INDIANA UNIVERSITY INFORMED CONSENT STATEMENT FOR RESEARCH

School Testing and Supports of Children with Pelizaeus-Merzbacher disease

ABOUT THIS RESEARCH

You are being asked to participate in a research study. Scientists do research to answer important questions which might help change or improve the way we do things in the future.

This consent form will give you information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

TAKING PART IN THIS STUDY IS VOLUNTARY

You may choose not to take part in the study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled and will not affect your relationship with Riley Hospital for Children or Indiana University School of Medicine.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to
1) Describe the evaluation methods being used nationally in schools to determine support needs for children with PMD
2) Better understand and describe the supports that children/adolescents/young adults in public schools with PMD are currently receiving

We are recruiting participation for children, adolescents, and young adults ages 3 years to 25 years with PMD, who are attending or have attended school. You were selected as a voluntary participant because of your participation in the PMD Family Support group and because your child(ren) has/have PMD. We are asking that you share your child's most recent school testing (psychoeducational evaluation) and IEP. Any additional school testing or IEP documents are also welcome, particularly if you have lived in more than one school district.

The study is being conducted by Riley Hospital for Children and Indiana University. The team is not receiving any money to do this.

WHAT WILL HAPPEN DURING THE STUDY?

If you agree to be in the study, you will do the following things:

- Sign this consent and return it to our team via one of the methods listed below
- Send the team a copy of your child's school evaluation(s)
    - Schools refer to this as a psychoeducational assessment or test
- Send the team a copy of your child's IEP(s)
- If your child has graduated, you can still participate by sending your child's last updated school evaluation and IEP

Submit information to:

By postal Service:	By email:	By fax:
Care of Dr. Michelle Curtin 1002 Wishard Blvd Suite 3120 Indianapolis IN 46202	mjcurtin@iu.edu Subject: PMD Study	Care of Dr. Michelle Curtin Number: 1-(317)-948-0126

WHAT ARE THE RISKS OF TAKING PART IN THE STUDY?
While participating in the study, there are no risks to your child's health and wellness and there will be no changes in your child's medical or school care. While there is always a possible risk of loss of confidentiality, measures will be taken by our team to protect your child's personal information (such as name, date of birth, and school information)

WHAT ARE THE POTENTIAL BENEFITS OF TAKING PART IN THE STUDY?
We don't expect you or your child to receive any benefit from taking part in this study, but we hope to learn things that will help scientists, doctors, and schools in the future.

HOW WILL MY CHILD"S INFORMATION BE PROTECTED?
Efforts will be made to keep all personal information confidential. We cannot guarantee absolute confidentiality. Personal information may be disclosed if required by law. No information which could identify your child will be shared in publications about this study.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the study investigator and research associates, the Indiana University Institutional Review Board or its designees, and state or federal agencies who may need to access the research records (as allowed by law).

WILL MY CHILD'S INFORMATION BE USED FOR RESEARCH IN THE FUTURE?
Information collected for this study may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify your child will be removed before any information are shared. Since identifying information will be removed, we will not ask for your additional consent.

WHO SHOULD I CALL WITH QUESTIONS OR PROBLEMS?
For questions about the study, contact the head researchers, Dr. Michelle Curtin or Dr. Celanie Christensen at 317-948-4846 or via email at mjcurtin@iu.edu.

For questions about your rights as a research participant, to discuss problems, complaints, or concerns about a research study, or to obtain information or to offer input, please contact the IU Human Subjects Office at 800-696-2949 or at irb@iu.edu.

CAN I WITHDRAW FROM THE STUDY?

If you decide to participate in this study, you can change your mind and decide to leave the study at any time in the future. The study team will help you withdraw from the study safely. If you decide to withdraw, this can only be done during the initial collection period. We will remove your child's school evaluation and IEP(s) and shred them if this occurs, but once the information is processed it will not be removable.

PARENTAL CONSENT

In consideration of all of the above, I give my consent for my child to participate in this research study. I will be given a copy of this informed consent document to keep for your records as you prefer. I agree to take part in this study.

My child has a diagnosis of Pelizeaus-Merzbacher disease **with**:

- ☐ PLP1 duplication
- ☐ PLP1 deletion
- ☐ PLP1 point mutation
- ☐ PLP1 gene change (type unknown)
- ☐ Unknown genetic change
- ☐ Other _____

Child's Printed Name:_____

For children over 17 years of age, do you have legal decision making rights (circle one)? Yes / No

Printed Name of Parent/Legal Authorized Representative:_____

Signature of Parent/Legal Guardian/Legal Authorized Representative:_____

Date:_____

Where you would like us to send a copy of this consent for your records to you? Yes / No

Either Post:

_____

_____

_____

Or Email: _____