Informed Consent Statement form

Study's Official Title: Validation of Indiana's Early Evaluation Hub System (EAER21)

NCT Number: NCT06586788

Date of document: 09-15-2021

INDIANA UNIVERSITY INFORMED CONSENT STATEMENT FOR RESEARCH

Validation of Indiana's Early Evaluation Hub System
Protocol Number: 1806262614

About this research
You and your child 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 your child to participate. Please read this form, and ask any questions you have, before agreeing for your child to be in the study.

Taking part in this study is voluntary
You may choose for your child 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 your child is entitled, and will not affect your child's relationship with Indiana University School of Medicine, Riley Hospital for Children, or Indiana University Health.

WHY IS THIS STUDY BEING DONE?
The purpose of the study is to evaluate the diagnostic validity (or accuracy) of Indiana's Early Evaluation (EE) Hub system. The EE Hub system is a network of primary care and subspecialist sites across the state of Indiana that evaluate children ages 14-48 months referred for neurodevelopmental concerns (i.e., to determine if they meet criteria for a diagnosis of autism spectrum disorder or developmental delay). This study will evaluate the agreement between diagnoses provided in the EE Hubs and those provided by an expert in the evaluation and diagnosis of children with neurodevelopmental disabilities. Your child was selected as a possible participant because he/she has been evaluated in one of Indiana's EE Hubs.

The study is being conducted by Rebecca McNally Keehn, PhD, HSPP of the Department of Pediatrics at Indiana University School of Medicine. Dr. McNally Keehn is a clinical psychologist and expert in the neurodevelopmental evaluation of young children. It is funded by the National Institute of Mental Health (NIMH), the Indiana Clinical Translational Sciences Institute (CTSI), and the Purdue University Big Idea Challenge (2.0).

HOW MANY PEOPLE WILL TAKE PART?
If you agree to participate, your child will be one of approximately 300 participants taking part in this research.

WHAT WILL HAPPEN DURING THE STUDY?
If you agree to be in the study, you and your child will do the following things:

- Your child will participate in a follow-up evaluation with a clinical psychologist who is an expert in the neurodevelopmental evaluation of young children. The evaluation will consist of assessments and interviews that are routinely administered during clinical neurodevelopmental evaluations. The follow-up evaluation will last for approximately 3 hours.
    - Your child will participate in three assessments. The first assessment will evaluate your child's developmental skills (Mullen Scales of Early Learning). During this assessment, your child will be asked to do simple activities such as build with blocks, point to pictures

in a book, complete puzzles, and follow simple directions with toys. The second assessment will evaluate his/her social communication and play skills (Autism Diagnostic Observation Schedule-2). During this assessment, your child will be asked to engage in simple social games and play with age-appropriate toys with you and the Autism Spectrum Disorder expert psychologist. Lastly, a shortened version of the Sensory Processing Assessment (SPA) will be used to measure your child's sensory responses to touch, sound, and/or visual information in social and nonsocial situations through playful interaction.
    - You will participate in a semi-structured clinical interview about your child's medical and developmental history and symptoms of autism spectrum disorder. You will also be asked questions about your child's adaptive skills (e.g., those related to communication, daily living skills, socialization, and motor skills).
    - You will be asked to complete a set of brief questionnaires about your family's demographic (e.g., race, ethnicity, household income, and caregiver education) and background medical information, as well as your child's behavior and intervention service history. We estimate that these questionnaires will take you no longer than 20-30 minutes to complete. We will give you the option to receive these questionnaires before your child's evaluation appointment to reduce the in-person time of the evaluation.
- We will record your child's eye movements and pupil size using an eye tracking system. For this activity, your child will sit on a chair or in your lap and will face a computer monitor. The eye tracker is non-invasive and only requires that a small sticker be applied to your child's forehead. Once calibrated, this system will follow eye movements and tell us exactly where on the screen your child is looking. Your child will see a series of different pictures and movies, which will last approximately 15 minutes.
- Following this evaluation, you will receive verbal feedback about your child's evaluation results and diagnosis as well as a brief research report summarizing this information. If you provide written permission, we will also send a copy of this report to your child's Early Evaluation Hub provider and his/her primary care provider.
    - If diagnosis differs between the Early Evaluation Hub and the expert neurodevelopmental evaluation, the study team will ask for your written permission to contact your child's Early Evaluation Hub provider and/or your child's primary care provider. If you provide permission, the study team will contact your child's providers to discuss the evaluation results, including your child's diagnosis and any recommendations for medical and developmental care. If you do not provide permission, we will not share the results.
- We will ask you to complete the same brief survey regarding your child's intervention service history that you completed before or at the research evaluation visit again 3, 6, 12 18, and 24 months following this visit. We estimate that this questionnaire will take you no longer than 15-20 minutes to complete and the questionnaire can be completed via secure electronic link or by phone with a member of our research team.

WHAT ARE THE RISKS OF TAKING PART IN THE STUDY?

While participating in the study, the risks, side effects, and/or discomforts include:

- Discomfort to you or your child as a result of participating in the evaluation.

- During the evaluation, you may tell the researcher if you or your child feels uncomfortable and you wish to stop participating in any part of the evaluation or stop participation in the study.

- Possible loss of confidentiality
  - The research team has taken many steps to protect the confidentiality of you and your child. See below for more information.

WHAT ARE THE POTENTIAL BENEFITS OF TAKING PART IN THE STUDY?

The benefit to participation in the study that is reasonable to expect is receipt of a research report summarizing the results of your child's evaluation, including neurodevelopmental diagnosis (when applicable). This report may be used by you or your child's health care provider(s) to document neurodevelopmental diagnosis and access related services or local resources.

WILL I RECEIVE MY RESULTS?

We may learn things about your child from the study activities which could be important to your child's health. We will provide you with a brief research report that summarizes the results of your child's evaluation, including neurodevelopmental diagnosis (when applicable). If you provide us with written permission, we will also share this report with your child's Early Evaluation Hub provider and/or primary care provider. You may need to meet with professionals with expertise to help you learn more about these research results. Your child's Early Evaluation hub provider or primary care provider can help you learn more about these research results. Should you wish to meet with a member of the research team at Indiana University School of Medicine/Indiana University Health, we will help to arrange this. However, the research team will not cover the costs of any follow-up consultations or actions.

By initialing below, I give permission to the study team to contact, share information, and provide my child's research evaluation report, including results of neurodevelopmental assessments and diagnosis, to the following providers:

_____ Yes, you can notify my Primary Care Provider and/or my child's Early Evaluation Hub Provider.

_____ No, you cannot notify my Primary Care Provider and/or my child's Early Evaluation Hub Provider.

☐My child's primary care provider: _____

Name of Primary Care Provider

☐My child's Early Evaluation Hub provider: _____

Name of Early Evaluation Hub Provider

HOW WILL MY INFORMATION BE PROTECTED?

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. No information which could identify you will be shared in publications about this study or databases in which results may be stored.

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 (as allowed by law) state or federal agencies, specifically the Office for Human Research Protections (OHRP) and the U.S. Food and Drug Administration (FDA), and the National Institute of Mental Health (NIMH) who may need to access your child's medical and/or research records.

In order to assure we are able to accurately and completely analyze all data, video and still photographs are taken your child. We will only use your child's photograph/video outside of the project aims (meaning for research talks and presentations, instructional/training presentations, bulletin board, website, newsletters, and/or study brochures) when you provide permission. Your name and your child's name will be kept private and never associated with the videos/photos.

_____ Yes, you can use my child's photograph/video for the purposes identified above.

_____ No, you cannot use my child's photograph/video for the purposes identified above.

WILL MY CHILD'S INFORMATION BE USED FOR RESEARCH IN THE FUTURE?

Information collected from you 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 is shared. Deidentified information means that all personal information about your child such as their name, address, and phone number is removed and replaced with a code number called the Global Unique Identifier (GUID). Using a GUID enables multiple research groups to use a common ID for your child, enabling your child's data to be linked across sites *without* exchanging personally identifiable information between research teams. This process also ensures that any deidentified datasets that involve multiple research teams do not accidentally include the same child multiple times unknowingly. More information about GUIDs may be found here: https://data-archive.nimh.nih.gov/guid. Since identifying information will be removed, we will not ask for your additional consent. With an easier way to share, researchers hope to learn new and important things about ASD and other conditions more quickly than before.

Data from this study may be submitted to the National Institute of Mental Health Data Archive (NDA). NDA is a data repository run by the National Institute of Mental Health (NIMH) that allows researchers studying ASD and other conditions to collect and share deidentified information with each other. A data repository is a large database where information from many studies is stored and managed.
During and after the study, the researchers will send deidentified information (i.e., using the GUID system) about your child's health and behavior to NDA. Other researchers nationwide can then file an application with the NIMH to obtain access to your child's deidentified study data for research purposes. Experts at the NIMH who know how to protect health and science information will look at every request carefully to minimize risks to your privacy. NIMH will report to Congress and on its web site about the different studies that researchers are conducting using NDA data. However, you will not be contacted directly about the data you contributed to NDA.

Data from this study may also be shared with other researchers at Purdue University who are working on studies related to ASD. If you choose to enroll your child in research studies at Purdue University, the Purdue University investigators may ask us to share your child's research data with the goal of working

together to further our understanding of ASD. Your child's deidentified research data will be shared using the GUID system.

You may not benefit directly from allowing your child's information to be shared with NDA or other research studies. However, the information may help researchers around the world treat future children and adults with ASD and other conditions so that they have better outcomes.

You may decide now or later that you do not want to share your child's information. If so, contact the researchers who conducted this study, and they will tell NDA and other researchers, which can stop sharing the research information. However, NDA and other researchers cannot take back information that was shared before you changed your mind. If you would like more information about NDA, this is available on-line at http://data-archive.nimh.gov.

WILL MY CHILD BE PAID FOR PARTICIPATION?

Your child will be compensated with a gift card in the amount of $25 per hour of completed research testing. The average length of the evaluation is estimated to be 3 hours. This hourly amount includes any travel related expenses. If you choose to withdraw from the study, your child will be compensated for the length of their participation (at the above rate of $25 per hour of evaluation). Following the initial research evaluation, if you choose to complete questionnaires about your child's interventions and services, you will be compensated with a $15 gift card each time you complete the questionnaire (e.g., at 3, 6, 12, 18, and 24 months after the research evaluation).

WILL IT COST ANYTHING TO PARTICIPATE?

There is no cost to your child for taking part in this study.

WHO SHOULD I CALL WITH QUESTIONS OR PROBLEMS?

For questions about the study, contact the researcher, Rebecca McNally Keehn, PhD, HSPP, at (317) 944-5396. In the event of a medical or behavioral emergency, please contact your child's primary care provider or call 911.

For questions about your child's 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 for your child 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 your child from the study. If you decide to withdraw your child, please contact Rebecca McNally Keehn, PhD, HSPP at (317) 944-5396.

PARTICIPANT'S CONSENT

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

Child's Printed Name:_____

Printed Name of Parent / Guardian: _____

Signature of Parent / Guardian:_____**Date:**_____

Printed Name of Person Obtaining Consent:_____

Signature of Person Obtaining Consent:_____**Date**:_____