2012

Sex Differences in Early Social Communication Skills in Children with Autism Spectrum Disorder

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SEX DIFFERENCES IN EARLY SOCIAL COMMUNICATION SKILLS IN CHILDREN WITH AUTISM SPECTRUM DISORDER

By

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A Thesis submitted to the Department of Psychology in partial fulfillment of the requirements for the degree of Master of Science

Degree Awarded:
Summer Semester, 2012
Vanessa Reinhardt defended this thesis on May 31, 2012

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ACKNOWLEDGMENTS

I would like to thank my major professor, Amy Wetherby for her guidance and helpful feedback throughout the completion of this manuscript. I would also like to thank Janet Kistner and Carol Connor for their helpful suggestions and feedback. Finally, I would like to thank the First Words Project staff and the families who participated in the project.
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ABSTRACT

Autism Spectrum Disorder (ASD) refers to a group of neurodevelopmental disorders characterized by impairments in the domains of communication, social interaction, and the presence of restricted and repetitive behaviors (American Psychiatric Association, 2000). ASD is diagnosed more frequently in males than females, with children receiving diagnoses of ASD at increasingly earlier ages. In spite of the tremendous amount of research documenting various aspects of ASD, only a modest body of research examining sex differences exists. The present study examined sex differences in adaptive behavior and autism symptomatology in children with ASD and also examined sex differences in developmental functioning and early social communication profiles in children with ASD and typical development (TD). There were 288 participants (54 female) in the ASD group and 222 (59 female) in the TD group. Participants were recruited from the Florida State University (FSU) FIRST WORDS® Project and University of Michigan Autism and Communication Disorders Center (UMACC). Analyses did not reveal significant effects of sex or a significant diagnostic group by sex interaction. The results from this study contributes to the conflicting research findings which have inconsistently documented sex differences in individuals with ASD with respect to cognitive functioning and autism symptomatology. Future research that systematically examines the ASD phenotype in males and females across age and developmental level is necessary.
INTRODUCTION

Autism Spectrum Disorder (ASD) refers to a group of neurodevelopmental disorders characterized by impairments in the domains of communication, social interaction, and the presence of restricted and repetitive behaviors (American Psychiatric Association, 2000; Volkmar, Chawarska & Klin, 2005). ASD affects approximately 1 in 88 children and is diagnosed more frequently in males than females, with an estimated male to female prevalence ratio between 2.7:1 and 7.2:1 (CDC, 2012). ASD is typically identified in toddlers between 2 and 3 years of age (Rapin, 1997; Volkmar et al.), with approximately 90% of parents recognizing developmental abnormalities by 24 months of age (De Giacomo & Fombonne, 1998).

Children are receiving diagnoses of ASD at increasingly earlier ages—a trend influenced by theories from developmental neuroscience, hypothesizing that neuroplasticity allows interventions to have a greater impact when delivered during infancy and early childhood than at later ages (Yirmiya & Ozonoff, 2007; Dawson, 2008). Research suggesting that early entry into intervention is associated with better developmental outcomes (Sallows & Graupner, 2005; Harris & Handleman, 2000) has led to an increased focus on the development and evaluation of interventions appropriate for young children with ASD (Dawson et al., 2010; Corsello, 2005; Coolican, Smith & Bryson, 2010). Additionally, clinical practice guidelines of the American Academy of Pediatrics recommend that all children be screened for ASD at 18 and 24 months of age (Johnson et al., 2007) which has contributed to an emphasis on early diagnosis. The recent development of diagnostic tools attuned to the presentation of ASD in toddlers (Robins et al. 2001; Luyster et al., 2009) have allowed for the provision of more stable diagnoses at younger ages (Chawarska, Klin, Paul, Macari, & Volkmar, 2009).

Despite consistent sex differences in rate of diagnosis (CDC, 2012), little research examining sex differences in early diagnostic features of ASD is available. Research examining sex differences in the presentation of ASD in toddlers is important to inform diagnostic practices and clinical intervention strategies for young children with ASD.

Infants and Toddlers with ASD

During the first years of life, children learn language and other cultural conventions through interactions with their caregivers and others in their environment
During everyday activities with caregivers, infants learn social scripts and routines and begin to internalize the reciprocal nature of social interactions (Snow, 1989). Prior to the onset of spoken words, typically developing infants and young toddlers are remarkably expressive—using eye gaze, vocalizations, body gestures, and emotional displays for communicating a variety of intentions. These early social experiences facilitate the acquisition of skills needed for language acquisition and word learning, including joint attention, imitation, and gesture development (Akhtar & Tomasello, 2000).

Children with ASD have varying degrees of difficulty processing and producing both verbal and nonverbal communication (Volkmar et al., 2005). Approximately 25-50% of children with ASD do not acquire functional verbal communication and many who do acquire verbal communication have unusual methods of expression, using idiosyncratic words and echolalic speech with limited communicative intent (Prizant, 1996; Volkmar et al.; Lord, Risi & Pickles, 2004). Expressive and receptive language delays are also common in young children with ASD. Many young children with ASD are first identified for further developmental evaluation due to a delay in speech production (De Giacomo & Fombonne, 1998; Wetherby et al. 2004); although such delays are not specific to children diagnosed with ASD (Dale, Price, Bishop & Plomin, 2003).

Research examining the early phenotype of ASD has identified a number of early markers in the core diagnostic domains of social-communication and restricted and respective behaviors. Children with ASD show less social interest and tend to have difficulty initiating and modulating social interaction using eye gaze, emotional displays, and appropriate nonverbal and verbal communication (Tager-Flusberg, 1999; Volkmar, et al., 2005). Infants later diagnosed with ASD show difficulties integrating eye gaze during social interaction, displaying shared affect, looking at faces and people in their environment, and responding to their name (Baranek, 1999; Brian et al., 2008; Bryson et al., 2007; Chawarska et al., 2009; Landa, Holman & Garrett-Mayer, 2007; Wetherby et al., 2004; Yirmiya & Charman, 2010; Zwaigenbaum et al., 2005). A longitudinal study of children referred for possible ASD found that children who retained their ASD diagnosis at age three were less likely to demonstrate several social and communicative
behaviors than children who did not meet diagnostic criteria at age three (Lord, 1995). These behaviors included showing interest in other children, seeking to share enjoyment with others, pointing to focus another’s attention, and attending to another person’s voice (Lord, 1995). Many researchers believe that the lack of social interest apparent in young children with ASD result in a lack of attention to and processing of social information, leading to a disruption in typical communicative, cognitive, and behavioral development (Mundy & Neal, 2000).

Triadic social interactions involve a ‘triangle’ of coordinated attention between the child, a social partner, and another object, person, or event (Chawarska et al., 2009; Mundy & Newell, 2007). Joint attention is a unique form of triadic communication, referring to the use of nonverbal communication for the purpose of directing a social partner’s attention to share interest. Joint attention deficits are apparent in children with ASD across the lifespan both in their ability to respond to other’s bids to direct their attention as well as to initiate nonverbal communication for directing another person’s attention or interest (Charman, Swettenham, Baron-Cohen, Cox, Baird & Drew, 1997; Dawson et al., 2004). The ability to respond to and initiate joint attention has been found to predict both concurrent and later expressive and receptive language ability for individuals with ASD (Charman et al., 2003; Chawarska et al., 2009; Dawson et al., 2004; Loveland & Landry, 1986; Luyster, Kadlec, Carter & Tager-Flusberg, 2008; Mundy, Sigman, & Kasari, 1990).

Sex Differences

Research suggests that parents and adults interact with infant males and females differently (Stern & Karraker, 1989), and it is theorized that many sex differences are a result of this differential socialization (Bussey & Bandura, 1999). For example, mothers tend to talk more and use more supportive speech with daughters than with sons (Leaper, Anderson & Sanders, 1998). Parents tend to acknowledge and respond to female infant’s emotional displays more than males (Malatesta & Haviland, 1982). It is theorized that parents’ differential socialization strategies used with males and females may provide an environment more supportive of social communication development for females (Huttenlocher et al. 1991), possibly contributing to observed differences between sexes in typical development.
In addition to examining the possible role that differential socialization may play in the development of sex differences, it is also important to consider the role of biological factors. Sex differences in certain social behaviors have been documented very early in development. It has been hypothesized that exposure to sex hormones in utero may affect brain organization, and research has documented that males exposed to higher levels of testosterone in utero score lower on measures of social development (Knickmeyer, Baron-Cohen, Raggatt & Taylor, 2005). Some studies have found that male newborns are less likely to maintain eye contact and attend less to social stimuli (Connellan, Baron-Cohen, Wheelwright, Batki & Ahluwalia, 2000). Studies examining sex differences in temperament suggest that males show higher levels of surgency while females show higher levels of effortful control (Else-Quest et al., 2006), providing additional support for the role of biological factors. It is possible that biological factors play an important role in the development of sex differences in language and social communication.

Research examining sex differences in the development of communication and language in typically developing infants and toddlers has documented small differences favoring females in a number of domains including the development of nonverbal communication, (Clarke-Stewart, 1973; Fenson et al. 1994), vocabulary acquisition (Fenson et al., 1994; Huttenlocher et al., 1991), and frequency of social initiations (Klein & Durfee, 1978). Fenson and colleagues (1994) examined the development of early communication with a large sample of typically developing infants and toddlers and documented small yet significant differences, favoring females in the rate of gestural development and receptive and expressive vocabulary between 8-18 months of age. Interestingly, Fenson and colleagues found a much stronger role of sex on gesture production for two subscales measuring gestures acquired through observational learning with a great deal of cultural content—‘pretending to be a parent’ for females and ‘imitating adult actions’ for males. Females also begin combining words earlier than males and produce longer and more complex utterances at earlier ages (Fenson et al., 1994). It is particularly important to note that all of the sex differences found in this study were small, accounting for approximately 1-2% of the variance.
In spite of the tremendous amount of research documenting various aspects of ASD, only a modest body of research examining sex differences exists. Most research focusing on sex differences has concentrated on documenting sex differences in incidence of the disorder. The high male to female ratio may reflect a true difference in incidence or it may suggest that females with ASD are under-diagnosed (Koenig & Tsatsanis, 2005). It is possible that current diagnostic criteria are not sensitive to posited sex differences in the manifestation and presentation of ASD because the DSM-IV-TR diagnostic criteria were developed and tested with an overwhelmingly male sample (Volkmar et al., 1994). Due to the high male to female ratio of incidence, recruiting female participants can be difficult, and studies often fail to recruit a sample of females that is large enough to analyze separately. Also, since more males than females are diagnosed with ASD, research focusing on ASD in males is generalizable to a larger proportion of the ASD population than research focusing on ASD females (Koenig & Tsatsanis, 2005).

In addition to sex differences in incidence, difference can also be found in age of diagnosis. ASD tends to be diagnosed later in females, and females who meet criteria for ASD are less likely to carry an ASD diagnosis (Giarelli et al., 2010). An epidemiological study found that both low and high functioning females were diagnosed later than males, and higher functioning females were diagnosed significantly later than both lower functioning females and higher functioning males (Shattuck et al., 2009). Koop and Gilberg (1992) reported on six females with social impairments who showed diagnostic features in the domains of social-communication and restricted and repetitive behavior before 24 months of age, yet none of these females received a diagnosis of ASD before six years of age. Wing and Gould (1979) examined the prevalence of autism in children with special needs and found no sex differences in social impairments in males and females who met criteria for ASD; however, males were 15 times more likely than females to carry a diagnosis of ASD (Wing & Gould, 1979). Kim and colleagues (2011) conducted a large-scale prevalence study, screening all 7-12 year old children for ASD in a South Korean community. The study found a 5.1:1 male to female ratio in the high-risk group (children receiving special education services or children with an identified disability) and a much lower 2.5:1 ratio in the general population. This study is unique in
many aspects, in that the research team screened all eight-year-old children in the population, likely allowing for the identification of ASD cases in females with less severe symptomatology.

In addition to sex differences in ASD diagnosis itself, research has also documented a higher incidence of severe cognitive and developmental delays in females than males with ASD (Lord, Schopler & Revicki, 1982). Little consensus exists on the prevalence of intellectual disability (ID) in children with ASD but studies have estimated between 25% (Chakrabarti & Fombonne, 2001) and 33.1-55.8% (ADDM, 2007) of children with ASD have concurrent ID. Nicholas et al. (2008) examined medical records for a population cohort of eight-year-old children and found that females were more likely to have an intelligence quotient (IQ) below 70 (72.7% vs. 56.4%) and that the sex ratio varied significantly between IQ levels. At very low levels of IQ (IQ < 34), the sex ratio was 1:1 (Male: Female) and in the range of intellectual disability (IQ < 70), the ratio was 2.4:1. However, at the highest level of functioning the sex ratio was much greater (4.9:1). It is important to note that this sample was relatively low functioning overall, with the majority of the sample (60.4%) within the range of ID (< 70), limiting the generalizability of these results to the broader ASD population. Sex ratios and the prevalence of ID also seem to be affected by the distribution of ASD within families. Banach and colleagues (2009) investigated the relationship between IQ and gender in a large sample of simplex (one child with ASD) and multiplex (more than one child with ASD) families and only found significant differences in IQ between simplex males and females with ASD. A few studies have documented lower sex ratios in younger siblings compared to first-born children diagnosed with ASD within samples of multiplex families (Zwaigenbaum et al. 2012; Jones et al. 1996).

A limited number of studies have examined sex differences in developmental functioning and diagnostic profiles with conflicting results. Carter and colleagues (2007) examined sex differences in developmental functioning in a sample of toddlers with ASD ($n = 22$ females) between 18 and 33 months. They reported significantly higher nonverbal cognitive scores (Visual Reception) in the female group after controlling for language level, but lower overall language and motor scores. Another study examining toddlers between 18 and 47 months ($n = 42$ females) did not reveal significant sex
differences in developmental functioning using the Mullen Scales of Early Learning (MSEL; Mullen, 1995) (Hartley & Sikora, 2009). Zwaigenbaum and colleagues (2012) examined sex differences in ASD symptoms, adaptive behavior, and cognitive functioning at three years of age in a sample of high-risk younger siblings of children with ASD with and without documented ASD diagnoses and low-risk controls. This study demonstrated that within all three groups, females showed more developed socialization and daily living skills as measured by the Vineland Adaptive Behavior Scales (VABS, Sparrow, Cichetti, & Balla, 2004) and higher fine motor scores as measured by the MSEL. With respect to ASD symptoms, Zwaigenbaum and colleagues found that within all three groups, males evidenced slightly more overall symptoms of ASD using the Autism Diagnostic Observation Scale (ADOS; Lord et al., 1999) Calibrated Severity Scores (Gotham et al., 2009), as well as more social and communication symptoms on the Autism Diagnostic Interview-Revised (ADI-R; Lord, Rutter & Le Coulter, 1994). It is notable that this study found similar patterns of sex differences in adaptive behavior, ASD symptoms, and cognitive functioning in low-risk controls and high-risk siblings with and without ASD.

Hjort and colleagues (Unpublished manuscript) examined sex differences in DSM-IV-TR diagnostic features in a national cohort of children diagnosed with ASD between 1.4-10.9 years and found that after controlling for age and ID (IQ < 70), males showed more diagnostic features than females in the domains of communication and restricted and repetitive behavior. Additionally, males without ID were found to have significantly more diagnostic features in the repetitive behavior domain while females without ID were more likely to show social-communication features. The documented differences in both number and pattern of diagnostic features revealed by Hjort and colleagues provide additional reason for further examinations of sex differences within the autism phenotype. Nicholas et al. (2008) examined a population cohort of eight year old children and found that females were less likely to present with the following repetitive behaviors: preoccupation with parts of objects and repetitive routines and rituals. Hartley and Sikora (2009) examined sex differences in developmental functioning, autism features, and behavior problems in a sample of 199 young children between 18 and 47 months (42 females) and found that females exhibited fewer repetitive behaviors and
restricted interests during the ADOS as well as a trend suggesting more impaired social communication. Studies have revealed sex differences on parent report measures such that females are reported to be less socially competent (Carter et al., 2007), prone to more sleep problems, and show more behaviors consistent with anxiety and depression (Hartley & Sikora, 2009). It is important to note that both the Carter et al. and Hartley and Sikora studies examined children less than four years of age and used more recently diagnosed samples than the Lord et al. and Nicolas et al. studies. The observed disparity in the prevalence of ID between sexes may reflect advances in diagnostic practices over the last 10 years. It may also suggest that sex differences in developmental functioning become more apparent as children age.

Research documenting differences in age of diagnosis as well as level of functioning for children with ASD raise the question, does the research literature accurately reflect the prevalence and developmental profile of females with ASD, or are higher functioning females being diagnosed less frequently? Advances in the area of diagnosis including the development of standardized assessment tools has allowed for the diagnosis of children with a more atypical presentation (Landa, Holman & Garret-Mayer, 2007). Despite this advancement, it is possible that diagnostic instruments are not sensitive to more subtle cases of ASD in females and thus are simply identifying females most affected by ASD due to increased prominence of diagnostic features and impairments (Koenig & Tsatsanis, 2005). Some researchers have hypothesized that higher functioning school-age females have fewer restricted interests and stronger social communication and conversational skills, enabling them to ‘blend in’ more easily (Gillberg & Coleman, 2000). This hypothesis has not been examined empirically although existing literature suggests that females tend to have fewer repetitive behaviors and more impaired social communication functioning.

The present study examined sex differences in adaptive behavior and autism symptomatology in children with ASD and also examined sex differences in developmental functioning and early social communication profiles in children with ASD and typical development (TD). This study utilized a data set from the FIRST WORDS® Project (Wetherby et al., 2008), an ongoing longitudinal, prospective study of toddlers with ASD, non-ASD communication delays, and typical development.
METHOD

Participants

**ASD Group.** All children included in the ASD groups participated in the FIRST WORDS® Project (Wetherby et al., 2008), an ongoing longitudinal, prospective study. A detailed description of inclusion criteria for the FIRST WORDS® Project can be found in Wetherby et al. (2008). Children were recruited from the Florida State University (FSU) FIRST WORDS® Project and University of Michigan Autism and Communication Disorders Center (UMACC). Participants in the FIRST WORDS Project consisted of children recruited from pediatrician offices, younger siblings of children with ASD, and children who were referred to the project because of concerns about development. Children were invited for a communication evaluation at the FSU Autism Institute or UMACC between 17-24 months of age ($M = 20.05$ months, $SD = 2.17$). During this evaluation, a skilled clinician administered and scored the CSBS Behavior Sample (Wetherby & Prizant, 2002). To determine diagnostic status, all children who completed a communication sample and displayed any red flags of ASD were invited to participate in a diagnostic evaluation ($M = 28.09$ months, $SD = 12.30$) that examined the child’s autism symptomatology with the Autism Diagnostic Observation Schedule (Lord et al., 1999), developmental functioning with the Mullen Scales of Early Learning (MSEL; Mullen, 1995), and adaptive behavior with the Vineland Adaptive Behavior Scales (VABS; Sparrow, Cicchetti, & Balla, 2005). Information gathered from parent report, clinician observation, and standardized measures was used to formulate a best-estimate clinical diagnosis. Children who received a best-estimate diagnosis of ASD were included in the ASD group. For children who completed multiple diagnostic batteries, the battery closest to 36 months of age was selected for data analysis. The final ASD sample consisted of 288 participants (54 female) who received best-estimate diagnoses of ASD. Table 1 contains information regarding the demographic and ethnic composition of the sample.

**Typically Developing Control Group.** Children in the TD group were recruited from a general population sample using the CSBS-DP Infant-Toddler Checklist (ITC; Wetherby & Prizant, 2002). Parents completed the ITC at their pediatrician’s office. Children who failed this screener were invited in for an evaluation at the FSU Autism Institute.
Institute. The evaluation consisted of the CSBS before 24 months of age ($M = 20.03$ months, $SD = 2.17$) and a MSEL at approximately 24-36 months of age ($M = 31.44$, $SD = 7.14$). Children were included in the TD group if: they did not show red flags of ASD or delayed development during the CSBS and MSEL, caregivers did not express concerns about the child’s development and were judged to be typically developing by an experienced clinician. During recruitment of children in the TD group, an effort was made to recruit males and females in similar proportions to the ASD group, therefore males with TD were oversampled, yielding a sample of 59 females and 164 males. Demographic and ethnic composition of participants can be found in Table 1.

**Measures**

**Autism Diagnostic Observation Schedule** (Lord et al., 1999; Luyster et al., 2009). Modules 1, 2, 3 and the Toddler Module of the *Autism Diagnostic Observation Schedule* (ADOS) were used to confirm participant’s diagnosis at the follow-up diagnostic evaluation. The ADOS is a semi-structured, standardized assessment completed by a trained experimenter based on the observations during one of four activity modules. The module administered depends on the participant’s level of expressive vocabulary and age (i.e., Module 1 is for individuals who are preverbal or who use single words to communicate, and Module 2 is for individuals with simple phrase speech; Lord et al. 1999). ADOS items are scored on a four point scale ranging from 0 (no evidence of abnormality related to ASD) to 3 (definite evidence of autistic behavior), yielding domain scores for Social Affect and Restricted and Repetitive Behaviors. Diagnostic classification is based upon exceeding a threshold in a combined Social Affect and Restricted and Repetitive Behavior score (Gotham, Risi, Pickles & Lord, 2007). The ADOS has been found to have good reliability and high sensitivity and specificity in identifying characteristics of ASD (Lord et al., 2000; Gotham et al., 2007; Luyster et al., 2009).

**Mullen Scales of Early Learning** (Mullen, 1995). The Mullen Scales of Early Learning (MSEL) is a measure of cognitive functioning used in infants and children up to 66 months of age. The MSEL consists of four cognitive scales: Visual Reception, Fine Motor, Receptive Language, and Expressive Language. The MSEL yields raw scores, t-scores, percentile ranks, and age equivalents.
**Vineland Adaptive Behavior Scales, Second Edition** (Sparrow, Cicchetti, & Balla, 2005). The Vineland Adaptive Behavior Scales (VABS) is a standardized parent interview used to assess adaptive behavior in four domains: Communication, Daily Living Skills, Socialization, and Motor Skills. This measure yields raw scores, standard scores, percentile ranks, and age equivalencies with higher scores indicating more mature adaptive behavior.

**Communication and Symbolic Behavior Scales-Developmental Profile** (CSBS; Wetherby & Prizant, 2002). The CSBS is a standardized tool for the assessment of early social communication abilities. The CSBS Behavior Sample consists of a standardized set of procedures and activities administered by a trained examiner that are designed to elicit spontaneous communicative behavior from very young children. The Behavior Sample consists of a number of communicative temptations using highly desirable materials such as a windup toy, a balloon, bubbles, a jar with food, and books. The child is then presented with opportunities to demonstrate functional and early emerging symbolic play. The Behavior Sample also includes probes to examine the child’s ability to initiate and respond to joint attention, understanding of object names, person names, and body parts. The Sample consists of six distinct activities, and social communication skills are scored throughout the Behavior Sample. The Behavior Sample is recorded and scored from video by a trained clinician. The CSBS has been found to have good psychometric properties (Wetherby, Allen, Cleary, Kublin & Goldstein, 2002; Wetherby and Prizant; 2002).

The CSBS Behavior Sample yields 20 items that form three composite scores (social, speech, and symbolic) and seven cluster scores. The Behavior Sample yields raw scores for each item, weighted raw scores for each cluster, and standard scores and percentile ranks for each composite score. Each cluster score is described below.

**Emotion and Eye Gaze:** Measures the child’s use of eye gaze and emotional expression during the six CSBS activities. This cluster is composed of three CSBS items: Gaze Shifts, Shared Positive Affect, and Gaze/Point Following. A gaze shift is defined as alternating eye gaze between a person’s face, an object, and back to the person’s face. Shared positive affect is defined as displays of positive affect combined with coordinated
gaze toward another person. A gaze or point follow is defined as the child looking where the examiner is looking or pointing.

Communication: Measures the child’s rate and use of communication during the six CSBS activities. This cluster is composed of four CSBS items: Rate of Communication, Acts for Behavior Regulation, Acts for Social Interaction, and Acts for Joint Attention. Rate of communication is defined as the number of direct communication acts used per activity. The child’s use of communication is measured by examining the reasons that the child directs communication—to regulate another person’s behavior, initiate social interaction, or share interest about an object or event in the child’s environment.

Gestures: This cluster measures the variety and complexity of the child’s gesture use during the entire sample. The Gestures cluster consists of two CSBS items: Inventory of Conventional Gestures and Rate of Distal Gestures. Conventional gestures include giving, showing, and pointing and must be directed toward another person and serve a clear communicative function.

Sounds: This cluster measures the child’s use and inventory of non-word vocalizations. It consists of two items: Syllables with Consonants and Inventory of Consonants.

Words: This cluster measures the child’s use and inventory of words and word combinations. It consists of four CSBS items: Words, Inventory of Words, Word Combinations, and Inventory of Word Combinations.

Understanding: This cluster is a measure of the child’s language comprehension. It is measured by a structured comprehension probe of object names, person names, and body parts and consists of the CSBS Understanding item.

Object Use: This cluster measures the quality and variety of the child’s functional, representational, and constructive play actions. It consists of four CSBS items: Inventory of Actions, Pretend Play Actions, Sequences of Action Schemes, and Stacking Blocks.
RESULTS

Prior to analyses, all variables were examined to ensure that the assumptions of Multivariate Analysis of Variance (MANOVA) were satisfied. Data were screened for skew, kurtosis and the presence of univariate and multivariate outliers. All skewness and kurtosis values for the full dataset did not identify problematic distributions of any variables. Multivariate normality was evaluated using Mahalanobis distances and identified five cases with multivariate outliers. Although MANOVA is sensitive to the presence of multivariate outliers, MANOVA can tolerate a few outliers given a large sample (Tabachnick & Fidell, 2007). Scatterplots for each pair of variables were examined separately for each group to identify non-linear relationships and did not reveal any obvious evidence of non-linearity.

Developmental Level

To examine sex differences in developmental level, a 2x2 MANOVA with diagnosis and sex entered as two-level between-subjects factors was conducted. Specifically, males and females were compared on MSEL T-Scores MSEL (i.e., Visual Reception, Fine Motor, Receptive Language, and Expressive Language) as well as ratio developmental quotients that reflect children’s overall nonverbal (NVDQ) and verbal (VDQ) functioning in relation to chronological age. Descriptive statistics for each MSEL subscale and ratio developmental quotient can be found in Table 2.

Analyses revealed a significant main effect of diagnostic group (Wilks’ Λ = 0.59, \( F [11,495] = 31.64, p < 0.001 \)). Follow-up analyses revealed that children with ASD demonstrated significantly lower scores than children in the TD group on all subscales of the MSEL as well as verbal and nonverbal developmental quotients (see Table 3). Analyses did not reveal a significant effect of sex (Wilks’ Λ = 0.97, \( F [11,495] = 1.18, p = 0.30 \)) or a significant diagnostic group X sex interaction (Wilks’ Λ = 0.98, \( F [11,495] = 1.00, p = 0.45 \)). For these and all subsequent analyses, Cohen’s \( d \) was calculated to quantify the magnitude of differences using pooled variance to account for unequal sample sizes (see Table 3). Within the TD group, small sex differences were observed for the Verbal and Nonverbal development quotients, Visual Reception, Fine Motor, and Expressive Language subscales, while a medium (Cohen’s \( d = .53 \)) difference was found for the Receptive Language subscale. Within the ASD group, small sex
differences were observed for all of the MSEL subscales. Omega squared calculations documented negligible effect sizes (<0.01) for diagnostic group X sex interactions.

Follow-up contrasts using Tukey HSD to control for Type I error due to multiple comparisons revealed significant differences between typically developing males and females with regard to receptive language MSEL T-Scores $F (1,505) = 4.90$, $p < 0.05$. Females in the TD group demonstrated significantly higher Receptive Language T-Scores than males and the magnitude of this difference, as measured by Cohen’s $d$ was medium (0.53).

**Adaptive Skills**

To examine sex differences in adaptive behavior, a one-way MANOVA was conducted. Specifically, males and females with ASD were compared on the four subscales of the Vineland Adaptive Behavior Scales (Communication, Socialization, Daily Living, and Motor Skills) and the Vineland Adaptive Behavior Composite. Analyses did not reveal significant difference between males and females with ASD with regard to overall adaptive behavior functioning (Wilks’ $\Lambda = 0.95$, $F [6, 79] = 0.68$, $p = 0.67$; see Table 4). The magnitude of the differences in means for males and females on VABS subscales, as measured by Cohen’s $d$ were small (see Table 4).

**Autism Symptomatology**

To examine sex differences on a measure of autism symptomatology, males and females with ASD were compared on ADOS domains scores (i.e., Social Affect and Restricted and Repetitive Behaviors see Table 3). As expected, the ADOS total score was correlated with MSEL NVDQ ($r = -0.51$, $p < 0.001$), so NVDQ was included in the model as a covariate. The one-way MANCOVA did not reveal significant sex differences (Wilks’ $\Lambda = 0.99$, $F [3,283] = 1.00$, $p = 0.40$), and effect sizes were negligible to small (see Table 4).

**Early Social Communication Skills**

To examine sex differences in early communication skills, a 2x2 MANOVA with diagnosis and sex entered as two-level between-subjects factors was conducted. Specifically, males and females were compared on CSBS Behavior Sample cluster and composite scores (see Table 5). Analyses revealed a significant main effect of diagnostic group (Wilks’ $\Lambda = 0.44$, $F [11,497] = 56.63$, $p < 0.001$). Follow up analyses revealed
significant differences between children with ASD and TD on all BS cluster and composite scores (i.e., cluster scores: Emotion and Eye Gaze, Communication, Gestures, Sounds, Words, Understanding, Object Use; composite scores: Social, Speech, and Symbolic), with children with TD demonstrating significantly higher scores. Analyses did not reveal a significant main effect of sex (Wilks’ Λ = 0.97, $F_{[11,497]} = 1.57, p = 0.11$) or a significant diagnostic group X sex interaction (Wilks’ Λ = 0.97, $F_{[11,497]} = 1.22, p = 0.27$). Cohen’s $d$ documented negligible to small differences between males and females in the TD group and males and females with ASD (see Table 6). Omega squared calculations documented negligible effect sizes (<0.001) for diagnostic group X sex interactions.

Follow-up analyses revealed a significant diagnostic status X sex interaction for the CSBS Words Cluster. Between subject effects can be found in Table 7. Contrasts using Tukey HSD to control for type one error revealed significant differences between males and females in the TD group, with females achieving significantly higher scores on the CSBS Words Cluster $F(1, 507) = 10.33, p < 0.05$, Cohen’s $d = 0.50$, the CSBS Speech Composite $F(1, 507) = 4.42, p < 0.05$, Cohen’s $d = 0.37$, and the CSBS Total Score $F(1, 507) = 4.23, p < 0.05$, Cohen’s $d = 0.35$. 
DISCUSSION

The present study examined sex differences in developmental functioning, adaptive behavior, autism symptomatology, and early social communication skills using a large, community sample of children with ASD and TD. As expected, the TD group showed more developed early communication skills as well as higher overall developmental functioning when compared to the ASD group. Analysis of the TD group revealed that females with TD showed slightly more developed receptive language skills on the MSEL and expressive language skills on the CSBS when compared to males with TD. Males and females with ASD in this sample evidenced similar patterns of scores with respect to sex differences in developmental functioning, adaptive skills, autism symptomatology, or early social communication skills.

The results from this study contribute to the conflicting research findings which have inconsistently documented sex differences in individuals with ASD with respect to cognitive functioning and autism symptomatology. There is some evidence from the existing literature that sex differences in diagnostic features are more likely to be detected when samples include older children (c.f. Carter et al., 2007 and Mandy et al., 2011), although some do find differences in toddlers (Hartley & Sikora, 2009). Further, given that the highest mean age of diagnosis is for high functioning females (Giarelli et al., 2010, Shattuck et al, 2009), the lack of sex differences found in this and other studies of toddlers may indicate that ASD unfolds more slowly in females than males or may indicate that parents and clinicians are less likely to express concern about high functioning females.

Measurement of autism symptoms may also influence the detection of differences, particularly when using a diagnostic instrument such as the ADOS. Prior to the release of the revised ADOS algorithms (Gotham et al., 2007), direct comparisons across modules were not possible given that the number of items within domain varied by module. To address this, some studies have calculated a percentage score, dividing each child’s total and domain scores by the total number of possible points. However, it is possible that this approach artificially exaggerates small differences in ADOS scores. In fact, the existing studies that demonstrated sex differences utilized percentage scores (Mandy et al., 2011; Harley & Sikora, 2009), while many studies that failed to
demonstrate sex differences on the ADOS did not utilize this method of analyzing ADOS total and domain scores (Carter et al., 2007; Holtmann, Bolte & Poutska, 2007). Additionally, the ADOS, which was developed primarily as a diagnostic tool rather than a metric of symptom severity, may not be the best tool to use when examining differences in symptoms and their severity. ADOS algorithms include the items that are most informative in a diagnostic context but may not provide a comprehensive sample of ASD features, or alternatively, it may be that ADOS algorithm items are not sensitive to sex differences in ASD symptomatology. Zwaigenbaum and colleagues (2012) used the recently developed ADOS Calibrated Severity Scores (CSS), a standardized metric that is intended to measure symptom severity and allows for the comparison of ADOS across modules (Gotham, Pickles & Lord, 2009) and found that within their sample of low-risk controls and high-risk children with and without ASD, females in all groups had slightly lower ADOS scores. Thus, it is possible that ADOS CSS scores provide a more promising avenue for detecting sex differences in this widely-used diagnostic tool. However, CSS scores are not yet available for the ADOS Toddler Module, and thus were unavailable for analysis in the present study.

A larger number of studies have documented sex differences using the Autism Diagnostic Interview-Revised (ADI-R), a semi-structured parent interview, particularly in the amount of repetitive behaviors. In contrast to the ADOS, the ADI-R has a greater number of items measuring both social communication and repetitive behavior features, thus making it easier to detect sex differences. However, it is also possible that the differences detected by studies using the ADI-R and other parent report measures are influenced by an interpretation bias that results from parents reporting on the atypicality of their child’s behavior in comparison to typically-developing same sex peers. In fact, one study demonstrated that although males and females with ASD did not differ with regard to social-communication and restricted and repetitive behaviors as measured by the ADOS, parents of females with ASD reported much lower levels of social competence (Carter et al., 2007). Using a sample of older children, Holtmann, Bolte, and Poustka (2007) also found that while females did not differ significantly from males with ASD on core ASD symptomatology, parents reported significantly more behavioral and emotional difficulties in females with ASD.
The lack of demonstrated sex differences in the present study may be due to limitations that should be acknowledged. While this study included 510 children (288 of whom were diagnosed with ASD), only 54 females with ASD were included. Thus, it is possible that the study failed to detect sex differences due to lack of statistical power. To further examine this possibility, a post hoc power analysis was conducted using the GPower computer program (Faul, Erdfelder, Buchner & Lang, 2009). Specifying 0.8 power, analyses revealed a minimally detectable effect size of $d = 0.26$. Therefore, this study had sufficient power to detect educationally meaningful effects (Rosenthal, 1991).

Additionally, a wide range of developmental functioning was documented in our ASD sample, which is frequently observed in ASD research but may have affected our ability to detect differences in ASD symptomatology and early social communication skills. Examination of sex differences in these areas in a more heterogeneous sub-sample of children with ASD may reveal different results. Finally, our conclusions regarding sex differences in autism symptomatology are limited because autism symptomatology was assessed using the ADOS, which may be limited in utility for sex differences research, and did not include parental report of ASD symptoms. The combination of direct clinical observation and parent report has been demonstrated to yield a more accurate representation of a child’s ASD phenotype (Risi et al., 2006; Kim & Lord, 2012).

This study provides several areas for future investigation. To examine the possibility that sex differences in children with ASD are more apparent as children age, future research that systematically examines the ASD phenotype in males and females across age and developmental level is necessary. Additionally, it may be useful to document sex differences using multiple sources of information including, structured clinical observations, parent report, and observation of behavior across contexts such as school or home environments.
Table 1.

Sample demographic characteristics

<table>
<thead>
<tr>
<th></th>
<th>Female ASD (n = 54)</th>
<th>Male ASD (n = 234)</th>
<th>Female TD (n = 59)</th>
<th>Male TD (n = 164)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ethnicity (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>African American</td>
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<td>15</td>
<td>8.5</td>
<td>10.4</td>
</tr>
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<td>Asian</td>
<td>0</td>
<td>1.3</td>
<td>1.7</td>
<td>0.6</td>
</tr>
<tr>
<td>Biracial</td>
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<td>6.4</td>
<td>5.1</td>
<td>7.3</td>
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<td>Hispanic</td>
<td>1.9</td>
<td>2.6</td>
<td>3.4</td>
<td>1.8</td>
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<tr>
<td>White</td>
<td>57.4</td>
<td>61.5</td>
<td>76.3</td>
<td>78.7</td>
</tr>
<tr>
<td>Not Provided</td>
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<td>13.2</td>
<td>5.1</td>
<td>1.2</td>
</tr>
<tr>
<td><strong>Parent Education (Years)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mother</td>
<td></td>
<td></td>
<td>14.80 (2.29)</td>
<td>16.07 (2.45)</td>
</tr>
<tr>
<td></td>
<td>(n = 50)</td>
<td>(n = 55)</td>
<td>(n = 223)</td>
<td>(n = 162)</td>
</tr>
<tr>
<td>Father</td>
<td></td>
<td></td>
<td>15.22 (2.42)</td>
<td>12.51 (2.25)</td>
</tr>
<tr>
<td></td>
<td>(n = 45)</td>
<td>(n = 56)</td>
<td>(n = 215)</td>
<td>(n = 157)</td>
</tr>
<tr>
<td>Prematurity (%)</td>
<td>9.3</td>
<td>10.2</td>
<td>8.5</td>
<td>6.1</td>
</tr>
</tbody>
</table>

**Site**

<p>| | | | | |</p>
<table>
<thead>
<tr>
<th></th>
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<th></th>
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<th></th>
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</thead>
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<tr>
<td>FSU</td>
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<td>57</td>
<td>202</td>
<td>162</td>
</tr>
<tr>
<td>UoM</td>
<td>9</td>
<td>2</td>
<td>32</td>
<td>2</td>
</tr>
</tbody>
</table>
Table 2.  
*MSEL descriptive statistics by sex and diagnostic status*

<table>
<thead>
<tr>
<th></th>
<th>Female</th>
<th></th>
<th>Male</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ASD (n = 54)</td>
<td>TD (n = 59)</td>
<td>ASD (n = 234)</td>
<td>TD (n = 164)</td>
</tr>
<tr>
<td>Age at MSEL</td>
<td>31.81 (8.71)</td>
<td>29.98 (8.22)</td>
<td>32.60 (9.28)</td>
<td>32.00 (6.67)</td>
</tr>
<tr>
<td>VR- T</td>
<td>38.70 (16.10)</td>
<td>62.10 (12.25)</td>
<td>38.23 (16.03)</td>
<td>59.56 (11.03)</td>
</tr>
<tr>
<td>FM-T</td>
<td>37.67 (15.20)</td>
<td>58.19 (11.24)</td>
<td>36.78 (14.96)</td>
<td>56.65 (12.11)</td>
</tr>
<tr>
<td>RL-T</td>
<td>35.20 (15.40)</td>
<td>60.22 (8.09)</td>
<td>34.75 (15.34)</td>
<td>55.93 (8.14)</td>
</tr>
<tr>
<td>EL-T</td>
<td>36.60 (15.24)</td>
<td>54.44 (9.40)</td>
<td>33.75 (14.06)</td>
<td>55.59 (9.60)</td>
</tr>
<tr>
<td>NVDQ</td>
<td>82.98 (25.91)</td>
<td>116.37 (15.63)</td>
<td>82.49 (23.76)</td>
<td>112.88 (16.08)</td>
</tr>
<tr>
<td>VDQ</td>
<td>71.82 (32.02)</td>
<td>116.92 (15.05)</td>
<td>70.05 (28.78)</td>
<td>110.92 (15.95)</td>
</tr>
</tbody>
</table>
Table 3

**MSEL MANOVA between subject effects**

<table>
<thead>
<tr>
<th></th>
<th>Effect of Diagnostic Status</th>
<th>Effect of Sex</th>
<th>Diagnostic Status * Sex Interaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>VR- T</td>
<td>F (1,505) 207.03 &lt; 0.001</td>
<td>F (1,505) 0.94</td>
<td>F (1,505) 0.44</td>
</tr>
<tr>
<td>FM-T</td>
<td>F (1,505) 188.24 &lt; 0.001</td>
<td>F (1,505) 0.68</td>
<td>F (1,505) 0.05</td>
</tr>
<tr>
<td>RL-T</td>
<td>F (1,505) 286.69 &lt; 0.001</td>
<td>F (1,505) 3.02</td>
<td>F (1,505) 1.97</td>
</tr>
<tr>
<td>EL-T</td>
<td>F (1,505) 255.77 &lt; 0.001</td>
<td>F (1,505) 3.09</td>
<td>F (1,505) 0.14</td>
</tr>
<tr>
<td>NVDQ</td>
<td>F (1,505) 200.91 &lt; 0.001</td>
<td>F (1,505) 0.76</td>
<td>F (1,505) 0.43</td>
</tr>
<tr>
<td>VDQ</td>
<td>F (1,505) 272.15 &lt; 0.001</td>
<td>F (1,505) 2.08</td>
<td>F (1,505) 0.59</td>
</tr>
</tbody>
</table>
Table 4.

*Effect sizes for MSEL scores by diagnostic group and sex*

<table>
<thead>
<tr>
<th>MSEL</th>
<th>ASD vs. TD</th>
<th>Male vs. TD</th>
<th>TD Male vs. TD</th>
<th>ASD Male vs. ASD</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Female</td>
<td>Female</td>
<td>Female</td>
</tr>
<tr>
<td>VR- T</td>
<td>-1.47</td>
<td>0.22</td>
<td>0.22</td>
<td>0.03</td>
</tr>
<tr>
<td>FM-T</td>
<td>-1.44</td>
<td>0.21</td>
<td>0.13</td>
<td>0.06</td>
</tr>
<tr>
<td>RL-T</td>
<td>-1.65</td>
<td>0.29</td>
<td>0.53</td>
<td>0.03</td>
</tr>
<tr>
<td>EL-T</td>
<td>-1.76</td>
<td>0.29</td>
<td>-0.12</td>
<td>0.06</td>
</tr>
<tr>
<td>NVDQ</td>
<td>-1.45</td>
<td>0.21</td>
<td>0.22</td>
<td>0.02</td>
</tr>
<tr>
<td>VDQ</td>
<td>-1.68</td>
<td>0.27</td>
<td>0.38</td>
<td>0.06</td>
</tr>
</tbody>
</table>

*Cohen’s d; Negative effect sizes indicate that the typically developing or male group demonstrated higher scores*
Table 5.
Descriptive statistics and effect sizes for VABS and ADOS scores by sex

<table>
<thead>
<tr>
<th>ASDB (Standard Score)</th>
<th>Female ASD (n = 54)</th>
<th>Male ASD (n = 234)</th>
<th>Effect Size*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Communication</td>
<td>81.10 (16.18)</td>
<td>82.64 (16.69)</td>
<td>-0.09</td>
</tr>
<tr>
<td>Socialization</td>
<td>78.93 (11.63)</td>
<td>77.83 (11.63)</td>
<td>0.09</td>
</tr>
<tr>
<td>Daily Living Skills</td>
<td>80.64 (13.71)</td>
<td>81.24 (12.90)</td>
<td>-0.05</td>
</tr>
<tr>
<td>Motor Skills</td>
<td>83.05 (14.97)</td>
<td>84.03 (14.10)</td>
<td>-0.07</td>
</tr>
<tr>
<td>Adaptive Behavior Composite</td>
<td>78.14 (13.35)</td>
<td>78.22 (12.53)</td>
<td>-0.01</td>
</tr>
</tbody>
</table>

ADOS Scores

<table>
<thead>
<tr>
<th>ADOS Module</th>
<th>Female n (%)</th>
<th>Male n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Social affect (SA)</td>
<td>11.33 (3.78)</td>
<td>11.80 (4.51)</td>
</tr>
<tr>
<td>Restricted and repetitive behaviors (RRB)</td>
<td>4.04 (2.02)</td>
<td>3.72 (2.08)</td>
</tr>
<tr>
<td>SA + RRB total</td>
<td>15.39 (3.78)</td>
<td>15.50 (5.54)</td>
</tr>
</tbody>
</table>

Age at ADOS (months) | 33.70 (9.77) | 35.12 (12.45) |

*Cohen’s d; Negative effect sizes indicate that males demonstrated higher scores
Table 6.
CSBS descriptive statistics by sex and diagnostic status

<table>
<thead>
<tr>
<th></th>
<th>Female ASD (n = 54)</th>
<th>Female TD (n = 59)</th>
<th>Male ASD (n = 234)</th>
<th>Male TD (n = 164)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CSBS Behavior Sample</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Mean Age</td>
<td>20.61 (2.32)</td>
<td>19.59 (1.81)</td>
<td>19.99 (2.25)</td>
<td>20.22 (2.27)</td>
</tr>
<tr>
<td>Cluster (SS)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Emotion and Eye Gaze</td>
<td>5.83 (3.04)</td>
<td>12.27 (3.10)</td>
<td>5.88 (3.03)</td>
<td>12.18 (3.35)</td>
</tr>
<tr>
<td>Communication</td>
<td>6.33 (2.80)</td>
<td>11.51 (3.22)</td>
<td>6.11 (2.99)</td>
<td>11.38 (3.07)</td>
</tr>
<tr>
<td>Gestures</td>
<td>6.20 (2.93)</td>
<td>11.15 (3.22)</td>
<td>5.87 (2.86)</td>
<td>11.01 (2.38)</td>
</tr>
<tr>
<td>Sounds</td>
<td>7.06 (2.33)</td>
<td>10.69 (2.69)</td>
<td>6.79 (2.40)</td>
<td>10.17 (2.52)</td>
</tr>
<tr>
<td>Words</td>
<td>7.09 (1.84)</td>
<td>10.83 (2.51)</td>
<td>7.12 (2.00)</td>
<td>9.80 (2.21)</td>
</tr>
<tr>
<td>Understanding</td>
<td>7.11 (3.39)</td>
<td>12.17 (3.53)</td>
<td>6.65 (2.85)</td>
<td>11.86 (3.79)</td>
</tr>
<tr>
<td>Object Use</td>
<td>7.22 (3.42)</td>
<td>11.49 (2.92)</td>
<td>7.14 (3.037)</td>
<td>11.52 (2.42)</td>
</tr>
<tr>
<td>Composite Scores</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Social</td>
<td>5.65 (2.75)</td>
<td>11.95 (2.87)</td>
<td>5.53 (2.64)</td>
<td>11.79 (2.60)</td>
</tr>
<tr>
<td>Speech</td>
<td>6.67 (2.57)</td>
<td>10.78 (2.30)</td>
<td>6.39 (2.64)</td>
<td>10.01 (2.00)</td>
</tr>
<tr>
<td>Symbolic</td>
<td>6.78 (3.31)</td>
<td>11.93 (2.83)</td>
<td>6.24 (2.74)</td>
<td>11.49 (2.53)</td>
</tr>
<tr>
<td>Total Score</td>
<td>77.22 (12.76)</td>
<td>106.44 (12.38)</td>
<td>75.00 (12.38)</td>
<td>102.80 (9.86)</td>
</tr>
<tr>
<td>CSBS Cluster (SS)</td>
<td>Effect of Diagnostic Status</td>
<td>Effect of Sex</td>
<td>Diagnostic Status * Sex Interaction</td>
<td></td>
</tr>
<tr>
<td>---------------------------</td>
<td>-----------------------------</td>
<td>---------------</td>
<td>------------------------------------</td>
<td></td>
</tr>
<tr>
<td></td>
<td>F (1,507)</td>
<td>Significance</td>
<td>F (1,507)</td>
<td>Significance</td>
</tr>
<tr>
<td>Emotion and Eye Gaze</td>
<td>358.03</td>
<td>&lt; 0.01*</td>
<td>0.01</td>
<td>0.94</td>
</tr>
<tr>
<td>Communication</td>
<td>257.19</td>
<td>&lt; 0.01*</td>
<td>0.28</td>
<td>0.60</td>
</tr>
<tr>
<td>Gestures</td>
<td>305.12</td>
<td>&lt; 0.01*</td>
<td>0.69</td>
<td>0.41</td>
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<tr>
<td>Sounds</td>
<td>176.53</td>
<td>&lt; 0.01*</td>
<td>2.23</td>
<td>0.14</td>
</tr>
<tr>
<td>Words</td>
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<td>&lt; 0.01*</td>
<td>4.92</td>
<td>0.03*</td>
</tr>
<tr>
<td>Understanding</td>
<td>208.97</td>
<td>&lt; 0.01*</td>
<td>1.17</td>
<td>0.28</td>
</tr>
<tr>
<td>Object Use</td>
<td>196.26</td>
<td>&lt; 0.01*</td>
<td>0.01</td>
<td>0.94</td>
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<tr>
<td>CSBS Composite (SS)</td>
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<td></td>
</tr>
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<td>Social</td>
<td>477.79</td>
<td>&lt; 0.01*</td>
<td>0.25</td>
<td>0.62</td>
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<tr>
<td>Speech</td>
<td>225.38</td>
<td>&lt; 0.01*</td>
<td>4.09</td>
<td>0.04*</td>
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<td>Symbolic</td>
<td>312.80</td>
<td>&lt; 0.01*</td>
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<td>0.10</td>
</tr>
<tr>
<td>CSBS Total Score</td>
<td>510.04</td>
<td>&lt; 0.01*</td>
<td>4.48</td>
<td>0.04*</td>
</tr>
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</table>
Table 8.
*Effect sizes for CSBS scores by diagnostic group and sex*

<table>
<thead>
<tr>
<th>CSBS Cluster (SS)</th>
<th>ASD vs. TD</th>
<th>Male vs. Female</th>
<th>TD Male vs. TD Female</th>
<th>ASD Male vs. ASD Female</th>
</tr>
</thead>
<tbody>
<tr>
<td>Emotion and Eye Gaze</td>
<td>-2.01</td>
<td>0.16</td>
<td>0.03</td>
<td>-0.02</td>
</tr>
<tr>
<td>Communication</td>
<td>-1.72</td>
<td>0.19</td>
<td>0.04</td>
<td>0.07</td>
</tr>
<tr>
<td>Gestures</td>
<td>-1.89</td>
<td>0.22</td>
<td>0.06</td>
<td>0.12</td>
</tr>
<tr>
<td>Sounds</td>
<td>-1.35</td>
<td>0.26</td>
<td>0.20</td>
<td>0.11</td>
</tr>
<tr>
<td>Words</td>
<td>-1.26</td>
<td>0.32</td>
<td>0.45</td>
<td>-0.02</td>
</tr>
<tr>
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<td>0.35</td>
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</table>

*Cohen’s $d$; Negative effect sizes indicate that the typically developing or male group demonstrated higher scores*
APPENDIX A

Office of the Vice President For Research
Human Subjects Committee
Tallahassee, Florida 32306-2742
(850) 644-4673, FAX (850) 644-4392

RE-APPROVAL MEMORANDUM

Date: 9/20/2011

To: Amy Wetherby

Address: MC 7814
Dept.: COLLEGE OF MEDICINE

From: Thomas L. Jacobson, Chair

Re: Re-appraisal of Use of Human subjects in Research
FIRST WORDS Project: Early Identification of Speech, Language, Communication, and Autism Spectrum Disorders

Your request to continue the research project listed above involving human subjects has been approved by the Human Subjects Committee. If your project has not been completed by 9/11/2012, you must request renewed approval by the Committee.

If you submitted a proposed consent form with your renewal request, the approved stamped consent form is attached to this re-appraisal notice. Only the stamped version of the consent form may be used in recruiting of research subjects. You are reminded that any changes in protocol for this project must be reviewed and approved by the Committee prior to implementation of the proposed changes in the protocol. A protocol change/amendment form is required to be submitted for approval by the Committee. In addition, federal regulations require that the Principal Investigator promptly report in writing any unanticipated problems or adverse events involving risks to research subjects or others.

By copy of this memorandum, the Chair of your department and/or your major professor are reminded of their responsibility for being informed concerning research projects involving human subjects in their department. They are advised to review the protocols as often as necessary to insure that the project is being conducted in compliance with our institution and with DHHS regulations.

Cc: []
HIC No. 2011.0960
Parent Permission Form

The FIRST WORDS Project is a federally-funded research study of early communication development in young children. We are interested in studying both children with typical development and children whose families have concerns about their child’s development. The Infant-Toddler Checklist is used as the first step in screening for communication delays to decide if a communication evaluation is needed.

The FIRST WORDS Project will send you a report to tell you how your child did on the Checklist. If your child is not developing as expected for his/her age based on the information that you provide on the Checklist, we will invite you to bring your child for a communication evaluation at no charge. However, you are under no obligation to provide any further information or have your child evaluated. We are also asking you to complete the attached Child and Family Information Form so that we can contact you if an evaluation is needed and we have background information about you and your child for our research. In order to estimate the percentage of young children with communication disorders born in the panhandle of Florida, we will be gathering information from your child’s birth certificate records obtained from the Florida Department of Health.

The information you provide may help your child access early intervention services and will help us identify children with communication problems earlier. Please be assured that the names of all children and families participating in the FIRST WORDS Project will be kept strictly confidential to the extent allowed by law.

By signing this permission form you are indicating that you have read this form and agree to have the information that you provide about your child and family included in this research project. If you have any questions about this study, please don’t hesitate to call the FIRST WORDS Project at (850) 488-5780. If you have any questions about your participation in this research, you can also contact the Chair of the FSU Human Subjects Committee, Institutional Review Board at (850) 644-8633.

I, __________________________, as legal guardian of __________________________
Parent/Legal Guardian’s Name (print clearly) Child’s Name (print clearly)
have read this form and give my permission for my child to be included in this research study.

Signature of Parent or Legal Guardian __________________________

Today’s Date: ______/____/____
Month Day Year

1940 N. Monroe Street, Suite 72, Tallahassee, Florida 32303
FSU Human Subjects Committee Approved 5/1/2000, Legal Addendum 4/22/2003
Telephone 850.644.5780 Fax 850.644.3644

28
Parent Permission Form

The FIRST WORDS® Project is a federally-funded research study of early communication development in young children. We are interested in studying both children with typical development and children whose families have concerns about their child's development. The Infant Toddler Checklist is used as the first step in screening for communication delays to decide if a communication evaluation is needed.

The FIRST WORDS Project will send you a report to tell you how your child did on the Checklist. If your child is not developing as expected for his/her age based on the information that you provide on the Checklist, we will invite you to bring your child for a communication evaluation at no charge. However, you are under no obligation to provide any further information or have your child evaluated. We are also asking you to complete the attached Child and Family Information Form so that we can contact you if an evaluation is needed and so we have background information about you and your child for our research. In order to estimate the percentage of young children with communication disorders born in the panhandle of Florida, we will be gathering information from your child's birth certificate records obtained from the Florida Department of Health.

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I, __________________________, as legal guardian of __________________________
Parent/Legal Guardian's Name (print clearly) Child's Name (print clearly)
have read this form and give my permission for my child to be included in this research study.

______________________________  ________________________________
Signature of Parent or Legal Guardian  Today's Date: __________/_______/________

FSU Human Subjects Committee Approved on 06/05/98. Review Date 06/05/03.
AGREEMENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY

Project Title: FIRST WORDS Project: Early Identification of Speech, Language, Communication, and Autism Spectrum Disorders

Principal Investigator: Amy M. Wetherby, Ph.D., CCC-SLP

Your child is being asked to participate in a research project as described in this form below. All such research projects carried out at the University are governed by the rules of both the federal government and Florida State University. These rules require that you give your signed agreement for your child to participate in this project.

The research staff who will evaluate your child will explain to you, in detail, the purpose of the project, the procedures to be used, and the potential benefits and possible risks of participation. You may ask any questions you have to help you understand the project. A basic explanation of the project is written below. Please read this explanation and discuss with the research staff any questions you might have.

If you then decide that your child may participate in the project, please sign this form in the presence of the person who explained the project to you. You will be given a copy of this form to keep.

1. Nature and Purpose of the Project: The purpose of this study is to determine if communication disorders can be identified in very young children who demonstrate delays in early communication development. Delays in language often the first symptoms evident to parents and professionals of children with communication disorders. Because children usually begin acquiring words between 12 and 18 months of age, a child may not be referred for a language delay until at least 20 to 24 months, but more typically, after 30 months. This longitudinal study of communication development in infants and toddlers will provide information on the predictive value of our checklist and early measures of social communication and play development in relation to performance on follow-up evaluations. We hope that this research project will help to develop better tools to guide referrals of children at risk for speech, language, communication, autism spectrum, and other developmental disorders at earlier ages. Early identification may lead to earlier treatment and support for children and families, which would have a positive effect on a child's development.

2. Explanation of Procedures: You and your child will be asked to participate in a number of procedures as part of this project. We will be giving you a questionnaire to complete to provide information about how your child communicates and plays with objects. Your child will participate in an evaluation lasting approximately 30-40 minutes. Activities during the session include: standard assessment procedures for young children to measure eye gaze, gestures, sounds, words, understanding, and play. This involves the presentation of toys and interesting materials to encourage our child to communicate and simple instructions. We will ask your permission to videotape the evaluation session to help us score behavior accurately. We will give you a summary of the results of this evaluation. If your child shows any red flags of autism spectrum disorders, we will invite your for a diagnostic evaluation to identify or rule-out autism spectrum. We may ask you to return to for a follow-up evaluation in 3 to 6 months in order to follow the
development of your child. However, the diagnostic evaluation for autism and the follow-up visit are optional, and you can decide to refuse at a later time. We will save the videotape of this evaluation session so we can continue to study precise measures of social communication and play of your child over the course of this longitudinal project. Because this study is exploratory in nature, research staff may review your child’s videotape at a later time to rate more precise measures of social communication and play. Your child’s scores on questionnaires and ratings of the videotape will become part of the FIRST WORDS Project database and may be used to study early indicators of typical development and communication delays.

3. Discomforts and Risks: All of the procedures to be used are commonly used with young children one to two years of age. Therefore, they do not involve activities that would cause discomfort to your child or put your child at any risk. However, if your child should become upset for any reason, the evaluation will be stopped, and rescheduled with your permission.

4. Benefits: You and your child may benefit from involvement in this project in a number of ways. First, we will provide you with information about your child’s social communication and play development. Second, the results of this study will provide information for professionals regarding patterns of early communication development, which will help with the early identification of communication delays in children. This information should lead to earlier and more appropriate services to young children and their families.

5. Confidentiality: All records relating to this project will be handled and safeguarded according to standard clinical policy for all patient records and will remain confidential to the extent allowed by law. Any research reports will carry no identifying information of individual children or families.

6. Refusal/Withdrawal: At any time during your participation in this study, you will have the opportunity to refuse to participate in any procedures or withdraw from the study at any time without prejudice or effect on you and your child. If you would like to remove your child’s records from the research database at any time in the future, call the project at 850-488-5730 to let us know.

7. Risks: We do not expect any unusual risks as a direct result of participation in this project, since all testing procedures are part of standard routine clinical test batteries.

8. Videotaping: You and your child will be videotaped by the clinician during the evaluation session. These videotapes will be kept by project staff in a locked room and will be saved indefinitely. These videotapes will be accessible only to research staff, unless otherwise specified by you. We may ask your permission to use segments of these videotapes for educational purposes; however, this is optional.

I acknowledge that I have read and fully understand the above explanation of the project, all of my questions have been satisfactorily answered, and I give permission for my child to participate in this research project. If I have any questions about my rights as a participant in this research, or if I feel I have been placed at risk, I can contact the chair of the human subjects committee, institutional review board, through the vice president for the office of research at (850) 644.8633.

__________________________
Signature of Parent

__________________________
Date

FSU Human Subjects Committee Approved on 9/14/2011 Valid After 9/13/2012 HSC # 2011.6960
AGREEMENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY

Project Title: FIRST WORDS Project: Early Identification of Speech, Language, Communication, and Autism Spectrum Disorders

Principal Investigator: Amy M. Wetherby, Ph.D., CCC-SLP

Your child is being asked to participate in a research project as described in this form below. All such research projects carried out at the University are governed by the rules of both the federal government and Florida State University. These rules require that you give your signed agreement for your child to participate in this project.

The research staff who will evaluate your child will explain to you, in detail, the purpose of the project, the procedures to be used, and the potential benefits and possible risks of participation. You may ask any questions you have to help you understand the project. A basic explanation of the project is written below. Please read this explanation and discuss with the research staff any questions you might have.

If you then decide that your child may participate in the project, please sign this form in the presence of the person who explained the project to you. You will be given a copy of this form to keep.

1. Nature and Purpose of the Project: The purpose of this study is to determine if communication disorders can be identified in very young children who demonstrate delays in early communication development. Being late in talking is often the first symptom evident to parents and professionals of children with communication disorders. Because children usually begin acquiring words between 12 and 18 months of age, a child may not be referred for a language delay until at least 20 to 24 months, but more typically, after 30 months. This longitudinal study of communication development in infants and toddlers will provide information on the precocious value of our checklist and early measures of social communication and play development in relation to performance on follow-up evaluations. We hope that this research project will help to develop better tools to guide referrals of children at risk for speech, language, communication, autism spectrum, and other developmental disorders at earlier ages. Early identification may lead to earlier treatment and support for children and families, which would have a positive effect on a child’s development.

2. Explanation of Procedures: You and your child will be asked to participate in a number of procedures as part of this project. We will be giving you a questionnaire to complete to provide information about how your child communicates and plays with objects. Your child will participate in an evaluation lasting approximately 30-40 minutes. Activities during this session include standard assessment procedures for young children to measure eye gaze, gestures, sounds, words, understanding, and play. This involves the presentation of toys and interesting materials to encourage our child to communicate and simple instructions. We will ask your permission to videotape the evaluation session to help us score behavior accurately. We will give you a summary of the results of this evaluation. If your child shows any red flags of autism spectrum disorders, we will invite you for a diagnostic evaluation to identify or rule-out autism spectrum. We may ask you to return to for a follow-up evaluation in 3 to 6 months in order to follow the
development of your child. However, the diagnostic evaluation for autism and the follow-up visit are optional, and you can decide to refuse at a later time. We will save the videotape of this evaluation session so we can continue to study precise measures of social communication and play of your child over the course of this longitudinal project. Because this study is exploratory in nature, research staff may review your child’s videotapes at a later time to rate more precise measures of social communication and play. Your child’s scores on questionnaires and ratings of the videotape will become part of the FIRST WORDS Project database and may be used to study early indicators of typical development and communication delays.

3. Discomforts and Risks: All of the procedures to be used are commonly used with young children one to two years of age. Therefore, they do not involve activities that would cause discomfort to your child or put your child at any risk. However, if your child should become upset for any reason, the evaluation will be stopped, and rescheduled with your permission.

4. Benefits: You and your child may benefit from involvement in this project in a number of ways. First, we will provide you with information about your child’s social communication and play development. Second, the results of this study will provide information for professionals regarding patterns of early communication development, which will help with the early identification of communication delays in children. This information should lead to earlier and more appropriate services to young children and their families.

5. Confidentiality: All records relating to this project will be handled and safeguarded according to standard clinical policy for all patient records and will remain confidential to the extent allowed by law. Any research reports will carry no identifying information of individual children or families.

6. Refusal/Withdrawal: At any time during your participation in this study, you will have the opportunity to refuse to participate in any procedures or withdraw from the study at any time without prejudice or effect on you and your child. If you would like to remove your child’s records from the research database at any time in the future, call the project at 850-488-5780 to let us know.

7. Risks: We do not expect any unusual risks as a direct result of participation in this project, since all testing procedures are part of standard routine clinical test batteries.

8. Videotaping: You and your child will be videotaped by the clinician during the evaluation session. These videotapes will be kept by project staff in a locked room and will be saved indefinitely. These videotapes will be accessible only to research staff, unless otherwise specified by you. We may ask your permission to use segments of these videotapes for educational purposes; however, this is optional.

I acknowledge that I have read and fully understand the above explanation of the project, all of my questions have been satisfactorily answered, and I give permission for my child to participate in this research project. If I have any questions about my rights as a participant in this research, or if I feel I have been placed at risk, I can contact the chair of the human subjects committee, institutional review board, through the vice president for the office of research at (850) 644-6633.

Signature of Parent  Date

FSU Human Subjects Committee Approved or 9/14/2011 Void After 9/12/2012 HSC # 2011.6960
AGREEMENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY

Project Title: FIRST WORDS Project: Early Identification of Speech, Language, Communication, and Autism Spectrum Disorders

Principal Investigator: Amy M. Wetherby, Ph.D., CCC-SLP

Your child is being asked to participate in a follow-up research project as described in this form below. All such research projects carried out at the University are governed by the rules of both the federal government and Florida State University. These rules require that you give your signed agreement for your child to participate in this project.

The research staff who will evaluate your child will explain to you, in detail, the purpose of the project, the procedures to be used, and the potential benefits and possible risks of participation. You may ask any questions you have to help you understand the project. A basic explanation of the project is written below. Please read this explanation and discuss with the research staff any questions you might have.

If you then decide that your child may participate in the project, please sign this form in the presence of the person who explained the project to you. You will be given a copy of this form to keep.

1. Nature and Purpose of the Project: The purpose of this study is to determine if communication disorders can be identified in very young children who demonstrate delays in early communication development. Being late in talking is often the first symptom evident to parents and professionals of children with communication disorders. Because children usually begin acquiring words between 12 and 18 months of age, a child may not be referred for a language delay until at least 20 to 24 months, but more typically, after 30 months. This longitudinal study of communication development in infants and toddlers will provide information on the predictive value of our checklist and early measures of social communication and play development in relation to performance on follow-up evaluations until 5 years of age. We hope that this research project will help to develop better tools to guide referrals of children at risk for speech, language, communication, autism spectrum, and other developmental disorders at earlier ages. This project will also help estimate the percentage of children born in the panhandle of Florida who have communication disorders. Early identification may lead to earlier treatment and support for children and families, which would have a positive effect on a child’s development.

2. Explanation of Procedures: You and your child will be asked to participate in a number of procedures as part of this project. We will be giving you questionnaires to complete to provide information about your child's development and experience. Your child will participate in an evaluation lasting approximately 60-90 minutes scheduled on one or two days. Activities during the session include standard assessment procedures for young children to measure social communication, language, nonverbal cognitive and emergent literacy skills. This involves the presentation of toys and interesting materials to encourage our child to communicate and will require your child to follow instructions, repeat sounds and words, name pictures, rhyme, and answer questions. We will ask your permission to videotape the evaluation session to help us
score behavior accurately. We will give you a summary of the results of this evaluation. If your child shows any red flags of autism spectrum disorders, we will invite you for a diagnostic evaluation to identify or rule-out autism spectrum. We may also ask your permission to send a videographer to your home to videotape you interacting with your child during everyday routines for about an hour. This will allow us to see how your child communicates and interacts at home compared to our clinical setting. We may ask you to return to for a follow-up evaluation in 6 to 12 months in order to follow the development of your child. However, the diagnostic evaluation for autism, home videotape, and follow-up evaluation are optional, and you can decide to refuse at a later time. We will save the videotape of this evaluation session and the home visit so we can continue to study precise measures of social communication and play of your child over the course of this longitudinal project. Because this study is exploratory in nature, research staff may review your child’s videotape at a later time to rate more precise measures of social communication and play. Your child’s scores on questionnaires, standardized tests, and ratings of the videotape will become part of the FIRST WORDS Project database and may be used to study early indicators of typical development and communication delays in relation to developmental outcomes.

3. Discomforts and Risks: All of the procedures to be used are commonly used with toddlers and preschool children. Therefore, they do not involve activities that would cause discomfort to your child or put your child at any risk. However, if your child should become upset for any reason, the evaluation will be stopped, and rescheduled with your permission.

4. Benefits: You and your child may benefit from involvement in this project in a number of ways. First, we will provide you with information about your child’s social communication and play development. Second, the results of this study will provide information for professionals regarding patterns of early communication development, which will help with the early identification of communication delays in children. This information should lead to earlier and more appropriate services to young children and their families.

5. Confidentiality: All records relating to this project will be handled and safeguarded according to standard clinical policy for all patient records and will remain confidential to the extent allowed by law. Any research reports will carry no identifying information of individual children or families.

6. Refusal/Withdrawal: At any time during your participation in this study, you will have the opportunity to refuse to participate in any procedures or withdraw from the study at any time without prejudice or effect on you and your child. If you would like to remove your child’s records from the research database at any time in the future, call the project at 850-488-5780 to let us know.

7. Risks: We do not expect any unusual risks as a direct result of participation in this project, since all testing procedures are part of standard routine clinical test batteries.

8. Videotaping: You and your child will be videotaped by the clinician during the evaluation session, and if you agree, during a home visit. These videotapes will be kept by project staff in a locked room and will be saved indefinitely. These videotapes will be accessible only to research staff, unless otherwise specified by you. We may ask your permission to use segments of these videotapes for educational purposes; however, this is optional.

I acknowledge that I have read and fully understand the above explanation of the project, all of my questions have been satisfactorily answered, and I give permission for my child to participate in this research project. If I have any questions about my rights as a participant in this research, or if I feel I have been placed at risk, I can contact the chair of the human subjects committee, institutional review board, through the vice president for the office of research at (850) 644-8633.

Signature of Parent

Date

FDU Human Subjects Committee Approved on 9/14/2011 Void After 9/12/2012 HSC # 2011.6960
AGREEMENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY

Project Title: FIRST WORDS Project: Early Identification of Speech, Language, Communication, and Autism Spectrum Disorders

Principal Investigator: Amy M. Wetherby, Ph.D., CCC-SLP

Your child is being asked to participate in a follow-up research project as described in this form below. All such research projects carried out at the University are governed by the rules of both the federal government and Florida State University. These rules require that you give your signed agreement for your child to participate in this project.

The research staff who will evaluate your child will explain to you, in detail, the purpose of the project, the procedures to be used, and the potential benefits and possible risks of participation. You may ask any questions you have to help you understand the project. A basic explanation of the project is written below. Please read this explanation and discuss with the research staff any questions you might have.

If you then decide that your child may participate in the project, please sign this form in the presence of the person who explained the project to you. You will be given a copy of this form to keep.

1. Nature and Purpose of the Project. The purpose of this study is to determine if communication disorders can be identified in very young children who demonstrate delays in early communication development. Being late in talking is often the first symptom evident to parents and professionals of children with communication disorders. Because children usually begin acquiring words between 12 and 18 months of age, a child may not be referred for a language delay until at least 20 to 24 months, and more typically, after 30 months. This longitudinal study of communication development in infants and toddlers will provide information on the predictive value of our checklist and early measures of social communication and play development in relation to performance on follow-up evaluations until 3 years of age. We hope that this research project will help to develop better tools to guide referrals of children at risk for speech, language, communication, autism spectrum, and other developmental disorders at earlier ages. This project will also help estimate the percentage of children born in the panhandle of Florida who have communication disorders. Early identification may lead to earlier treatment and support for children and families, which would have a positive effect on a child’s development.

2. Explanation of Procedures: You and your child will be asked to participate in a number of procedures as part of this project. We will be giving you questionnaires to complete to provide information about your child’s development and experience. Your child will participate in an evaluation lasting approximately 60-90 minutes scheduled on one or two days. Activities during the session include standard assessment procedures for young children to measure social communication, language, nonverbal cognitive and emergent literacy skills. This involves the presentation of toys and interesting materials to encourage the child to communicate and will require your child to follow instructions, repeat sounds and words, name pictures, rhyme, and answer questions. We will ask your permission to videotape the evaluation session to help us
score behavior accurately. We will give you a summary of the results of this evaluation. If your child shows any red flags of autism spectrum disorders, we will invite you for a diagnostic evaluation to identify or rule-out autism spectrum. We may also ask your permission to send a videographer to your home to videotape you interacting with your child during everyday routines for about an hour. This will allow us to see how your child communicates and interacts at home compared to our clinical setting. We may ask you to return to for a follow-up evaluation in 6 to 12 months in order to follow the development of your child. However, the diagnostic evaluation for autism, home videotape, and follow-up evaluation are optional, and you can decide to refuse at a later time. We will save the videotape of the evaluation session and the home visit so we can continue to study precise measures of social communication and play of your child over the course of this longitudinal project. Because this study is exploratory in nature, research staff may review your child’s videotape at a later time to rate more precise measures of social communication and play. Your child’s scores on questionnaires, standardized tests, and ratings of the videotape will become part of the FIRST WORDS Project database and may be used to study early indicators of typical development and communication delays in relation to developmental outcomes.

3. Discomforts and Risks: All of the procedures to be used are commonly used with toddlers and preschool children. Therefore, they do not involve activities that would cause discomfort to your child or put your child at any risk. However, if your child should become upset for any reason, the evaluation will be stopped, and rescheduled with your permission.

4. Benefits: You and your child may benefit from involvement in this project in a number of ways. First, we will provide you with information about your child’s social communication and play development. Second, the results of this study will provide information for professionals regarding patterns of early communication development, which will help with the early identification of communication delays in children. This information should lead to earlier and more appropriate services to your child and their families.

5. Confidentiality: All records relating to this project will be handled and safeguarded according to standard clinical policy for all patient records and will remain confidential to the extent allowed by law. Any research reports will carry no identifying information of individual children or families.

6. Refusal/Withdrawal: At any time during your participation in this study, you will have the opportunity to refuse to participate in any procedures or withdraw from the study at any time without prejudice or effect on you and your child. If you would like to remove your child’s records from the research database at any time in the future, call the project at 860-480-6780 to let us know.

7. Risks: We do not expect any unusual risks as a direct result of participation in this project, since all testing procedures are part of standard routine clinical test batteries.

8. Videotaping: You and your child will be videotaped by the clinician during the evaluation session, and if you agree, during a home visit. These videotapes will be kept by project staff in a locked room and will be saved indefinitely. These videotapes will be accessible only to research staff, unless otherwise specified by you. We may ask your permission to use segments of these videotapes for educational purposes; however, this is optional.

I acknowledge that I have read and fully understand the above explanation of the project, all of my questions have been satisfactorily answered, and I give permission for my child to participate in this research project. If I have any questions about my rights as a participant in this research, or if I feel I have been placed at risk, I can contact the chair of the human subjects committee, institutional review board, through the vice president for the office of research at (860) 644-8633.

Signature of Parent
Date

FSLU Human Subjects Committee Approved on 9/14/2011 Yield After 9/1/2012 HSC # 2011-6960
AGREEMENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY

Project Title: FIRST WORDS Project: Early Identification of Speech, Language, Communication, and Autism Spectrum Disorders

Principal Investigator: Amy M. Webertey, Ph.D., CCC-SLP

Your child is being asked to participate in a follow-up research project as described in this form below. All such research projects carried out at the University are governed by the rules of both the federal government and Florida State University. These rules require that you give your signed agreement for your child to participate in this project.

The research staff who will evaluate your child will explain to you, in detail, the purpose of the project, the procedures to be used, and the potential benefits and possible risks of participation. You may ask any questions you have to help you understand the project. A basic explanation of the project is written below. Please read this explanation and discuss with the research staff any questions you might have.

If you then decide that your child may participate in the project, please sign this form in the presence of the person who explained the project to you. You will be given a copy of this form to keep.

1. Nature and Purpose of the Project: The purpose of this study is to determine if communication disorders can be identified in very young children who demonstrate delays in early communication development. Being late in talking is often the first symptom evident to parents and professionals of children with communication disorders. Because children usually begin acquiring words between 12 and 18 months of age, a child may not be referred for a language delay until at best 20 to 24 months, but more typically, after 30 months. This longitudinal study of communication development in infants and toddlers will provide information on the predictive value of our checklist and early measures of social communication and play development in relation to performance on follow-up evaluations until 5 years of age. We hope that this research project will help to develop better tools to guide referrals of children at risk for speech, language, communication, autism spectrum, and other developmental disorders at earlier ages. This project will also help estimate the percentage of children born in the Panhandle of Florida who have communication disorders. Early identification may lead to earlier treatment and support for children and families, which would have a positive effect on a child’s development.

2. Explanation of Procedures: You and your child will be asked to participate in a number of procedures as part of this project. We will be giving you questionnaires to complete to provide information about your child’s development and experience. Your child will participate in an evaluation lasting approximately 60-90 minutes scheduled on one or two days. Activities during the session include standard assessment procedures for young children to measure social communication, language, nonverbal cognitive and emergent literacy skills. This involves the presentation of toys and interesting materials to encourage our child to communicate and will require your child to follow instructions, repeat sounds and words, name pictures, rhyme, and answer questions. We will ask your permission to videotape the evaluation session to help us

1940 N. Monroe Street, Suite 72, Tallahassee, Florida 32303
FSU Human Subjects Committee Approved 12/16/2015
Telephone (850) 599-5740 Fax (850) 644-3611
score behavior accurately. We will give you a summary of the results of this evaluation.

We will also be completing a standardized diagnostic measure to identify or rule-out autism spectrum disorder which lasts about an hour. We will ask your permission to send a videographer to your home to videotape you interacting with your child during everyday routines for about an hour. This will allow us to see how your child communicates and interacts at home compared to our clinical setting. The home observation is optional. We may ask you to return to for a follow-up evaluation in 6 to 12 months in order to follow the development of your child. The follow-up evaluation is optional, and you can decide to refuse at a later time. We will save the videotape of this evaluation session and the home visit so we can continue to study precise measures of social communication and play of your child over the course of this longitudinal project. Because this study is exploratory in nature, research staff may review your child’s videotape at a later time to rate more precise measures of social communication and play. Your child’s scores on questionnaires, standardized tests, and ratings of the videotape will become part of the FIRST WORDS Project database and may be used to study early indicators of typical development and communication delays in relation to developmental outcomes. If you choose to participate in the diagnostic evaluation for autism, information obtained about your child as part of this study will be shared with the National Institutes of Health National Database for Autism Research (NIMH NDAR). The information will include standardized test scores, observation ratings, and information provided on questionnaires. The information will be available for researchers to use in research about autism and other social communication disorders to answer questions about etiology, diagnosis, development, and response to treatment. All personal details identifying you or your child will be removed before information becomes a part of this database. No video recordings will be provided to you if you do not want your or your child’s research information to be used in this way, you should not participate in the diagnostic evaluation for autism.

3. Discomforts and Risks: All of the procedures to be used are commonly used with toddlers and preschool children. Therefore, they do not involve activities that would cause discomfort to your child or put your child at any risk. However, if your child should become upset for any reason, the evaluation will be stopped, and rescheduled with your permission.

4. Benefits: You and your child may benefit from involvement in this project in a number of ways. First, we will provide you with information about your child’s social communication and play development. Second, the results of this study will provide information for professionals regarding patterns of early communication development, which will help with the early identification of communication delays in children. This information should lead to earlier and more appropriate services to young children and their families.

5. Confidentiality: All records relating to this project will be handled and safeguarded according to standard clinical policy for all patient records and will remain confidential to the extent allowed by law. Any research reports will carry no identifying information of individual children or families.

6. Refusal/Withdrawal: At any time during your participation in this study, you will have the opportunity to refuse to participate in any procedures or withdraw from the study at any time without prejudice or effect on you and your child. If you would like to remove your child’s records from the research database at any time in the future, call the project at 850-488-5780 to let us know.

7. Risks: We do not expect any unusual risks as a direct result of participation in this project, since all testing procedures are part of standard routine clinical test batteries.

8. Videotaping: You and your child will be videotaped by the clinician during the evaluation session, and if you agree, during a home visit. These videotapes will be kept by project staff in a
locked room and will be saved indefinitely. These videotapes will be accessible only to research staff, unless otherwise specified by you. We may ask your permission to use segments of these videotapes for educational purposes; however, this is optional.

I acknowledge that I have read and fully understand the above explanation of the project, all of my questions have been satisfactorily answered, and I give permission for my child to participate in this research project. If I have any questions about my rights as a participant in this research, or if I feel I have been placed at risk, I can contact the chair of the human subjects committee, institutional review board, through the vice president for the office of research at (850) 644-8633.

______________________________
Signature of Parent

______________________________
Date
AGREEMENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY

Project Title: FIRST WORDS Project: Early Identification of Speech, Language, Communication, and Autism Spectrum Disorders

Principal Investigator: Amy M. Wetherby, Ph.D., CCC-SLP

Your child is being asked to participate in a follow-up research project as described in this form below. All such research projects carried out at the University are governed by the rules of both the federal government and Florida State University. These rules require that you give your signed agreement for your child to participate in this project.

The research staff who will evaluate your child will explain to you, in detail, the purpose of the project, the procedures to be used, and the potential benefits and possible risks of participation. You may ask any questions you have to help you understand the project. A basic explanation of the project is written below. Please read this explanation and discuss with the research staff any questions you might have.

If you then decide that your child may participate in the project, please sign this form in the presence of the person who explained the project to you. You will be given a copy of this form to keep.

1. Nature and Purpose of the Project: The purpose of this study is to determine if communication disorders can be identified in very young children who demonstrate delays in early communication development. Being late in talking is often the first symptom evident to parents and professionals of children with communication disorders. Because children usually begin acquiring words between 12 and 18 months of age, a child may not be referred for a language delay until at best 20 to 24 months, but more typically, after 30 months. This longitudinal study of communication development in infants and toddlers will provide information on the predictive value of our checklist and early measures of social communication and play development in relation to performance on follow-up evaluations until 5 years of age. We hope that this research project will help to develop better tools to guide referrals of children at risk for speech, language, communication, autism spectrum, and other developmental disorders at earlier ages. This project will also help estimate the percentage of children born in the panhandle of Florida who have communication disorders. Early identification may lead to earlier treatment and support for children and families, which would have a positive effect on a child’s development.

2. Explanation of Procedures: You and your child will be asked to participate in a number of procedures as part of this project. We will be giving you questionnaires to complete to provide information about your child’s development and experience. Your child will participate in an evaluation lasting approximately 60-90 minutes scheduled on one or two days. Activities during the session include standard assessment procedures for young children to measure social communication, language, nonverbal cognitive and emergent literacy skills. This involves the presentation of toys and interesting materials to encourage our child to communicate and we will require your child to follow instructions, repeat sounds and words, name pictures, rhyme, and answer questions. We will ask your permission to videotape the evaluation session to help us
score behavior accurately. We will give you a summary of the results of this evaluation.

We will also be completing a standardized diagnostic measure to identify or rule out autism spectrum disorder which lasts about an hour. We will ask your permission to send a videographer to your home to videotape you interacting with your child during everyday routines for about an hour. This will allow us to see how your child communicates and interacts at home compared to our clinical setting. The home observation is optional. We may ask you to return for a follow up evaluation in 6 to 12 months in order to follow the development of your child. The follow-up evaluation is optional, and you can decide to refuse at a later time. We will save the videotape of this evaluation session and the home visit so we can continue to study precise measures of social communication and play of your child over the course of this longitudinal project. Because this study is exploratory in nature, research staff may review your child’s videotape at a later time to rate more precise measures of social communication and play. Your child’s scores on questionnaires, standardized tests, and ratings of the videotape will become part of the FIRST WORDS Project database and may be used to study early indicators of typical development and communication delays in relation to developmental outcomes. If you choose to participate in the diagnostic evaluation for autism, information obtained about your child as part of this study will be shared with the National Institutes of Health National Database for Autism Research (NIH NDAR). The information will include standardized test scores, observation ratings, and information provided on questionnaires. The information will be available for researchers to use in research about autism and other social communication disorders to answer questions about etiology, diagnosis, development, and response to treatment. All personal details identifying you or your child will be removed before information becomes a part of this database. No video records will be provided to NDAR. If you do not want your child’s research information to be used in this way, you should not participate in the diagnostic evaluation for autism.

3. Discomforts and Risks: All of the procedures to be used are commonly used with toddlers and preschool children. Therefore, they do not involve activities that would cause discomfort to your child or put your child at any risk. However, if your child should become upset for any reason, the evaluation will be stopped and rescheduled with your permission.

4. Benefits: You and your child may benefit from involvement in this project in a number of ways. First, we will provide you with information about your child’s social communication and play development. Second, the results of this study will provide information for professionals regarding patterns of early communication development, which will help with the early identification of communication delays in children. This information should lead to earlier and more appropriate services to young children and their families.

5. Confidentiality: All records relating to this project will be handled and safeguarded according to standard clinical policy for all patient records and will remain confidential to the extent allowed by law. Any research reports will carry no identifying information of individual children or families.

6. Refusal/Withdrawal: At any time during your participation in this study, you will have the opportunity to refuse to participate in any procedures or withdraw from the study at any time without prejudice or effect on you and your child. If you would like to remove your child’s records from the research database at any time in the future, call the project at 850-486-5780 to let us know.

7. Risks: We do not expect any unusual risks as a direct result of participation in this project, since all testing procedures are part of standard routine clinical test batteries.

8. Videotaping: You and your child will be videotaped by the clinician during the evaluation session, and if you agree, during a home visit. These videotapes will be kept by project staff in a

Page 2
FSU Human Subjects Committee Approved on 5/14/2011 Void After 5/12/2012 HSC # 2011.663
locked room and will be saved indefinitely. These videotapes will be accessible only to research staff, unless otherwise specified by you. We may ask your permission to use segments of these videotapes for educational purposes; however, this is optional.

I acknowledge that I have read and fully understand the above explanation of the project, all of my questions have been satisfactorily answered, and I give permission for my child to participate in this research project. If I have any questions about my rights as a participant in this research, or if I feel I have been placed at risk, I can contact the chair of the human subjects committee, institutional review board, through the vice president for the office of research at (550) 644-6633.

____________________________________  ______________________
Signature of Parent                    Date
To: Dr. Catherine Lord

From:
Michael Geisser
John Weg

Cc:
Catherine Lord
Sheri Lindsay
Danette Morrison
Susan Risi
Alayna Schreier
Julie McCormick

Subject: Scheduled Continuing Review [CR00018891] Approved for [HUM00041234]

SUBMISSION INFORMATION:
Study Title: FIRST WORDS Project: Early Indicators of Autism Spectrum Disorders in the Second and Third Years of Life - IRBMED#2003-0739
Full Study Title (if applicable): FIRST WORDS Project: Early Indicators of Autism Spectrum Disorders in the Second and Third Years of Life
Study eResearch ID: HUM00041234
SCR eResearch ID: CR00018891
SCR Title: HUM00041234_Continuing Review - Mon Dec 6 13:33:08 EST 2010
Date of this Notification from IRB: 1/19/2011
Date Approval for this SCR: 1/13/2011
Expiration Date: Approval for this expires at 11:59 p.m. on 1/12/2012
UM Federalwide Assurance: FWA00004969 expiring on 11/17/2011
OHRP IRB Registration Number(s): IRB000062-44

Approved Risk Level(s) as of this Continuing Report:
Name          Risk Level
HUM00091234   No more than minimal risk

NOTICE OF IRB APPROVAL AND CONDITIONS:
The IRBMED has reviewed and approved the scheduled continuing review (SCR) submitted for the study referenced above. The IRB determined that the proposed research continues to conform with applicable guidelines, State and federal regulations, and the University of Michigan's Federalwide Assurance (FWA) with the Department of Health and Human Services (DHHS). You must conduct this study in accordance with the description and information provided in the approved application and associated documents.

APPROVAL PERIOD AND EXPIRATION DATE:
The updated approval period for this study is listed above. Please note the expiration date. If the approval lapses, you may not conduct work on this study until appropriate approval has been re-established, except as necessary to eliminate apparent immediate hazards to research subjects or others. Should the latter occur, you must notify the IRB Office as soon as possible.

IMPORTANT REMINDERS AND ADDITIONAL INFORMATION FOR INVESTIGATORS

APPROVED STUDY DOCUMENTS:
You must use any date-stamped versions of recruitment materials and informed consent documents available in the eResearch workspace (referenced above). Date-stamped materials are available in the "Currently Approved Documents" section on the "Documents" tab.

In accordance with 45 CFR 46.111 and IRB practice, consent document(s) and process are considered as part of Continuing Review to ensure accuracy and completeness. The dates on the consent documents, if applicable, have been updated to reflect the date of Continuing Review approval.

RENEWAL/TERMINATION:
At least two months prior to the expiration date, you should submit a continuing review application either to renew or terminate the study. Failure to allow sufficient time for IRB review may result in a lapse of approval that may also affect any funding associated with the study.

AMENDMENTS:
All proposed changes to the study (e.g., personnel, procedures, or documents), must be approved in advance by the IRB through the amendment process, except as necessary to eliminate apparent immediate hazards to research subjects or others. Should the latter occur, you must notify the IRB Office as soon as possible.

AEs/ORIOs:
You must continue to inform the IRB of all unanticipated events, adverse events (AEs), and other reportable information and occurrences (ORIOs). These include but are not limited to events and/or information that may have physical, psychological, social, legal, or economic impact on the research subjects or others.

Investigators and research staff are responsible for reporting information concerning the approved research to the
IRB in a timely fashion, understanding and adhering to the reporting guidance
(http://sso.med.umich.edu/hp/enrollment/index.htm), and not implementing any changes to the research
without IRB approval of the change via an amendment submission. When changes are necessary to eliminate
apparent immediate hazards to the subject, implement the change and report via an ORIO and/or amendment
submission within 7 days after the action is taken. This includes all information with the potential to impact the
risk or benefit assessments of the research.

SUBMITTING VIA eRESEARCH:
You can access the online forms for continuing review, amendments, and A/B/IRIO reporting in the eResearch
workspace for this approved study, referenced above.

MORE INFORMATION:
You can find additional information about UM’s Human Research Protection Program (HRPP) in the Operations

Michael Geisser  
Co-chair, IRB MED

John Weg  
Co-chair, IRB MED
UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

INFORMATION ABOUT THIS FORM

You and your child may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of the study, and the risks and possible benefits of participating in the study. Parents or legal guardians who are giving permission for a child, please note: in the sections that follow the word ‘you’ refers to ‘you and your child.’

Please take time to review this information carefully. After you have finished, you should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or other doctors) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.

1. GENERAL INFORMATION ABOUT THIS STUDY AND THE RESEARCHERS

1.1 Study title: FIRST WORDS Project: Early Indicators of Autism Spectrum Disorders

1.2 Company or agency sponsoring the study: National Institute of Child Health and Human Development (NICHD)

1.3 Names, degrees, and affiliations of the researchers conducting the study:
Catherine Lord, Ph.D.
Director, University of Michigan Autism and Communication Disorders Center
Professor of Psychology and Psychiatry

Amy Wetherby, Ph.D., CCC-SLP
Director, FIRST WORDS Project
Professor of Communication Disorders
Florida State University

2. PURPOSE OF THIS STUDY

2.1 Study purpose: The University of Michigan Autism and Communication Disorders Center (UMACC) seeks to provide diagnostic and treatment services, and to advance understanding of autism spectrum disorders. The purpose of this study is to collect information on young children who are developing typically, young children with an autism spectrum disorder and young children with communication or social delays. By comparing information from different groups we will better understand how to reliably identify early indicators of autism spectrum disorders. With this study, we hope to improve identification of autism spectrum disorders in very young children and enable children and families to access intervention earlier.
3. INFORMATION ABOUT STUDY PARTICIPANTS (SUBJECTS)

Taking part in this study is completely voluntary. You do not have to participate if you don’t want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study? Children between 12 and 24 months of age and their parent(s) may participate.

3.2 How many people (subjects) are expected to take part in this study? We expect to include 600 young children and their parents in this study.

4. INFORMATION ABOUT STUDY PROCEDURES

4.1 What will happen to me in this study?
You will complete questionnaires and interviews about your child’s development. Your child will complete tests that assess verbal and nonverbal skills as well as a play observation to assess communication and social skills and to determine if your child may have an autism spectrum disorder. If your child is between 18 and 24 months of age when you enter the study, you will participate in an evaluation that will be scheduled on two separate days. We will also ask to come to your home to videotape you and your child interacting for one hour. You will be asked to do specific activities with your child such as play with toys or have a snack.

If your child is between 12 and 18 months of age when you enter the study, you and your child will participate in an evaluation that is scheduled on one day. When your child reaches 18 to 24 months of age, you will be asked to complete the longer assessment that is scheduled on two days and the in-home videotaping described in the paragraph above.

Some of the tests completed during the evaluation will be videotaped so that the clinician and another person can verify the assessment of your child’s skills. You will be present during all testing with your child.

If you choose to participate, information obtained as part of your participation in this study will be put into the UMACC Data Bank (IRB# FD HUM 894). Your information will also be shared with the National Institutes of Health National Database for Autism Research (NIH NDAR). The information will include standardized test scores, observation ratings, and information provided on questionnaires. The information will be available for researchers to use in research about autism and other social-communication disorders to answer questions about etiology, diagnosis, development, and response to treatment. All personal details identifying you or your child will be removed before information becomes a part of either database. No video records will be provided to NDAR. If you do not want you or your child’s research information to be used in this way, you should not participate in the diagnostic evaluation for autism.

4.2 How much of my time will be needed to take part in this study?
The entire assessment requires about 5 hours. You will complete the parent portion on one day and the child portion on another day. Children entering the study between the ages of 12 and 18 months require an additional 2 hour assessment and return for the full assessment and in-home taping between the age of 18 to 24 months. The videotaping of you and your child interacting in your home will last one hour and will occur within a week of the full assessment.
4.3 When will my participation in the study be over?
Your participation will end once the full assessment and videotaping are completed.

5. INFORMATION ABOUT RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?
Because the child assessment portion of this study takes about 2 hours, there is a risk that your child will become bored or tired. This amount of time is typical for an assessment with a young child. We minimize this risk by allowing breaks and snacks. About half of the assessment is play-based involving toys and fun activities that are not test-like or school-related.

There are unavoidable risks to children during play activities. Children may trip and fall. Care will be taken during all activities to avoid these types of situations.

You may experience feelings of disappointment if study results indicate that your child is not developing like other children his/her age or if he/she meets criteria for a diagnosis of an autism spectrum disorder or other developmental disability. If this occurs, you may contact your assessment clinician, the study Coordinator, or Principal Investigator for assistance. Contact information for the Study Coordinator and Principal Investigator is listed at the end of this document. You will receive the contact information for your clinician at your assessment.

Since this study involves personal information, there is the risk of breach of confidentiality. To minimize this risk, we will use identification codes on all research records; no names or other personal identifying information about you or your child will be included. The videotape made during assessment will be included in the UMACC research database, but will not include names. The University of Michigan Autism and Communication Disorders Center is working collaboratively with Florida State University-Department of Communication Disorders on this project; thus we share data collected from this project. UMACC is also a member of the Collaborative Programs in Excellence in Autism (CPEA). UMACC shares research information with colleagues at other research centers.

As with any research study, there may be additional risks that are unknown or unexpected.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?
The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study.

5.3 If I take part in this study, can I also participate in other studies?
Yes. You may participate in other research studies or any services or programs you choose for you and your child in the community.

5.4 How could I benefit if I take part in this study? How could others benefit?
You or your child may not receive any personal benefits from being in this study. However, we will provide you with a written summary of all test results. We believe findings from this research will contribute to better and more accurate identification of individuals with autism spectrum disorders and thereby help individuals with autism and their families.
5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?
Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. OTHER OPTIONS

6.1 If I decide not to take part in this study, what other options do I have?
Your access to services here at UM ACC or the University of Michigan Health System for yourself and/or your child will not be affected if you do not participate in this study.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?
You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please notify one of the persons listed in Section 10 “Contact Information” (below).

7.2 Could there be any harm to me if I decide to leave the study before it is finished?
There is no foreseeable harm if you decide to leave this study before it is finished.

7.3 Could the researchers take me out of the study even if I want to continue to participate?
Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

✓ The researcher believes that it is not in your best interest to stay in the study.
✓ You become ineligible to participate.
✓ Your condition changes and you need treatment that prevents you from taking part in the study.
✓ The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Will taking part in this study cost me anything? Will I or my insurance company be billed for any costs of the study? There is no cost for participation in this study. By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?
Yes. You will receive a $22 gift card to a selection of stores for completing the full assessment when your child is between 18 and 24 months old and another $25 gift card for completing the in-home videotaping. These gift cards are meant to compensate for the time involved in participating in the study.
8.3 Who could profit or financially benefit from the study results?

The researchers conducting the study, Dr. Catherine Lord and Dr. Amy Wetherby, along with the other authors of some of the instruments used in the assessment, receive 1 to 5% of the profit in royalties from the distribution of these instruments when they are used at other institutions; profits from the use of the instruments at UMACC or FSU are donated to charity.

9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how your privacy and the confidentiality of your research records will be protected in this study.

9.1 How will the researchers protect my privacy?

We will keep your research record confidential, to the extent provided by federal, state and local law. All information collected about you and your child will be maintained in a manner specified by professional ethics and codes. Written records will be kept in locked cabinets in locked offices at our Center. All information maintained in an electronic database will use identification codes (i.e., no names). We will not allow anyone to see your record, other than people who have a right to see it. Any research reports will carry no identifying information of individual children, parents or families.

In general, we will not disclose any information about you or your child without your written permission. However, there are some exceptions to sharing your information as required by law. We will disclose your information if it is necessary to protect your rights or welfare, for example if you are injured or need emergency care. We will disclose your information if a researcher becomes aware that you may be a danger to yourself or to others. We will disclose your information if a researcher becomes aware that acts of child, elder, or dependent adult abuse or neglect may have occurred.

9.2 What information about me could be seen by the researchers or by other people? Why? Who might see it?

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study. Information about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- Hospital doctor’s office records, including test results (X-rays, blood tests, urine tests, etc.)
- Mental health care records (except psychotherapy notes not kept with your medical records)
- All records relating to your diagnosis, the treatment you have received, and your response to the treatment

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- University, Food and Drug Administration (FDA), and/or other government officials may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to make sure the study is done safely and properly and/or to analyze the results of the study.
• The researchers may need to use the information to create a databank of information about your condition or its treatment.
• If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, social security number, payment amount, and related information for tax reporting purposes.
• Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study may be published or presented at a scientific meeting. If your name and pictures will be used in any publications or presentations, the researchers will ask for your separate written permission.

9.3 What happens to information about me after the study is over or if I cancel my permission?
As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over. Examples of reasons for this include:

• To avoid losing study results that have already included your information
• To provide limited information for research, education, or other activities (This information would not include your name, social security number, or anything else that could let others know who you are.)
• To help University and government officials make sure that the study was conducted properly

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System’s privacy policies. For more information about these policies, ask for a copy of the University of Michigan Notice Of Privacy Practices. This information is also available on the web at http://www.med.umich.edu/hipaa/index.htm. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

9.4 When does my permission expire?
Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 “Contact Information” (below).

10. CONTACT INFORMATION

10.1 Who can I contact about this study?
Please contact the researchers listed below to:
• Obtain more information about the study
• Ask a question about the study procedures or treatments
• Report an illness, injury, or other problem (you may also need to tell your regular doctors)
• Leave the study before it is finished
• Express a concern about the study
  Principal Investigator: Catherine Lord, Ph.D.
  Mailine Address: 1111 E. Catherine St., Ann Arbor, MI 48109

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Study Coordinator: Danette Morrison
Mailing Address: 1111 E. Catherine St., Ann Arbor, MI 48109
Telephone: (734) 936-8600

You may also express a concern about a study by contacting the Institutional Review Board listed below, or by calling the University of Michigan Compliance Help Line at 1-888-296-2481.

University of Michigan Medical School Institutional Review Board (IRB MED)
2800 Plymouth Rd., Building 200, Room 2086,
Ann Arbor, MI 48109-2300

Telephone: 734-615-4768
Fax: 734-615-1622
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy, contact the University of Michigan Health System Privacy Officer at 1-888-296-2481.

When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRB MED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

Your signature in the next section means that you have received copies of all of the following documents:

☐ This "Consent to be Part of a Research Study" document. (Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.)

☐ Other (specify): UMACC DATA BANK FACT SHEET
12. SIGNATURES

Research Subject:

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with __________________________. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Legal Representative (if applicable):

Signature of Person Legally Authorized to Give Consent __________________________ Date: __________________________

Name (Print legal name): ________________ Phone: __________________________

Address: ______________________________________________________________________

Check Relationship to Subject: ☐Parent ☐Spouse ☐Child ☐Sibling ☐Legal Guardian ☐Other: __________________________

*If this consent is for a child who is a ward of the state (for example, a foster child), please tell the study team immediately. The researcher may need to contact the JREMED.*

Principal Investigator (or Designee):

I have given this research subject (or his/her legally authorized representative, if applicable) information about this study that I believe is accurate and complete. The subject has indicated that he or she understands the nature of the study and the risks and benefits of participating.

Name: ________________ Title: ________________

Signature: ________________ Date of Signature: __________________________
Protection of Human Subjects

Assurance Identification/IRB Certification/Declaration of Exemption
(Common Rule)

Policy: Research activities involving human subjects may not be conducted or supported by the Departments and Agencies adopting the Common Rule (55 FR 28003, June 18, 1991) unless the activities are exempt, formalized, or approved in accordance with the Common Rule. See section 101(a) of the Common Rule for exemptions. Institutions submitting applications as proposals for support must submit certification of appropriate Institutional Review Board (IRB) review and approval to the Department or Agency in accordance with the Common Rule.

1. Request Type
   [x] ORIGINAL
   [] CONTINUATION
   [] EXEMPTION
   [] OTHER:

2. Type of Mechanism
   [x] GRANT
   [] CONTRACT
   [] FELLOWSHIP
   [] COOPERATIVE AGREEMENT
   [] OTHER:

3. Name of Federal Department or Agency and, if known, Application or Proposal Identification No.
   1R01 HD 065272

4. Title of Application or Activity
   Improving and Streamlining Screening and Diagnosis of ASD at 18-24 Months of Age

5. Name of Principal Investigator, Program Director, Fellow, or Other
   Catherine Lord

6. Assurance Status of this Project (Respond to one of the following)
   [x] This Assurance, on file with Department of Health and Human Services, covers this activity:
      Assurance Identification No. FWA00000093, the expiration date 4-20-2014 IRB Registration No. 0000617

   [] This Assurance, on file with (agency/dept) covers this activity:
      Assurance No. , the expiration date .

   [] No assurance has been filed for this Institution. This institution declares that it will provide an Assurance and Certification of IRB review and approval upon request.

7. Certification of IRB Review (Respond to one of the following IF you have an Assurance on file)
   [x] This activity has been reviewed and approved by the IRB in accordance with the Common Rule and any other governing regulations.
      Full IRB Review on (date of IRB meeting) 11/28/2011 or Expedited Review on
      If less than one year approval, provide expiration date

   [] This activity contains multiple projects, some of which have not been reviewed. The IRB has granted approval on condition that all projects covered by the Common Rule will be reviewed and approved before they are initiated and that appropriate further certification will be submitted.

8. Comments

   Weill Cornell Medical College
   1300 York Avenue
   New York, NY 10065

   Rosemary Kraemer
   Director, Human Research Protections Program

9. The official signing below certifies that the information provided above is correct and that, as required, future reviews will be performed until study closure and certification will be provided.

   10. Name and Address of Institution

   11. Phone No. (with area code) 646-628-8196

   12. Fax No. (with area code) 646-628-0533

   13. Email: rtkraemer@med.cornell.edu

   14. Name of Official

   15. Title

   16. Signature

   17. Date: 12/10/2011

Public reporting burden for this collection of information is estimated to average less than an hour per response. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: OMB Reports Clearance Officer, Room 503, 1400 Independence Avenue, SW, Washington, DC 20503. Do not return the completed form to this address.
INTRODUCTION
You are invited to consider participating in a research study. The study is called the First Words Project. You were selected as a possible participant in this study because you have indicated an interest in having your child participate in an assessment that may identify a possible autism spectrum disorder.

Please take your time to make your decision. It is important that you read and understand several general principles that apply to all who take part in our studies:

) Taking part in the study is entirely voluntary.

) Personal benefit to you may or may not result from taking part in the study, but knowledge gained from your participation may benefit others;

) You may decide not to participate in the study or you may decide to stop participating in the study at any time without loss of any benefits to which you are entitled.

The purpose and nature of the study, possible benefits, risks, and discomforts, other options, your rights as a participant, and other information about the study are discussed below. Any new information discovered which might affect your decision to participate or remain in the study will be provided to you. You are urged to ask any questions you have about this study with members of the research team. You should take whatever time you need to discuss the study with your physician and family. The decision to participate or not to participate is yours. If you decide to participate, please sign and date where indicated at the end of this form.

The research is being sponsored by the National Institute of Child Health and Human Development (NICHD). NICHD is called the Sponsor and Weill Cornell Medical College ("WCMC") is being paid by NICHD to conduct this study. Dr. Catherine Lord is the primary investigator.
The study will take place at Weill Cornell Medical College. Some portions of the study may take place at facilities of New York Presbyterian Hospital, where the investigators are members of the medical staff. New York Presbyterian Hospital is neither a sponsor nor an investigator for this study.

**WHY IS THE STUDY BEING DONE?**

The FIRST WORDS research project represents a collaborative effort between the Weill Cornell Medical College (WCMC) and the Florida State University (FSU) Department of Communication Disorders. The goal of this research study is to identify tools that will improve the screening and referral processes of very young children with communication delays or autism spectrum disorders. To achieve this goal, we are collecting information on young children who are developing typically, young children with an autism spectrum disorder, and young children with communication or social delays.

**HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?**

Participants in the study are referred to as subjects.

About 600 subjects will take part in this study nationwide; about 100 subjects will be recruited at this site.

**WHAT IS INVOLVED IN THE STUDY?**

You will complete questionnaires and interviews about your child’s development. Your child will complete tests that assess verbal and nonverbal skills as well as a play observation to assess communication and social skills and to determine if your child may have an autism spectrum disorder. This evaluation is typically scheduled on two separate days. We will also ask you to come to your home to videotape you and your child interacting for one hour. You will be asked to do specific activities with your child such as play with toys or have a snack.

Some of these tests completed during the evaluation will be videotaped so that the clinician and another person can verify the assessment of your child’s skills. You will be present during all testing with your child.

If you choose to participate, information obtained as part of your participation in this study will be put into a data bank at Weill Cornell under the supervision of Dr. Catherine Lord. Your information will also be shared with the National Institutes of Health National Database for Autism Research (NIH NDAR). The information will include standardized test scores, observation ratings, and information provided on questionnaires. The information will be available for researchers to use in research about autism and other social-communication disorders to answer questions about etiology, diagnosis, development, and response to treatment. All personal details identifying you or your child will be removed before information becomes a part of either database. No video records will be provided to NDAR. If you do not want you or your child’s research information to be used in this way, you should not participate in the diagnostic evaluation for autism.
If you take part in this study, you and your child will participate in the following assessments:

### Assessment Battery

<table>
<thead>
<tr>
<th>Item</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>Child Cognitive Assessment</td>
<td>In Clinic</td>
</tr>
<tr>
<td>Autism Diagnostic Measure</td>
<td>In Clinic</td>
</tr>
<tr>
<td>Communication and Behavior Sample</td>
<td>In Clinic</td>
</tr>
<tr>
<td>Parent Interviews</td>
<td>In Clinic</td>
</tr>
<tr>
<td>Parent Questionnaires</td>
<td>At home</td>
</tr>
</tbody>
</table>

### Video Taping

<table>
<thead>
<tr>
<th>Item</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parent taping</td>
<td>In Home</td>
</tr>
</tbody>
</table>

**HOW LONG WILL I BE IN THE STUDY?**

You will be in the study for the amount of time it takes for you and your child to complete the 2-day assessment and in-home videotaping.

You can stop participating at any time. However, if you decide to stop participating in the study, we encourage you to talk to the researcher first.

There is no foreseeable harm if you decide to leave this study before it is finished.

**Withdrawal by investigator, physician, or sponsor**

The investigators, physicians or sponsors may stop the study or take you out of the study at any time should they judge that it is in your best interest to do so, if you experience a study-related injury, if you need additional or different medication, or if you do not comply with the study plan. They may remove you from the study for various other administrative and medical reasons. They can do this without your consent.

**WHAT ARE THE RISKS OF THE STUDY?**

For trials of assessment procedures, there may be risks. These risks will be discussed with you by research staff.

Risks and side effects related to the procedures we are studying include:

*Possible:*

- The assessment will with your child will take about 3 hours so there is a risk that your child may become tired or bored. This amount of time is typical for an assessment with children; we minimize this risk by providing breaks and snacks as needed. We can reschedule if necessary. In addition, about half of the assessment is play-based with toys and/or fun activities that do not resemble a test or school related activities. You will be in the room...
with your child during all testing and can let the clinician know if your child needs a break or if you want to end the session.

- There are unavoidable risks to children and adults during play activities. Children may trip and fall; adults working with them may be hurt by the children or receive accidental injuries. Care will be taken during all assessment activities to avoid these types of situations.

- You may experience feelings of disappointment if study results indicate that your child is not developing like other children his/her age or if he/she meets criteria for a diagnosis of an autism spectrum disorder or other developmental disability. If this occurs, you may contact your assessment clinician, the study coordinator, or Principal Investigator for assistance. You will receive the contact information for your study coordinator, clinician, and Principal Investigator following enrollment in the study.

Rare:

- With the use of personal information there is the risk of a breach in confidentiality. To minimize this risk, all clinical and videotaped records are stored by project staff in a locked room. Identification codes will be used on all research records; no names or other identifying personal information about you or your child will be included.

There may also be side effects, other than listed above that we cannot predict.

For more information about risks and side effects, ask the researcher, Dr. Catherine Lord.

ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?

We cannot and do not guarantee that you will receive any benefits from this study. However, you and your child may benefit from involvement in this project in a few ways. First, we will provide you with a written summary of all the test results following each assessment. This information may be of benefit in planning future school and treatment choices. Second, we will provide you with referrals to service providers in your area. We hope findings for this research will contribute to better and more effective services for young children with autism spectrum disorders and their families.

WHAT OTHER OPTIONS ARE THERE?

Instead of being in this study, you have the option of seeking diagnostic and intervention services in the community. We can provide you with a list of resources in your area if you would like them.

WHAT ABOUT CONFIDENTIALITY?

Efforts will be made to protect your medical records and other personal information to the extent allowed by law. However, we cannot guarantee absolute confidentiality. Records of research study participants are stored and kept according to legal requirements. You will not be identified personally in any reports or publications resulting from this study. Organizations that may request to inspect and/or copy your research and medical records for quality assurance and data analysis include groups such as: Weill Cornell Medical College, the Weill Cornell Institutional Review Board (IRB), all appropriate federal research oversight agencies, and National Institute of Child Health and Human Development (NICHD).
If information about your participation in this study is stored in a computer, we will take the following precautions to protect it from unauthorized disclosure, tampering, or damage: All research information stored in an electronic database will use identification codes (i.e., no names). The database is kept on a computer in a locked room and password protected. We will not allow anyone to see your record, other than people who have the right to see it. Any published research report will carry no identifying information of individual children, parents, or families.

Although we will take many steps to protect your confidential information, there are some exceptions to sharing your information as required by law. We will disclose your information if a researcher becomes aware that you may be a danger to yourself or to others. We will disclose your information if the researcher becomes aware that acts of child, elder, or dependent adult abuse or neglect may have occurred.

WHAT ARE THE COSTS?
You or your insurance company will be charged for continuing medical care and/or hospitalization that are not a part of the study.

POLICY/PROCEDURES FOR RESEARCH RELATED INJURY
The Policy and Procedure for Weill Cornell Medical College are as follows:
In accordance with Federal regulations, we are obligated to inform you about WCMC’s policy in the event injury occurs. If, as a result of your participation, you experience injury from known or unknown risks of the research procedures as described, immediate medical care and treatment, including hospitalization, if necessary, will be available at the usual charge for such treatment. No monetary compensation is available from WCMC or New York Presbyterian Hospital. Further information can be obtained by calling the Institutional Review Board at (646) 962.8200.

COMPENSATION FOR PARTICIPATION
You will compensation for participating in this study. You will receive a $25 gift card for completing the full assessment and another $25 gift card for completing the in-home videotaping. These gift cards are meant to compensate for the time involved in participating in the study.

You should not expect anyone to pay you for pain, worry, lost income, or non-medical care costs that occur from taking part in this research study.

COMMERCIAL INTEREST
This study is paid for by the National Institute of Child Health and Human Development which has no financial interest in its outcome. Payments are made to Weill Cornell Medical College (WCMC) and the funds are used to cover the expenses of the study and related academic and research activities of the institution.

Dr. Catherine Lord was involved in the development of some of the instruments used in this research and receives royalty income from the sale of those instruments. If you have any questions about Dr. Lord’s financial interest in these instruments, please feel free to contact the Weill Cornell Conflicts Management Office at (646) 962-8200.
WHAT ARE MY RIGHTS AS A PARTICIPANT?
Taking part in this study is voluntary. You may choose to not take part in the study or to leave the study at any time. If you choose to not participate in the study or to leave the study, your regular care will not be affected nor will your relations with the Weill Cornell Medical College, your physicians, or other personnel. In addition, you will not lose any of the benefits to which you are entitled.

We will tell you about new information that may affect your health, welfare, or participation in this study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or a research-related injury, any problems, unexpected physical or psychological discomforts, or if you think that something unusual or unexpected is happening, call Dr. Catherine Lord at 914-997-5848 or the Department of Psychiatry. Be sure to inform the physician of your participation in this study.

If you have questions about your rights as a research participant, contact the WCMC IRB Office. Direct your questions to:

Institutional Review Board at:
Address: 407 East 61st Street, RR-110
New York, New York 10065
Telephone: (646) 962-8200
RESEARCHER’S STATEMENT

I have fully explained this study to the subject. As a representative of this study, I have explained the purpose, the procedures, the benefits and risks that are involved in this research study. Any questions that have been raised have been answered to the individual’s satisfaction.

Signature of person obtaining the consent  Print Name of Person  Date / Time

(Principal Investigator or Co-investigator)

SUBJECT’S STATEMENT

I, the undersigned, have been informed about this study’s purpose, procedures, possible benefits and risks, and I have received a copy of this consent. I have been given the opportunity to ask questions before I sign, and I have been told that I can ask other questions at any time. I voluntarily agree to participate in this study. I am free to withdraw from the study at any time without need to justify my decision. This withdrawal will not in any way affect my future treatment or medical management and I will not lose any benefits to which I otherwise am entitled. I agree to cooperate with Dr. Catherine Lord and the research staff and to inform them immediately if I experience any unexpected or unusual symptoms.

Signature of Subject  Print Name of Subject  Date / Time

Signature of Legally Authorized Representative and Relationship to Participant (When Appropriate)  Date / Time
REFERENCES


BIOGRAPHICAL SKETCH

EDUCATION

2009-Present, Florida State University, Tallahassee, Florida
Master of Science, Department of Psychology

- Expected date of completion 2012

2009-Present, Florida State University, Tallahassee, Florida
Clinical Psychology

- Major Area: Clinical Psychology
- Major Professor: Amy M. Wetherby, Ph.D.
- Expected date of completion 2015

2004-2008, Queen’s University, Kingston, Ontario
Honours Bachelors of Arts Degree in Psychology

- Faculty Advisor: Elizabeth Kelley, Ph.D.

RESEARCH PRESENTATIONS


**RESEARCH EXPERIENCE**

**Florida State University, Autism Institute**  
*Research Assistant*  
Advisor: Amy M. Wetherby, Ph.D.

- Research Assistant: Collaborated to design a novel observational coding system “Measure of Parent Transactional Support” to measure change in parent behavior as a result of participation in parent-mediated intervention using Noldus Observer. Responsible for training and supervising 8 undergraduate coders.
- Research Assistant: Collaborated to operationalize behavioral flexibility for an observational coding system “Measure of Active Engagement”. Responsible for training and supervising 2 undergraduate coders.
- Research Assistant: Conduct analyses and provide support for clinical measure of caregiver and child outcomes following a parent mediated intervention “Measure of Active Engagement and Transactional Support”
- Clinician Reviewer: CDC Autism and Developmental Disabilities Monitoring Group- Early Prevalence Subgroup

**Hospital for Sick Children, Autism Research Unit**  
*Clinical Project Research Assistant*  
Supervisors: Dr. Wendy Roberts, MD, FRPC. & Dr. Jessica Brian, Ph.D., C. Psych.

- Conducted diagnostic assessments, data entry and participant recruitment for “Identifying Early Markers in Autism: A longitudinal study of infant siblings”

**Minnes Disability Studies Lab at Queen’s University**  
*Special Directed Lab Course*  
Advisor: Dr. Patricia Minnes, Ph.D., C. Psych.

- Conducted follow up parent interviews for “Factors Contributing to the Successful Transition
of Preschoolers with Intellectual Disability into School”
- Performed data entry, coding and analysis

**ASD Studies at Queen’s University**  
**Honours Student**  
Advisor: Dr. Elizabeth Kelley, Ph.D.
- Administered Mullen Scales of Early Learning, Vineland Adaptive Behavior Scales, Autism Diagnostic Observation Schedule, Peabody Picture Vocabulary Test-IV
- Assisted in data collection and participant recruitment for “Social Cognitive Skills in Young Children with Autism Spectrum Disorders and their Siblings”
- Trained volunteers and lab members on lab procedures, the Mullen Scales of Early Learning and Vineland Adaptive Behaviour Scales

**ASD Studies at Queen’s University**  
**Research Assistant**  
Supervisors: Dr. Elizabeth Kelley, Ph.D. & Dr. Valerie Kuhlemier, Ph.D.
- Assisted in data collection, coding and analysis as well as participant recruitment for “Social Cognitive Skills in Young children with Autism Spectrum Disorders and their Siblings”
- Administered Mullen Scales of Early Learning, Vineland Adaptive Behavior Scales, Autism Diagnostic Observation Schedule (Module 1, 2 and 3)
- Designed and created lab website with Dreamweaver CS [http://psyc.queensu.ca/asdstudies](http://psyc.queensu.ca/asdstudies)
- Designed and created participant database using Microsoft Access.
- Created and implemented visual schedules, social stories and reinforcer surveys to help increase performance and engagement of participants with Autism Spectrum Disorders

**ASD Studies at Queen’s University**  
**Special Directed Lab Course**  
Supervisor: Dr. Elizabeth Kelley, Ph.D.
- Assisted with data collection, entry and analysis for “Social Cognitive Skills in Young children with Autism Spectrum Disorders and their Siblings”

**The Bully Lab at Queen’s University**  
**Research Volunteer**  
Supervisor: Dr. Wendy Craig, Ph.D., C. Psych.
- Assisted with data collection, data entry and analysis

**CLINICAL EXPERIENCE**

**FSU Autism Institute: First Words Project**  
**Clinical Research Diagnostician**  
Supervisors: Dr. Amy M. Wetherby, Ph.D. & Dr. Therese Kemper, Ph.D.
- Providing integrated diagnostic assessments for young children at high risk for Autism
Spectrum Disorder using: Autism Diagnostic Observation Schedule-Toddler, Mullen Scales of Early Learning and Vineland Adaptive Behavior Scales

**Florida State University Psychology Clinic**  
*Psychological Trainee*  
Supervisors: Dr. Jesse Cougle, Ph.D.; Dr. Thomas Joiner, Ph.D.; Dr. Donald Kerr, Ph.D. & Dr. Pamela K. Keel, Ph.D.

- Providing psychotherapy for adult and adolescent clients using empirically supported treatments including: Cognitive Behavior Therapy, Motivational Interviewing and Behavior Activation for Depression

**Center for Addiction and Mental Health & Aspergers Society of Ontario: Children’s Social Skills Group,**  
*Clinical Volunteer*  
Supervisor: Dr. Leon Sloman, MD, FRCP.

- Assisted in the planning and execution of group activities to improve social skills with a group of children with Asperger’s Syndrome (8-12 years)

**Toronto District School Board- Cordella Junior Public School and Seneca School 2006- 2008**  
*Special Needs Assistant*  

- Worked as a member of the school team in Special Education Classes to provide and facilitate curriculum activities
- Utilized behavior management and behavior modification techniques to address difficult behaviors
- Utilized alternative communication methods such as the picture exchange communication system (PECS) and basic sign language

**AWARDS**

- Graduate Research Development Travel Award: 2011
- Queen’s University Dean’s Honour List: 2006-2008
- Ontario Scholar Award: 2004
INVITED PRESENTATIONS


DEPARTMENTAL/UNIVERSITY SERVICE

Interview Weekend Committee 2010

- Florida State University, Psychology Department Clinical Area.