course of performing their respective functions related to the Registry, including performing routine and ad hoc maintenance.
- Other research personnel with access to the databases for research and/or study coordination and as otherwise approved by the University of Pennsylvania IRB and any other IRBs or Ethics Committees (ECs) that have reviewed and approved this study
- Your/ Your child's clinician, but only with your permission (this permission is an optional part of the Registry)
- Your/ Your child's personal information may be given out if required by law.

Additionally, as part of the study, the Principal Investigator, study team and the Registry's scientific advisors may disclose your/ your child's personal information, with all identifiable information removed, outside of the University of Pennsylvania for future research efforts without additional consent from participants. In records and information disclosed outside of the University of Pennsylvania, your/ your child's information will be de-identified using a unique code number. The Registry data set will be shared with qualified researchers who apply for access to conduct exploratory research. If information from this Registry is published or presented at scientific meetings, your/ your child's name and other personal information will not be used. Once information is disclosed to others outside the University of Pennsylvania, the information may no longer be covered by federal privacy protection regulations, such as HIPAA.

How long may the University of Pennsylvania School of Medicine use or disclose my/ my child's personal health information?
Your authorization for use of your/ your child's personal information for this specific study does not expire. This information will be maintained in a research database, per local regulations. The University of Pennsylvania School of Medicine may not re-use or re-disclose the personal information collected in this study for another purpose other than the purposes described in this document, unless you have granted written permission for the Principal Investigator to do so. However, the University of Pennsylvania Institutional Review Board may grant permission to the Principal Investigator or others to use your/ your child's information for another purpose after ensuring that appropriate privacy safeguards are in place. The Institutional Review Board is a committee whose sole job it is to protect the safety and privacy of research subjects.

Can I change my mind about participating in the Registry?

You have the right to withdraw yourself/ your child from the Registry at any time. To formally withdraw from the Registry you should follow the instructions in the patient portal for withdrawal or email the Orphan Disease Center at **ODCRegistry@pennmedicine.upenn.edu**. If you stop the study early, the study information that was obtained up until that time will still be used for the purposes described in this document unless you direct the team otherwise in your withdrawal request. If your/ your child's de-identified data has already been shared with a third party, the ODC cannot reverse this action but can ensure no data is shared moving forward. As described above, any information shared outside of the University of Pennsylvania will be de-identified.

What if I decide not to give permission to use and give out my health information?

If you decide not to give the ODC research team permission to use and give out your/ your child's de-identified health information, you/ your child will not be able to participate in this Registry.

How does the Registry protect the confidentiality and personal information of participants?
The University of Pennsylvania and its affiliated hospital(s) have rules to protect information about you/ your child. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. All research projects have some risk that people outside of the project may learn information about you/ your child. While we cannot guarantee total confidentiality, we believe the risk of loss of confidentiality is very small, as access to the database with protected health information is limited to selected and qualified study personnel. We have taken important action to reduce this risk, and we will do our best to make sure that the directly identifiable information within the Registry will be kept confidential. We will assign a special research code number to your/ your child's information stored in the Registry, and this code will be used instead of directly identifiable information to identify you/ your child in all data shared with researchers.

Furthermore, we will use a highly secure data storage system. The registry's platform is powered by Pulse Infoframe.

- Pulse is compliant with both HIPAA (Health Insurance Portability and Accountability Act) and PHIPA (Personal Health Information Protection Act).
- The Registry is also compliant with the General Data Protection Regulation (GDPR) (Regulation (EU) 2016/679). You will receive a separate Data Privacy Notice for your review that will provide additional information regarding data privacy.
- Additionally, the Pulse computer program does not interfere with the settings, preferences or commands of a user's computer or device, nor does it change or interfere with data stored on the device. It does not connect to or send messages to other computer systems without the user's authorization, or install programs that may be activated by a third party without the user's knowledge.

For any additional questions or concerns, please reach out to the Orphan Disease Center:

Email: ODCRegistry@pennmedicine.upenn.edu ***Phone: 215-746-2704**

(*To ask a question in a language other than English, please contact the Orphan Disease Center by email.)

What if the information collected in my Registry profile strongly suggests that I/ my child has a disease other than my/ my child's currently diagnosed disease?
If during review of your/ your child's information, the physicians and researchers determine that your/ your child's data strongly suggest that you/ your child has a clinically actionable and life-threatening disease other than CDD, you will be contacted to inform you of this potential finding and to determine to which physician you would like us to disclose this possible finding. We cannot guarantee that alternative diagnoses will be identified during reviews of the data entered in this Registry.

What are the possible risks of my participation in the Registry?
There is no known harm or risk of physical injury associated with participation in this study. The greatest risk is that someone not authorized to review your/ your child's data would be able to see it, figure out that

it is your data, and share it with others. We think the risk of loss of confidentiality is very small, as access to the database with protected health information is limited to selected and qualified study personnel. Furthermore, we will use a highly secure data storage system. Another risk is that you may feel uncomfortable or anxious answering some of the questions in the Registry because the Registry includes questions that may be sensitive. These questions include those about you/ your child's or your family's health and treatment for a serious medical condition. You do have the option to skip these questions; however, it is important to keep in mind that the data collected in this registry may be very important to researchers and the patient community..

What are the possible benefits of my participation in the Registry?
You/ Your child will not benefit directly from participating in this study; however, if you provide consent, you may be contacted in the future about clinical trials that could benefit you/ your child. Further, information contained within the Registry will be used for research directed at improving our knowledge and treatment of CDD, and this knowledge may benefit patients with this disease in the future. You may feel a sense of satisfaction knowing you/ you child is facilitating rare disease research, even though you may not personally receive information back from the study. Additionally, you will be able to view information you have entered in the Registry to help you track changes over time.

Who is paying for this Registry?
This study is being supported by the Orphan Disease Center at the University of Pennsylvania. Throughout the life of the Registry, the Orphan Disease Center will seek additional funding from companies, foundations, and other sources. All financial sponsors will be disclosed on the ODC website and in the patient portal of the Registry.

Will I/ my child be paid for being in this Registry?
You/ your child will not be paid for being in this Registry.

Will I have to pay for anything?
There will be no costs to you or your insurance provider to participate in this Registry.

When will data collection for the Registry end?
This Registry does not have a defined, final data collection date. Data collection for the Registry may be stopped at any time by the Orphan Disease Center.

What other choices do I have if I/ my child does not participate?
Instead of taking part in this study, you may choose not to participate.

If I have given data or information to doctors, researchers, clinics or hospitals in the past, is it OK to give my/ child's data to the Registry now?
Yes. We will be taking precautions to make sure information used is not redundant with data that may have been collected previously.

I want to be involved in a clinical trial or I want my child to be involved in a clinical trial. If I register, is this guaranteed?
Although one of the main goals of the Registry is to make it easier for patients to participate in clinical research, there is no guarantee that that you/ your child will be contacted or eligible for a trial.

I don't want to be involved in a clinical trial or I don't want my child to be involved in a clinical trial. Should I still register?
Of course, this is up to you, but we hope that you will still be willing to register, even if you don't want to take part in a trial or you don't want your child to take part in a trial. Your/ your child's information may still be useful to researchers who are trying to learn more about patients with rare diseases.

Who can I call with questions, complaints or if I'm concerned about my/ my child's rights as a research subject?

You may ask questions about this study at any time. If you have questions, concerns or complaints regarding your/ your child's participation in this research Registry, or if you have any questions about your/ your child's rights as a research subject, you should email the Orphan Disease Center. If a member of the research team cannot be reached or you want to talk to someone other than those team members working on the Registry, you may contact the Office of Regulatory Affairs at the University of Pennsylvania with any question, concerns or complaints by calling (215) 898-2614.

Privacy Notice

This Privacy Notice explains how personal data about your child and/or you as his/her legal guardian are used in connection with the Orphan Disease Center CDKL5 Deficiency Disorder International Patient Registry ("**Registry**").

This Privacy Notice supplements the form titled "Orphan Disease Center University of Pennsylvania, Perelman School of Medicine Informed Consent Form" ("**Form**"), available in the online Registry.

1. **What personal data will be collected?**

- If you or your child joins the Registry, the Orphan Disease Center ("**ODC**") team will collect personal data about you and your child through an online portal hosted by Pulse Infoframe, the company that manages the online Registry procured by the ODC.

. This data will become part of a Registry. Such personal data may include:

- you and your child's names, contact details (e.g., phone number, email, address), demographics (e.g., date of birth, age and gender) and Study documentation (such as signed Form);
- your child's habits, preferences and behaviors;
- your child's current and historical heath information and information from his/her medical records;
- your child's health information as it relates specifically to CDKL5 Deficiency Disorder (CDD)
- family medical/ health and genetic history;
- other (sensitive) personal data, such as genetic data, ethnicity and race.

The personal data will be collected directly from you and your child. You and your child's provision of personal data is voluntary. However, if you or your child do not provide such data, you and your child may not be able to participate in the Study.

You are providing this personal data to limited individuals at the **Orphan Disease Center at the University of Pennsylvania** based in the United States (TRL Suite 1200, 125 South 31st Street, Philadelphia, PA 19104) which is the organization overseeing the Registry. You will do so by entering information in relation to the personal data described above (such as names, dates of birth or genetic information), into a database procured by the ODC and hosted by Pulse Infoframe.

2. **How will personal data be used?**

The personal data above will be recorded in a secure, online portal and will be used to:

- learn more about CDD through analysis of data regarding patient experiences, signs and symptoms;
- contact you or your child regarding clinical research studies or trials in which you may be interested, if you choose this option when you complete the informed consent form;
- perform further research as set out in Section 5;
- answer questions from and report to authorities, such as regulatory authorities, ethics committees or institutional review boards that review the Registry to verify that it meets ethical and scientific standards ("**Authorities**"); and/or
- improve the quality, accuracy and design of the Registry and other research studies/ registries.

The ODC performs the above activities in order to pursue their **legitimate interests** and/or **public interests**, including **scientific research** or to **comply with laws** applicable to research studies.

3. To whom may personal data be disclosed?

Aside from the ODC (or its legal successor), the personal data as described in Section 1 above may only be sent to or accessed in a *non-coded* form, that includes direct identifiers such as names and contact details by:

- Authorities as defined in Section 2 above;

- service providers that support the Study, such as Pulse Infoframe.

4. How is your privacy protected?

Before disclosing personal data to anyone other than the persons identified in Section 3 above, your personal data will be coded by the ODC. This means that a unique code will be used in place of other data that could directly identify you or your child, such as a name or contact detail. Only the team at Pulse Infoframe will have the link between the code and such identifiers and will keep this information confidential.

Such coded data may be sent to or accessed by:

- companies or individuals with an agreement in place with the ODC to utilize coded data to contribute to the public interest and/or for scientific research purposes;
- other researchers and peer reviewers with an agreement in place with the ODC, such as expert clinicians or researchers focused in CDD;
- Authorities as defined in Section 2 above; and/or
- service providers that support the Registry, such as data hosting providers.

Coded data may also be used in presenting Registry outcomes in meetings, promotional materials or in publications, but again, you and your child will not be directly identified in any such materials.

5. What about further research?

When you agree for your child to participate in the Registry, coded data about his/her health or care (which as explained in Section 4 will not identify you or your child by name) may be provided to conduct further research, to researchers running other research studies , or the ODC and other organizations with which an agreement has been implemented, even following your participation in this Study. These other organizations may be universities or other health organizations or companies involved in health and care research in your country or abroad.
Personal data (in a *non-coded* form) may also be used by the ODC for further research in any aspect of health or care, and could be combined with information from other sources held by researchers, other health organizations, companies or governments. These sources may include: coded electronic health records, claims and health care data or databases, other product and disease registries, data gathered through your mobile devices, social media, pharmacy data, biobanks, or patient engagement programs.
The data described in this Section 5 will only be used for the purposes of health and care research (e.g., to understand how to detect, diagnose and treat, to inform value or optimize access to medical care), as set out in form titled “Understanding Your Participation”.

Further research as described in this Section 5 may occur on the basis of researchers’ legitimate interest and/or public interests, including for scientific research or to comply with applicable laws. The data will not be used to make decisions about future services available to your child, such as insurance. Where required by applicable law, the ODC will seek the approval of ethic committees or institutional review boards.

6. How long will personal data be stored?

The ODC will retain personal data for as long as needed or permitted in light of the purposes for which they were obtained, as set out in the relevant Form and this Privacy Notice and consistent with applicable law. The criteria used to determine such retention periods include:

- whether there is a legal or regulatory obligation to which ODC is subject;
- whether the retention is advisable in light of the ODC’s legal position, such as in case of regulatory demands; and
- technical and operational standards, such as ensuring system and data integrity, continuity availability and resilience, including preventing Study biases or data corruption.

7. How will personal data be protected when transferred outside the EU/EEA?

Your own or your child's personal data may be transferred to countries around the world for the purpose of the Registry, including outside your country. Some countries may have data protection and privacy laws that are different from your country, including the United States. Some of the non-European Economic Area ("**EEA**") countries are recognized by the European Commission as providing an adequate level of data protection according to EEA standards (a list of which is available at https://ec.europa.eu/info/law/law-topic/data-protection/data-transfers-outside-eu/adequacy-protection-personal-data-non-eu-countries_en).
For transfers from the EEA to other countries, including the United States, adequate measures are sought to protect personal data under the Registry and to permit the cross-border transfer of such personal data, such as standard contractual clauses adopted by the European Commission and similar data transfer agreements. To know more about or obtain a copy of these measures, please contact the ODC.

8. **What privacy rights do you and your child have?**

You and your child have the right to request to review, correct, delete, restrict or object to the use of your personal data. To make such a request, please contact the ODC team using the contact information in the Form. Note that such rights may be limited, as the ODC needs to manage personal data in specific ways in order for the Registry to be reliable and accurate. If you choose to withdraw/ withdraw your child from the registry, you will be given an option to remove all data collected to date so that it is not shared moving forward or to leave all data entered to date so that the ODC will keep the data about you and your child that they have already obtained, but will not include any new data in the Registry as of the date of withdrawal. To safeguard your and your child's rights, the ODC will use the minimum amount of personally-identifiable information possible.
If you have any question or inquiry for the ODC, please contact the team using the contact information below, who may direct your questions or concerns to the Penn Medicine Privacy Office.
For more information about privacy rights, or if you are not able to resolve a problem directly with us and wish to make a complaint, you can contact a competent data protection authority in the EEA, a list of which is available at https://edpb.europa.eu/about-edpb/board/members_en).

Informed Consent Form

For the purpose of this document "you," "your," "me," and "I," refers to the registrant (the person completing the Informed Consent), which is either the individual affected by CDD or the legal guardian (parent or caregiver) providing the information on behalf of the patient, if the patient is unable to provide informed consent.

By checking a box beside each applicable statement below, I am acknowledging that I understand and agree with the statement. If a statement is not applicable to me, I will not check it.

- ☐ I have read and understand the "Understanding Your Participation" and “Data Privacy Notice” sections of this form (both above).
- ☐ As the legal guardian of a patient who will be participating in the study, I have explained the research study to the patient to the extent that the patient is capable of understanding, using the script on page 2 of this document.
- ☐ I voluntarily agree that my child will take part in the Registry.
- ☐ I voluntarily give permission for the information I share in the Registry to be used for the purposes described in this document, without my additional permission or consent.
- ☐ I voluntarily give permission to the Orphan Disease Center to contact me at least once per year for updates, to request that I upload particular attachments, and to complete forms associated with my participation in the Registry.
- ☐ I understand that my/ my child’s participation in the Registry is voluntary.
- ☐ I understand that if I change my mind and wish to withdraw from the Registry, I am free to do so at any time without giving a reason.
- ☐ I have had the opportunity to ask questions of the Orphan Disease Center, and I do not have any unanswered questions about participation in the Registry.
- ☐ I understand that I can return to this page at any time in the future if I want to review it.
- ☐ I understand that the information collected about me/ my child will be used to support other research in the future, may be shared with other researchers or companies contracted by the University of Pennsylvania, and may be used in publications in scientific journals, to compare to data from studies/ trials that test new investigational medications, and to obtain approval for new medications, as long as as it has been de-identified, meaning that any personal health information that could identify me/ my child has been removed.

By checking a box beside a statement below, I am acknowledging that I understand and agree with the statement. If I do not consent to any of the **optional** items below or if a statement is not applicable to me, I will not check it.

- ☐ I agree to allow the Orphan Disease Center to contact the clinician whose information I provide in the registry. I agree to allow this clinician to enter information about me/ my child into the registry

on my/ my child's behalf. I also agree to allow this clinician to view information I enter into the registry.

☐ I would like to be contacted through the Registry in the future about research developments regarding CDD.

☐ I would like to be contacted by the Orphan Disease Center if I/ my child may be eligible* for a clinical trial or clinical study. Participation in a clinical trial may involve use of the patient's personal data as well as data from the Registry. The patient's Registry data will not be shared directly with the group conducting the clinical trial unless I give permission as a part of the clinical trial process. I may be given this option at the time of the clinical study or trial.

*__Please note__ that even if you/ your child's data suggests that you/ your child might be eligible for the trial, it is possible that you/ your child will not go on to meet the trial inclusion criteria. Please also be aware that if we inform you about the existence of a trial, this does not imply that we endorse it. In order for you/ your child to participate in any trial, you will need to complete and sign a separate informed consent form.

Name of Patient:_____

Name of Parent or Legal Guardian: _____

Signature and Date: _____