

## Research Plan

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

**PI:** \_\_\_\_\_ Name \_\_\_\_\_

### Overview

This project will be carried out as a formative research study in support of the National Children’s Study. The \_\_\_\_\_ Institution Name \_\_\_\_\_ houses a National Children’s Study (NCS) Center (PI: \_\_\_\_\_ NCS\_PI\_Name \_\_\_\_\_).

The \_\_\_\_\_ Institution Name \_\_\_\_\_ NCS Center is working with a group of nine other NCS Centers on this formative research project to examine the criterion validity of three autism case-confirmation instruments that could potentially be incorporated into the final NCS protocol. This project will not involve subjects from other NCS activities but will involve recruitment of a new, purposive sample from the ten participating NCS Centers. The lead NCS Center for this project is the Johns Hopkins Study Center (PI Laura Caulfield). The investigator leading this formative project is Craig Newschaffer of Drexel University who collaborates with the Johns Hopkins Center team.

### Research Questions Addressed by this Project

As mentioned, the goal of this project is to assess the criterion validity of new autism spectrum disorder (ASD) case confirmation instruments. The three instruments being considered are designed to be administered by staff without special training and experience related to neurodevelopmental disabilities, and to be less time-consuming to administer than current gold-standard tools. Project goals are as follows:

- To assess criterion validity by estimating sensitivity and specificity for three new ASD case confirmation tools (individually and in combinations) against gold standard classification based on the current accepted gold-standard tools - the Autism Diagnosis Observation Schedule (ADOS) and the Autism Diagnostic Interview-Revised (ADI-R).
- To provide qualitative information on the implementation of ASD case confirmation assessment using streamlined tools and staff without special training and experience in neurodevelopmental assessment.

### Rationale for Research

Most ASDs can be reliably identified by age three, but the average age of diagnosis is considerably later. Recent CDC data indicate that community diagnoses still underestimate ASD prevalence by >20%. Passive surveillance of community diagnosis is therefore problematic as an NCS case identification strategy. NCS Research Plans have endorsed an active approach to autism case-identification, including administration of a parent self-report autism

PI: \_\_\_\_\_ Name \_\_\_\_\_



Children will be enrolled from March 1, 2011 through December 31, 2011. We expect to enroll a total of **XX** children – **XX** in the main sample and **XX** in the supplemental sample.

**b. Consent Process**

Consent will be obtained by **INDICATE WHICH STUDY STAFF WILL DO THIS / UNDER WHAT CONDITIONS ETC.** Informed consent of the parents will be obtained before the commencement of any study procedures.

**c. Data Collection**

Once consented, subjects will be scheduled for a study visit where they will complete the **parent self-report, direct observation, and parent interview** instruments. The order in which the instruments are completed will be randomized. Study visits must occur at least one week prior to the date of the already-scheduled autism or developmental delay assessments. Each of the instruments is described in more detail below.

**Parent Self-Report.** Parent self-report data will be collected through a web-based, video-guided survey tool. The tool includes video clips that will be presented in pairs, with the first clip showing a child with typical development (TD) in order to provide a point of comparison for the behaviors exhibited in the second clip by a child with an ASD. Voiceovers describing and contrasting the behaviors are incorporated and parents will answer questions after viewing the video clips. The 20 questions involve rating relevant behaviors as absent, possibly present, or definitely present. Questions are constructed at a 6th grade comprehension level with options to either read or listen. Average time to complete is 20 minutes.

**Parent Interview.** The parent interview will employ the Autism Diagnostic Interview-Screener (ADI-S) – a measure was developed based on questions from the ADI-R. The Preschool version of the ADI-S is for children under the age of five and includes approximately 30 to 40 questions, depending on the language level of the child (i.e., parents of children who have not yet acquired phrase speech are not administered the verbal items). The ADI-S items inquire about social and communication behaviors, and restricted and repetitive behaviors and interests that have been observed during the past 3 months. The measure also includes a small set of questions regarding early history. The interview takes approximately 25 minutes to administer and is designed to be administered by interviewers with minimal levels of training.

**Direct Observation.** The direct observation will use the STAT-NCS, an interactive, play-based assessment adapted from the Screening Tool for Autism in Two-year-olds (STAT). The STAT-NCS takes 20 minutes to administer and consists of 12 items assessing social-communicative behavior in the areas of play (2 items), imitation (4 items), and communication (6 items). The examiner presents each item in a prescribed manner and then observes and scores the child’s response live. Each item is scored on two separate dimensions: Response to Press and Social Engagement. STAT-NCS has been designed to be administered by assessors with no previous autism or child development expertise who receive a web-based training tutorial modified from an existing training tutorial previously developed for the STAT.

Study assessors will be staff with backgrounds similar to future NCS field workers. They will **not** have substantive prior experience in child development and/or autism/developmental delay assessment. Prior to beginning data collection they will complete web-based training modules and pass online tests of competency in instrument administration procedures. Study assessors will be blinded to whether a particular subject is part of the MAIN or SUPPLEMENTAL sample.



