

Informed Consent

Using Speech as an Early Marker and Predictive Classifier of Autism Spectrum Disorder (ASD)

What is the purpose of this project?

You are invited to participate in a research study about children's vocalizations. This study is being conducted by Drs. Christian Poellabauer and Patrick Flynn at the University of Notre Dame and Drs. Susan Latham and Sandra Schneider at St. Mary's College. The Advanced Diagnostics and Therapeutics Initiative at the University of Notre Dame has provided funding for this study. You are invited to participate in this study because we want to collect voice/speech recordings from children at risk of autism between the age of 0 months and 9 months.

Participation in this study is voluntary and consent may be withdrawn at any time without penalty. Only Dr. Latham at St. Mary's College will know the identities of the participating families. Participation in this study will not involve any additional costs to you or your healthcare insurance provider and refusal to participate will not affect any benefits, services, etc., received now or in the future.

If you agree to participate in this study, you will be given an iPod device with speech collection software installed. If your child is an infant, we ask you to record approximately 2 hours per week of your child making various sounds and noises using the device's microphone. All data collection will take place in your home at your own convenience. In addition, we ask you to answer a brief questionnaire at the end of the 9-month period.

Are there any risks in this research?

We don't believe this study will involve any risks for you and your child. If you find any portion of the data collection process or any questionnaire questions upsetting, please tell us. You can choose to stop your participation or skip any question. The risks involved are no more than minimal.

What are the benefits of being in this study?

We hope that you and your child will have fun during the data collection and hope that it will help strengthen your relationship with your child. If your child has autism, it is known that most autistic children interact wonderfully with electronic devices and we expect that your child will enjoy the activities on the mobile device and possibly improve his/her communication skills.

Compensation for time and effort

We will give you a gift cards totaling \$135.- (\$15 per month for 9 months, paid in two installments).

How will we protect your privacy?

We will collect voice recordings of your child and some questions in the questionnaire may be very personal. We will protect your privacy to the extent allowed by law in several ways. First, all of our records for your family will be identified only by a code number. Only the research staff will have your names and contact information, and the list that links your name to your code number. Audio recordings will be saved electronically and will be labeled by ID number only and only authorized personnel will have access to the recordings. When we report the results of this study, you and your child will never be named or identified in any way.

Last, you should know that we are required by Indiana state law to make reports to prevent serious harm to you, your child, or others. If we see child abuse or neglect, we have to report it.

If you agree to participate, can you change your mind later?

Yes. You are free to join the study or not. If you join and later change your mind, you can withdraw from the study at any point, without any penalty, and recordings from your participation will be destroyed immediately. Choosing not to join the study will not affect any services you can get from the University of Notre Dame.

If you have any questions about this study, please contact Dr. Susan Latham (574-284-4686, slatham@saintmarys.edu) or Dr. Christian Poellabauer (574-631-9131, cpoellab@nd.edu). If you have questions about your rights as a research participant, please contact the University of Notre Dame Institutional Review Board (IRB), Office of Research Compliance, (compliance@nd.edu), phone (574-631-1389).

Participant Certification:

I have read this form (or, it has been read to me), and have had a chance to ask questions. My questions have been answered. I know that the data on me and my child will be kept private.

I give permission to be part of this study. I know that I can drop out of the study at any time. I also agree to the use and sharing of my information as described above. By signing this, I verify that I am at least 18 years old. I have received a copy of this consent form to keep.

Name of Parent/Guardian (Please print clearly)

Signature of Parent/Guardian

Date Signed

Current Address _____

Current Phone Number _____

Please check and sign below if you agree to the following:

Permission for to future contact

_____ I give permission to be contacted about opportunities to participate in future research studies.

Printed Name: _____

Signature: _____ Date: _____