CONSENT FORM
Main Sample Version

Principal Investigator: **XXXX XXXXXXXXXXXX**
Project Title: **NCS Formative Research Project #8: Development and Validation of an Autism Case Confirmation Approach for Use in the National Children's Study**

Introduction:

This consent form explains the research study you are being asked to join. Please review this form carefully and ask any questions about the study before you agree to join. You may also ask questions at any time after joining the study.

Purpose of Research Project:

The XXXXXGROUPXXXXXXX at XXXXXUNIVERSITY OR INSTITUTIONXXXXXXX is doing this project to help the National Children's Study (NCS) find the best way to identify children with autism spectrum disorders (ASD) during the NCS research period. The NCS is a study of 100,000 pregnant women and their babies, who will be followed all the way to age 21. As part of the NCS, babies will be checked for a number of conditions, including ASDs, as they grow. The study you are now being asked to join will test some new ways to ask about, or watch for, behaviors in young children that might indicate that they have an ASD. You are being asked to join because your child is, or will be, between 33 and 39 months old and is already scheduled to be evaluated for an ASD at XXXXINDICATE WHETHER PART OF RESEARCH STUDY / AT CLINIC / OR BOTH XXXXXX.

Procedures:

If you join the study, you and your child will make a visit to XXXLOCATIONXXXX before the visit you already have scheduled at XXXXINDICATE WHETHER PART OF RESEARCH STUDY / AT CLINIC / OR BOTH XXXXXX. During the visit, you will watch video of children's behaviors on a computer screen and type answers to questions about your child's behavior based on what you see on the videos. You will also be asked to answer questions about your child's behavior and development asked by an interviewer. Lastly, your child will also be observed in a short series of play activities. You can stay with your child during these activities. This visit will take no more than three hours. The observation of your child's play may be videotaped. We videotape some visits so that we can check to make sure that that the play activities are being done with children in the best way for the study. You will be told if we will be videotaping your visit before it starts.

We will also check with the clinician who performs your child's scheduled ASD evaluation and get some data from them on the results of that evaluation. We will get information on ASD-related test results, cognitive functioning test results, ASD diagnostic impression, and indications of other conditions your child may have.

Confidentiality:

We will make every effort to keep both your identity and your child's identity confidential. You will be assigned an ID number that will be used on all of the information that we collect about you and your child. The ID number is the only identifying information that will be connected with the information gathered for this study. We will not use names or other information that can identify you or your child in the study database. ADD LANGUAGE ABOUT HOW YOU WILL BE KEEPING THE LINK BETWEEN STUDY ID AND PERSONAL IDENTIFIERS LOCALLY - WHAT FOLLOWS IS AN EXAMPLE, FEEL FREE TO ADAPT: Any record of names we have on pieces of paper, like this consent form, will be kept in locked files in XXLOCATIONXXX

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separate from study data. A computer file linking the ID number and your name will be maintained only here at XXLOCATIONXXX on a single, password-protected computer.

The information we collect about your child for this study may also be helpful to other autism research projects being done by the investigators working on this study or other scientists. By checking 'Yes' below you give permission for the information we collect for this study to be used in other autism research studies. These data will be shared without providing information that identifies your child.

May we share the data we collect about your child for this study with other autism research projects (no information identifying your child will be shared)?

☐ YES ☐ NO

If your child's evaluation is video-recorded, the ID number will be the only information labeling the video data file. The video file of your child will be shared with the experts who developed the play observation for the study. Before the video file is sent to these experts, it will be changed so that it can not be opened or viewed without a password. Only the experts working on the study will have the password. After the study is completed, unless you indicate that you are willing to let us keep video files to help train future staff (see box below), all video files will be destroyed.

Since the observations of child play that we used in this study may also be used in the NCS, the video we collect in this study could be helpful in training future NCS study staff. By checking 'Yes' below you give permission for video of your child to be used in future NCS training material. If you indicate 'Yes' the expert who developed the play observation will keep the video of your child for possible use in training materials for the NCS.

May we keep your child's video and possible use portions of the video in training material that will be shown to staff at NCS study sites for training purposes?

☐ YES ☐ NO

Risks/Discomforts:

There are no known physical or medical risks to participation. If your child becomes tired or cranky during the visit, we can take a break. If you would rather not finish with the visit, we will stop anytime you tell us to.

We will make every effort to keep your identity confidential. However, it is possible, that despite the steps we talked about above, somehow your identity is accidently revealed to someone outside the study team.

Benefits:

You and your child will not benefit directly by participating in this study. However, you will be part of research that could help the NCS do a good job studying ASD.

Because the new approaches we are trying here are unproven and we do not know yet how results should be explained to families, we will not share the individual results from the computer questionnaire, the interview, or the play observations with you. However, because your child is receiving other assessments as part of the already-scheduled visit at XXXSTUDY/CLINIC VISIT/ETCXXXXX, you will still receive those results [NOTE: FOR SUBJECTS COMING FROM OTHER STUDIES – THIS NEEDS TO BE PHRASED CONSISTENT WITH RESULTS REPORTING THERE] – but that is ***not*** a benefit of this study, because you would have received those even if you did not participate here.

Compensation:

You will be reimbursed $50 for your time and travel expenses associated with participation in this study.

Voluntary Participation:

Your participation in this research project is completely voluntary. You have the right to withdraw from the study at any time. You can ask the investigator listed below any questions you may have about this study. You may ask her/him questions in the future if you think of a question later.

Persons to Contact:

If you have any questions about this study you can contact the lead investigator here at XXXLOCATIONXXX, XXXSITE LEAD INVESTIGATORXXXX at XXXXCONTACT INFOXXXXXX.

If you think you or your child have not been treated fairly or you think that you or your child has been hurt by joining the study, or if you have any other questions about the study you would like to ask someone not directly involved with the study, you can contact the XXXLOCAL IRBXXXXX at XXXCONTACT INFORMATIONXXXXX.

If you have read this document, or if the document has been read and explained to you, and you have been given the chance to ask any questions, please sign below.

Print Name of Subject	
Signature of Subject	Date
Print Name of Person Obtaining Consent	Date
Signature of Person Obtaining Consent	Date