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Protocol Title: NCS Formative Research Project #8 – Development and Validation of Autism Case Confirmation Approaches for Use in the National Children's Study
Application No.: NA_00046473
Principal Investigator: Rebecca Landa, Ph.D., CCC-SLP
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Kennedy Krieger Institute
CONSENT SCRIPT TO SCREEN FOR RESEARCH
Participants Scheduled or Waiting to be Scheduled for a Clinical Assessment at Kennedy Krieger Institute

NCS Formative Research Project #8 – Development and Validation of Autism Case Confirmation Approaches for Use in the National Children's Study

Kennedy Krieger Institute Center for Autism and Related Disorders Research Team Member
Hello, my name is _____ from the Center for Autism and Related Disorders at the Kennedy Krieger Institute.

Kennedy Krieger Institute Center for Development and Learning (CDL) Research Team Member
Hello, my name is _____ from the Center for Development and Learning at the Kennedy Krieger Institute.

I am calling you about the study in which you had expressed some interest, titled *Development and Validation of Autism Case Confirmation Approaches for Use in the National Children's Study*. Is this is a good time to speak now? **[If so, continue script. If not, ask when would be a better time, thank them for their time and end call].** I need to ask you a few questions in order to determine whether your child and you may be eligible for this research study. I will ask you general questions about your child's development and medical history. Before I begin I would like to tell you a little bit about the research.

This research is being done to examine three new ways to possibly identify children with autism spectrum disorders (ASD). If one or more of these new ways are able to identify children with ASD, they might be used in the National Children's Study (NCS) protocol. If you are eligible for this study and if you agree to do so, you and your child will come into our Center for a three hour visit. This visit, which will be at least one week before your scheduled clinic visit, will consist of a parent interview, a computerized parent questionnaire, and a child play assessment. Your second visit will be your scheduled clinic visit. After this second visit, we will follow up with the clinician who will be working with you and your child regarding the diagnosis given by that clinician.

Would you like to continue with the screening? The screening will take about 5 minutes and we will be collecting information about you. You do not have to answer any questions you do not wish to answer and you may stop at any time. Your participation in the screening is voluntary. Your information will only be seen by the research team. We

try to make sure that the information we collect from you is kept private and used only for the research study we are discussing. If you do not agree to continue the phone call, it will not affect your care at Johns Hopkins or at the Kennedy Kreiger Institute.

If your child does not qualify for the study, we will destroy the information we have. If your child does qualify for the study and you agree to participate, we will schedule the visit to our Center. It is at that point, you will sign the research informed consent form.

Would you like to continue with the screening?

[if no, thank the person and hang up]
[if yes, continue with the screening.]

Please answer the following 6 questions individually. After each question please respond with a "yes" or "no" answer.

1. Does your child have a clinical diagnosis of autism or PDD-NOS or autism spectrum disorder or Asperger's syndrome?

YES NO

[Note to research staff: If the answer is yes to the above question, he/she does not meet eligibility requirements for the study. You may discontinue the screening and say: "Thank you for your interest in this study. Due to your child's previous diagnosis of autism, your child does not meet eligibility criteria. Would you like to receive information about assessment services within Kennedy Krieger Institute?"

If the answer is no to the above question, he/she currently meets eligibility for the study and you can continue with the questions below.

If the child is scheduled or waiting to be scheduled for a visit to the Kennedy Krieger Institute Center for Autism and Related Disorders, ask questions 2A and 2B to confirm. If the child is scheduled or waiting to be scheduled for a visit to the Center for Development and Learning, ask question 3A-3C to confirm.]

2A. Are you currently scheduled or waiting to be scheduled for an autism evaluation at the Center for Autism and Related Disorders at Kennedy Krieger Institute?

YES NO

2B. Is your child between the ages of 30 and 39 months at the time of this scheduled visit?

YES NO

[If the answer is no to either of the above questions (2A, 2B) and he/she also is not scheduled or waiting to be scheduled for a visit to the Center for Development and Learning, he/she currently does not meet eligibility for the study. You may discontinue the screening and say: "We appreciate your time but because you responded "no" to one or more of the questions, we are unable to enroll you in this project."

If the answer is yes to both questions above (2A, 2B), he/she currently does meet eligibility for the study and you may ask question 4.]

3A. Are you currently scheduled or waiting to be scheduled for an evaluation at the Center for Development and Learning at Kennedy Krieger Institute?

YES **NO**

3B. Do you have any concerns that your child might have autism?

YES **NO**

3C. Is your child between the ages of 30 and 39 months at the time of this scheduled visit?

YES **NO**

[If the answer is no to question 3C, he/she currently does not meet eligibility for the study. You may discontinue the screening and say: "We appreciate your time but because you responded "no" to one or more of the questions, we are unable to enroll you in this project."

If the answer is yes, he/she currently does meet eligibility for the study and you may ask the next question.]

4. Is English the primary language spoken in the home?

YES **NO**

[If the caregiver answers "no" to questions 4, the child does not meet the eligibility requirements for this study, say, "We appreciate your time but because you responded "no" to one or more of the questions, we are unable to enroll you in this project." Please continue if the caregiver answers "yes" to all questions.]

Thank you for answering the screening questions.

We appreciate your time. We have determined that your child and you are eligible for the study. I would like to tell you a little bit more about the study.

All research studies have some degree of risk or discomfort. Time burden and discomfort during interviews using sensitive questions are common risks and discomforts of minimal risk studies such as this. You may choose not to answer any questions that you do not wish to answer. Also, your child may get tired during the play-based testing, at which time your child would be given a break to rest or have a snack. We will also be flexible as possible when scheduling testing to address these risks.

There are no direct health benefits for you or your child from this study. However, your participation in this study will help the National Children's Study investigate autism more effectively.

There are not any costs to participants except those of transportation. You will be provided $50 for your time and travel costs.

Do you have any questions about the screening or the research study?

Do you think you would like to take part in this research?

[if no, thank the person for their time and hang up]
[if yes] We would like to schedule you and your child for your visit to our Center. We would also like to send you a consent form to review prior to your visit to the center.

I am going to give you a couple of telephone numbers to call if you have any questions later. Do you have a pen? If you have questions about the research study, you may call Sarah Warnet at 443-923-7644 and she will answer your questions.

If you have questions about your rights as a research subject, please call the Johns Hopkins Medicine Office of Human Subjects Research at 410-955-3008.

Thank you again for your willingness to answer our questions.

Caller's Name_____

Parent's Name_____

Child's Name_____

Date and Time_____

Qualify for Study? YES NO