



Georgia State University
Department of Psychology
Informed Consent Form

Title: Early Detection and Description of Developmental Delays: A Longitudinal Study

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Sponsor: National Institute of Child Health and Human Development

Dear Parent,

We are studying different steps in a child's life, such as learning to walk and talk. It is important to find out if a child is late in learning these skills. Some children qualify for help from the state early intervention system. We are asking you to be in a research study. In this form, "you" means you and your child. We will ask you to answer questions about your child. If we want to talk to you about your answers, or if you are eligible for another part of our study, one of the researchers will call you. We may offer you one or more free evaluations for your child. Your answers and your name will be kept private. You may change your mind about being in the study at any time. This will not affect your medical services or your relationship with your child's doctor. This form will tell you more about our research and you can decide whether you would like to be in the study. This study is funded by the National Institute of Child Health and Human Development. This study includes researchers from Georgia State University, University of Connecticut, University of Washington, and Vanderbilt University.

I. Introduction/Background/Purpose: Children with developmental delays need treatment. Starting treatment when they are very young is better for the child. It is important to give children the chance to get help. We are inviting you and your child to participate in a study that will help us to find specific developmental delays. There are several steps to this study. Most families will only do Step 1. Step 1 is to fill out this form. We expect to screen 40,000 children. As many as 5,000 families will be invited to complete other steps. Some of these children may be at risk for developmental delays. Others are typically developing peers.

II. Procedures: Step 1. During your child's visit to a pediatrician or healthcare provider, you will fill out this packet. You will be contacted by phone or mail when your child is approximately 4 years old to complete a follow-up screening packet.

Step 2. We will call some parents to ask more questions. You may choose to check a box asking us not to call unless we have specific concerns. **Step 3.** Some children will be asked to come to the Georgia State University for one or more visits based on this interview. These visits are called screening, play, and evaluation sessions. Additional children will be invited for one or more visits without an interview. Your child's pediatrician may be informed that you are invited for Step 2 and/or 3, unless you ask us not to. Visits are *free of charge*. At the beginning of your first visit to Georgia State, we will give you a new consent form. This will explain the next part of the study. Clinicians, faculty, graduate students, staff, and research assistants will conduct the sessions. The interview typically lasts for 5-30 minutes. It is usually on the phone. The play session is about 2-3 hours. It includes two activities with an examiner and one with the parent. The additional screening session is about 30 minutes. The evaluation is about 3-4 hours. The evaluation includes testing to examine cognitive, language, and play, and social behaviors. Several team members are involved in sessions. One or more members of the team will test your child using toys, while others will talk with you about your child. We will all be in the same room. You will be able to see and interact with your child. One member of the evaluation team is a licensed clinical psychologist. The others are graduate students and research assistants working under the psychologist's supervision. Following the evaluation, we will tell you if your child has a clinical diagnosis. We will also recommend intervention services for your child. We will video record all sessions. All recordings are kept private. We only share recordings with other members of the research team. You may be invited to return for several sessions. We will explain each session when we ask you to participate.

III. Risks: There are few potential risks of the study. We will only use child-safe toys in this study. The sessions described above pose no foreseeable risks. Some parents may experience discomfort when learning that their child has developmental delays. However, the benefits of early identification far outweigh the risk of parental distress. If you experience any distress, we will talk to you about it. The researchers also will help you find a counselor. You will be responsible for all costs of counseling or other treatment. Some children get tired or frustrated. We will give breaks as needed.

IV. Benefits & Compensation: There are large benefits of finding delays early. Early diagnosis will help your child get intervention services. Specific recommendations will be provided in writing. For those children who do not require intervention services, there is benefit to society by allowing us to study typical development. Parking or compensation for public transportation to GSU will be provided. We also provide compensation for completing evaluation sessions.

V. Voluntary Participation and Withdrawal: Participation in research is voluntary. You have the right to refuse to be in this study. If you decide to be in the study and change your mind, you have the right to drop out at any time. You may remove your child from the study. You may skip questions or discontinue participation at any time. Whatever you decide, you will not lose any benefits to which you are otherwise entitled. Your permission for your child to participate in this study is voluntary. If you decide not to participate, your relationship with your pediatrician will not change in any way. You can stop participating at any time without having to explain and with no penalty.

VI. Confidentiality: We will keep your records private to the extent allowed by law. Your name, your child's name, and other facts that might identify you will not appear when we share data with other researchers, present this study, or publish its results. The findings will be summarized and reported in group form. You will not be identified personally. We intend to keep all information derived from assessments as research records in the GSU research laboratory. The health information you give us will be used in this research study. We will protect all information that can identify you. We will share it only with other members of the research team. If you decide you want to be in this study it means that you agree to let us use and share your





M-CHAT-R Child's Name: _____ DOB: _____ Date: _____

M-CHAT-R™

Please answer these questions about your child. Keep in mind how your child usually behaves. If you have seen your child do the behavior a few times, but he or she does not usually do it, then please answer **no**. Please circle **yes** or **no** for every question. Thank you very much.

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| 1. If you point at something across the room, does your child look at it?
(FOR EXAMPLE , if you point at a toy or an animal, does your child look at the toy or animal?) | Yes | No |
| 2. Have you ever wondered if your child might be deaf? | Yes | No |
| 3. Does your child play pretend or make-believe? (FOR EXAMPLE , pretend to drink from an empty cup, pretend to talk on a phone, or pretend to feed a doll or stuffed animal?) | Yes | No |
| 4. Does your child like climbing on things? (FOR EXAMPLE , furniture, playground equipment, or stairs) | Yes | No |
| 5. Does your child make <u>unusual</u> finger movements near his or her eyes?
(FOR EXAMPLE , does your child wiggle his or her fingers close to his or her eyes?) | Yes | No |
| 6. Does your child point with one finger to ask for something or to get help?
(FOR EXAMPLE , pointing to a snack or toy that is out of reach) | Yes | No |
| 7. Does your child point with one finger to show you something interesting?
(FOR EXAMPLE , pointing to an airplane in the sky or a big truck in the road) | Yes | No |
| 8. Is your child interested in other children? (FOR EXAMPLE , does your child watch other children, smile at them, or go to them?) | Yes | No |
| 9. Does your child show you things by bringing them to you or holding them up for you to see – not to get help, but just to share? (FOR EXAMPLE , showing you a flower, a stuffed animal, or a toy truck) | Yes | No |
| 10. Does your child respond when you call his or her name? (FOR EXAMPLE , does he or she look up, talk or babble, or stop what he or she is doing when you call his or her name?) | Yes | No |
| 11. When you smile at your child, does he or she smile back at you? | Yes | No |
| 12. Does your child get upset by everyday noises? (FOR EXAMPLE , does your child scream or cry to noise such as a vacuum cleaner or loud music?) | Yes | No |
| 13. Does your child walk? | Yes | No |
| 14. Does your child look you in the eye when you are talking to him or her, playing with him or her, or dressing him or her? | Yes | No |
| 15. Does your child try to copy what you do? (FOR EXAMPLE , wave bye-bye, clap, or make a funny noise when you do) | Yes | No |
| 16. If you turn your head to look at something, does your child look around to see what you are looking at? | Yes | No |
| 17. Does your child try to get you to watch him or her? (FOR EXAMPLE , does your child look at you for praise, or say “look” or “watch me”?) | Yes | No |
| 18. Does your child understand when you tell him or her to do something?
(FOR EXAMPLE , if you don't point, can your child understand “put the book on the chair” or “bring me the blanket”?) | Yes | No |
| 19. If something new happens, does your child look at your face to see how you feel about it?
(FOR EXAMPLE , if he or she hears a strange or funny noise, or sees a new toy, will he or she look at your face?) | Yes | No |
| 20. Does your child like movement activities?
(FOR EXAMPLE , being swung or bounced on your knee) | Yes | No |