# INTERVENING TO ENHANCE EMOTION REGULATION: EARLY CHILDHOOD ADVERSITY, PARENT-CHILD MUTUAL POSITIVE AFFECT, AND LATER CHILD REGULATION CAPABILITIES

by

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## ABSTRACT

Early experiences of adversity and maltreatment are linked to later difficulties with emotion regulation. This study sought to examine the role of early risk and parent-child mutual positive affect in influencing children's later emotion regulation, as well the effects of a preventative intervention, Attachment and Biobehavioral Catch-up (ABC) on these capabilities. Parent-child dyads referred to Child Protective Services (CPS) due to concerns of maltreatment were randomly assigned to ABC or a control intervention when children were infants, and a follow-up assessments measured parent-child mutual positive affect at 24 months old and child emotion regulation at 8 years old. Risk indices were developed across three domains: child, parent, and instability, and for two developmental periods: 0-24 months old and 8-10 years old. Results showed that parent-child dyads randomly assigned to ABC displayed a significantly higher percentage of mutual positive affect at 24 months old, compared with parent-child dyads assigned to DEF, controlling for risk. At the 8year-old follow-up, no significant intervention effects were found for child emotion regulation. However, early parent-child mutual positive affect at 24 months old was linked to later child positive emotion regulation at 8 years old, controlling for early and concurrent risk. In addition, early parent risk at 24 months old was found to play a significant role in predicting later child emotion lability/negativity at 8 years old,

controlling for concurrent parent risk. These findings highlight the importance of early parent risk and parent-child mutual positive affect for the development of later emotion regulation skills, and the role that early intervention can play in enhancing early parent-child mutual positive affect.

## Chapter 1

## **INTRODUCTION**

Child exposure to early adversity is linked to a range of developmental problems, particularly difficulties with emotion regulation (Thompson & Calkins, 1996). However, the mechanisms through which these early experiences of adversity "get under the skin" (Evans, Chen, Miller, & Seeman, 2012, pg. 12) have not been clearly delineated, and the role of early intervention in ameliorating these effects have not been fulling explored. The nature, timing, and dose of early adverse experiences, as well as early parenting, may influence the negative impact of adversity on emotion regulation (Shonkoff, Siegel, Dobbins, Earls, & Garner, 2012). This longitudinal study sought to examine the influence of early parent-child co-regulation on later child emotion regulation, and consider the impact of risk across several domains and at different developmental time periods on child emotion regulation. It also tested whether parent-child dyads randomly assigned to a preventative intervention administered in infancy, Attachment and Biobehavioral Catch-up (ABC), would show enhanced parent-child mutual positive affect at 24 months old and later child emotion regulation at 8 years old.

## **Emotion Regulation**

Specific definitions of emotion regulation have been the source of debate, but the developmental literature generally defines emotion regulation as the ability to regulate the expression, magnitude, or duration of an emotional response to either support a goal or to prevent the emotion from getting in the way of the goal (Cole, Martin, & Dennis, 2004; Thompson, 1994a). Thus, a distinction is made between a) the expression of emotion, and b) the regulation of emotion (Posner & Rothbart, 2000). Expression of emotion is observed through indicators such as certain facial arrangements (Izard, 2007). In contrast, regulation of emotion describes the processes that monitor, facilitate, or inhibit emotions (Cole et al., 2011). In young children, regulating processes can include child behaviors as well as parent emotion expression or parent behavior.

This conceptualization has critical implications for how emotion regulation is measured and evaluated, and several important recommendations have emerged from the literature. The first key criterion in measuring emotion regulation is to obtain independent measurement of: a) the activated emotion, and b) the regulatory strategy of either the child or parent (Cole et al., 2004). In young children this requires independent measurement of the emotion expression of each member of a dyad, meaning that the child's expression of emotion is coded as a separate stream from the parent's expression of emotion. A criticism of many studies examining emotion regulation is that the expression of negative emotion is interpreted as poor regulation, which fails to recognize the regulatory and regulated aspects of emotion (Cole,

Michel, & Teti, 1994; Thompson, 1994b). Child emotion expression and emotion regulation should be viewed as a separate, but related, constructs. A second important consideration is the temporal relationships between the emotion expression of both the child and parent. The process of emotion regulation is inherently linked to change – how environmental stimuli, regulatory behaviors, and input from the other member of the dyad influence the activation, intensity, and course of emotion expression. Through the use of time-synchronized assessment and temporal analyses, the relation between the emotion expression of the child and parent can be evaluated, and therefore the process of mutual positive affect can be inferred. The statistical methods of sequential and time-series analyses are particularly helpful in capturing mutual positive affect as a process (Bakeman, Deckner, & Quera, 2005; Sackett, 1987).

#### Early Adversity, Maltreatment and Emotion Regulation

Children exposed to early adversity and maltreatment display deficits in skills related to both emotion expression and emotion regulation (Luke & Banerjee, 2013). Specifically, maltreated infants at 12 to 18 months old have been found to exhibit patterns of excessive negative affect or blunted patterns of expression when interacting with their parents (Gaensbauer, 1982), and 42-month-old maltreated children have been found to display higher levels of anger, noncompliance, and distractibility during a problem solving task than non-maltreated children (Egeland, Sroufe, & Erickson, 1983). In response to peer distress, maltreated toddlers have been shown to exhibit inappropriate affect and behavior, including anger, fear, and aggression (Main & George, 1985). These difficulties with emotion expression and regulation extend into middle childhood, with maltreated children exhibiting higher levels of emotion dysregulation, affective lability/negativity, and socially inappropriate emotion expressions than non-maltreated children (Maughan & Cicchetti, 2002; Shields & Cicchetti, 1998).

In addition to these problems with emotion expression and regulation, maltreated children have also been found to exhibit disruptions in emotion recognition. Young maltreated children, ages 3-7 years old, have been shown to be less accurate in discriminating emotions than non-maltreated children (Camras, Ribordy, Hill, Martino, & et al, 1988; Pollak, Cicchetti, Hornung, & Reed, 2000; Rogosch, Cicchetti, & Aber, 1995). At school-age, maltreated children have demonstrated a hyper-focus on expressions of negative affect. When shown the unfolding of a facial expression from neutrality to peak emotion, maltreated children were able to more quickly recognize anger in the formation of the facial expression than non-maltreated children (Pollak, Messner, Kistler, & Cohn, 2009). In addition, the speed of children's recognition was associated with the degree of anger/hostility exhibited by the children's parents. Studies of the neural correlates of emotion recognition have found that young maltreated infants (ages 15 months old, 30 months old, and 42 months old) displayed greater amplitude of an early positive frontal-central event related potential (ERP) component (P260) in response to viewing angry facial expressions, relative to happy, than non-maltreated children (Cicchetti & Curtis, 2005; Curtis & Cicchetti, 2011; 2013). School-age maltreated children showed greater P3b

amplitude and hyper-responsive to angry facial expressions than among nonmaltreated children (Pollak & Tolley-Schell, 2003; Pollak, Cicchetti, Klorman, & Brumaghim, 1997; Pollak, Klorman, Thatcher, & Cicchetti, 2001; Shackman, Shackman, & Pollak, 2007). Thus, maltreated children appear to be more sensitive to expressions of negative affect than non-maltreated children.

These difficulties with emotion regulation-related skills have been linked to behavior problems, as emotion regulation competence serves as the foundation for self-regulation capabilities. Maltreated children have been found to display higher levels of aggression and non-compliance than their non-maltreated peers, and these difficulties often co-occur with anger expression problems (Crittenden, 1985; Dodge, Pettit, Bates, & Valente, 1995; Herrenkohl & Herrenkohl, 2007; Woodruff & Lee, 2011). Indeed, these emotion-related deficits have been found to mediate the links between maltreatment and children's externalizing problems (Shields & Cicchetti, 1998; 2001). In addition, these regulation deficits place maltreated children at risk for developing further psychopathology in the future (Alink, Cicchetti, Kim, & Rogosch, 2012; Shipman & Zeman, 2001). Overall, the deficits in emotion regulation have critical implications for maltreated children's functioning in a variety of domains.

## **Cumulative Risk**

Exposure to early risk also negatively influences children's emotion regulation capabilities (Chang, Shelleby, Cheong, & Shaw, 2012; Kim et al., 2013). In conceptualizing this exposure to early adversity, cumulative risk models are often

helpful. These models theorize that the greater number of risk factors a child is exposed to, the greater the prevalence of problems (Ackerman, Izard, Schoff, Youngstrom, & Kogos, 1999; Deater-Deckard, Dodge, Bates, & Pettit, 1998). The Isle of Wight study showed that the presence of two or more indicators of family adversity were associated with a two- to four-fold increase in child behavior problems (Rutter, Cox, Tupling, Berger, & Yule, 1975; Rutter, Yule, et al., 1975). Similarly, Sameroff and colleagues in the Rochester Longitudinal Study (RLS) found that a higher number of risk factors was associated with more negative developmental outcomes, with children with the higher number of risk factors almost seven times more likely to have poor academic outcomes than children with few risk factors (Sameroff, 2000; Sameroff, Seifer, Zax, & Barocas, 1987; Sameroff, Bartko, Baldwin, Baldwin, & Seifer, 1998). Finally, the Adverse Early Childhood Experiences (ACEs) found that the number of adverse early experiences was linked to later psychosocial and medical problems in adults (Anda et al., 2006; Felitti et al., 1998).

The impact of cumulative risk during different developmental periods has been less studied than concurrent cumulative risk. However, many of the factors contributing to cumulative risk models are not stable over the short-term. For example, families may have large changes in income over short periods, even while remaining generally economically disadvantaged (Duncan & Brooks-Gunn, 2000). In addition, families may experience multiple residence changes or changes in romantic partner relationships (Ackerman et al., 2002; Seccombe, 2000; White & Rogers, 2000). Therefore, studies that examine the association between concurrent risk factors

and development are only able to look at the association at a single point in time. This does not allow the consideration of the impact of risk across children's development, and the possible relative importance of early risk on child development.

A few studies that have examined risk at different time points have found that early risk is more important in predicting functioning than later risk (Appleyard, Egeland, Dulmen, & Sroufe, 2005; Mistry, Benner, Biesanz, Clark, & Howes, 2010). Appleyard and colleagues found that the number of risks in early childhood (0 - 64months old) predicted behavior problems in adolescence, even after including the effects of risk in middle childhood (Appleyard et al., 2005). Other studies have also found that risk exposure during infancy was most detrimental for children's school readiness skills in preschool (Mistry et al., 2010). Therefore, there is initial evidence that early cumulative risk may play a particularly important role in children's development.

## **Parenting and the Development of Emotion Regulation** Another important factor in early adversity "getting under the skin" is

parenting (Evans, Chen, Miller, & Seeman, 2012, pg. 12). Parents play critical role in the development of emotion regulation through their role as extrinsic regulators of children's emotion and behavior. Sensitive caregivers are able to be alert to infant signals, provide appropriate and prompt responses, and negotiate conflicting goals (Ainsworth, 1979). Children's regulatory abilities develop through their positive interactions with a responsive and sensitive caregiver. During the first months of life, young infants do not possess the motor or cognitive capabilities to independently regulate their emotions (Kopp, 1982). Instead, they respond to discomfort by reflexively signaling by crying. A responsive caregiver reads an infant's signs of distress and other affective communications, interprets these signals, and responds to them (Sroufe, 1996). This interactive regulation, or co-regulation, means that all emotion expression and behavior is unfolding in the child while simultaneously modifying and being modified by the changing emotion expression and behavior of the parent (Fogel, 1993).

As infants develop simple motor skills and attentional control capabilities between three and six months old, they gradually gain the ability to engage in some self-regulatory behaviors. These regulatory skills include self-initiated distraction, such as moving attention away from the source of negative arousal to a more neutral stimuli (Calkins & Leerkes, 2011). After about six months of age, infant begins to specifically and intentionally direct communications to the parent, purposefully acting to achieve contact with the parent, and employing relevant emotion expression and behavior to achieve the goal of interaction and emotional calming (Kopp & Neufeld, 2003). In the context of a responsive parent, the infant learns that emotional arousal does not necessarily lead to dysregulation, and that when arousal does exceed the infant's modulation capacities, the parent will be there and help to reestablish equilibrium (Sroufe, 1996). The infant can recognize the parent's role in affect modulation and his or her own role with respect to eliciting parent availability and assistance. As children become more independent through advances in gross motor, cognitive, and language abilities, continuing positive interactions with their parents help them to take a more active role in their own self-regulation (Diener & Mangelsdorf, 1999; Fox & Calkins, 2003). The parent's use of specific strategies and behaviors within these dyadic interactions means that these strategies become integrated into the child's repertoire of emotion regulation skills, presumably across both biological and behavioral levels of functioning (Calkins & Dedmon, 2000). The child may then draw on this repertoire in a variety of contexts, in both conscious, effortful ways (e.g., walking away from a confrontation with a peer) and nonconscious, automatic ways (e.g., averting gaze when confronted by a frightening movie scene or reducing vagal regulation of the heart to facilitate behavior coping) (Calkins, Graziano, Berdan, Keane, & Degnan, 2008).

#### **Examining Parent-Child Interactions**

Early parent-child interactions serve a foundational role in the development of child emotion regulation. Early studies sought to characterize these interactions through the use of temporally sensitive methods. Specifically, micro-analytic coding was used to code behaviors related to vocalization, attention, affect, head orientation, and touch separately for parents and infants. Using these methods, Tronick and colleagues (1989) found that face-to-face interactions of infants and parents were bidirectional (or mutually regulated), starting as young as three months. Infant smiles and vocalizations were found to be contingent on specific maternal affective turn-taking signals, suggesting that infants modified their affective displays and behaviors

on the basis of their mothers' affective displays and behavior (Cohn & Elmore, 1988; Cohn & Tronick, 1987; Tronick & Cohn, 1989). In turn, mother affect, vocalizations, and behaviors were found to be contingent on infant cues (Tronick, 1989). Field (1994) also found that mother and infant physiological responses followed a similar contingent pattern with facial and vocal expressive behavior. Overall, these findings suggest that mothers and infants are sensitive to each other's emotional signals, reciprocate by matching emotion or modifying behavior to amplify or modulate the other's emotion, and sustain an ebb and flow of emotional interaction that maintains the relationship in a sensitive, optimal way.

Shared positive affect plays a critical role in these early parent-child emotion interactions. Sensitivity can be conceptualized as the process through which parent and child match each other's positive affect to jointly moderate the dyad's level of positive arousal (Cohn & Tronick, 1988; Feldman, 2003, 2007; Feldman & Greenbaum, 1997). Some researchers argue that shared or match affect is a defining characteristic of sensitive interaction (Cole, Teti, & Zahn-Waxler, 2003; Kochanska & Aksan, 1995), though others believe sensitive interactions are possible even with mismatched affective states (Gottman & DeClaire, 1997). A recent study utilizing micro-analytic coding found that sensitive parent-child interactions are characterized by shared positive affect among both securely and insecurely attached dyads (Lindsey & Caldera, 2015). Thus, parent-child mutual positive affect is a critical component of early parent-child co-regulatory interactions.

## **Maltreating Parent-Child Interactions**

Though maltreating parent-child interactions have not been studied using these temporally sensitive methods, evidence suggests that disturbances in the co-regulation would be found. For example, temporally sensitive methods have been used to study the influence of maternal depression on the infant-parent interaction. Depressed parents have been observed to engage in less vocalization, smiling, imitation, and game-playing than non-depressed parents (Field, Diego, Hernandez-Reif, & Fernandez, 2007). In response, infants of depressed mothers become less upset when the mother disengages during the still-face paradigm, and are less responsive to cues from the mother, than infants of non-depressed mothers (Field, Diego, & Hernandez-Reif, 2009). These disturbances in early interactions had been found to lead to a variety of negative outcomes for children of depressed parents (Goodman et al., 2011).

Parenting behavior in the context of maltreatment has been primarily observed using global coding methods. Compared with non-maltreating mothers, maltreating mothers have been found to demonstrate higher levels of expression of negative affect (Bousha & Twentyman, 1984; Edwards, Shipman, & Brown, 2005; Pianta, Sroufe, & Egeland, 1989). They also were significantly less responsive to their children than non-maltreating mothers, showing more ignoring more, less play initiation, fewer responses to their children's bids, and a lack of empathic responding to children's emotional displays (Alessandri, 1992; Frodi & Lamb, 1980; Kavanagh, Youngblade, Reid, & Fagot, 1988; Wasserman, Green, & Allen, 1983). Several studies found that maltreating parents tended to be more controlling than non-maltreating parents

(Aragona & Eyberg, 1981; Wilson, Rack, Shi, & Norris, 2008). These parenting behaviors are thought to negatively affect child development, particularly in the area of emotion regulation (Chang, Schwartz, Dodge, & McBride-Chang, 2003; Denham & Grout, 1993).

## Attachment and Biobehavioral Catch-up (ABC)

To address these difficulties in families with a history of maltreatment, the Attachment and Biobehavioral Catch-up (ABC) intervention aims to promote parenting behaviors that enhance children's regulatory capabilities. Specifically, ABC focuses on three main targets: a) increasing parents' sensitive behavior, b) increasing parents' nurturing behavior, and c) decreasing parents' intrusive and frightening behaviors (Dozier, Meade, & Bernard, 2014). ABC is a manualized, 10-session intervention implemented in the family's home. During sessions, the therapist (referred to as a "parent coach") emphasizes the importance of the intervention targets through discussion of child development research, showing video clips, and making "in the moment" comments. These comments help to communicate the intervention targets to the parents, and allow parents to practice the behaviors in session.

The efficacy of the ABC intervention has been assessed in randomized clinical trials with both foster parent and CPS-involved biological parents. These studies found that parents who received the ABC intervention interacted with their children in more sensitive ways than parents who received a control intervention (Bick & Dozier, 2013). In addition, children randomly assigned to the ABC intervention showed lower

rates of disorganized attachment (Bernard et al., 2012; Dozier et al., 2009), more normative patterns of cortisol production (Bernard, Butzin-Dozier, Rittenhouse, Dozier, 2010; Bernard, Hostinar, Dozier, 2015), lower levels of negative affect expression during a frustrating task (Lind, Bernard, Ross, & Dozier, 2014), and stronger executive functioning capabilities (Lind, Lee Raby, Caron, Roben, & Dozier, 2017) than children in a control intervention.

#### **Present Study**

The present study sought to evaluate the effects of ABC on early parent-child mutual positive affect and later child emotion regulation capabilities, controlling for the effects of risk. Parent-child dyads who had been involved with CPS due to concerns of maltreatment were randomly assigned to ABC or a control intervention in infancy, and a follow-up assessment of mutual positive affect was conducted at 24 months old, using temporally sensitive coding of parent-child interaction. Later child emotion regulation was measured through a parent report measure when children were 8 years old. Risk indices were developed for two different developmental periods: early risk 0-24 months old and 8-10 years old, and across three domains: child, parent, and instability.

## Chapter 2

## **METHODS**

## **Participants**

Participants were 107 parent-child dyads who had been investigated by CPS for reports of maltreatment. Following an investigation, these children remained living with their biological parents as part of a foster-care diversion program. Families had been identified by CPS primarily due to concerns of domestic violence, parental substance use, homelessness, and medical or supervisional neglect. Descriptive statistics for the sample of parents and children are presented in Tables 1 and 2.

Child Characteristics	ABC ( <i>n</i> = 50)	DEF ( <i>n</i> = 57)	
Sex, No. (%)			
Male	30 (60.0)	29 (50.9)	$\chi^2 (1, N = 107) = .90, p = .34$
Female	20 (40.0)	28 (49.1)	$\chi$ (1, N = 107) = .90, p = .34
Race/Ethnicity, No. (%)			
White	5 (10.0)	2 (3.5)	
African American	31 (62.0)	36 (63.2)	$\chi^2$ (3, N = 107) = 2.82, p = .42
Hispanic	9 (18.0)	15 (26.3)	$\chi$ (3, N - 107) - 2.82, p42
Biracial	5 (10.0)	4 (7.0)	
Age at 24-Month Assessment, Months			
Mean (SD)	25.1 (3.2)	25.4 (3.8)	t(105) = 20 = 70
Range	16.1-32.8	14.0-34.1	t(105) = .39, p = .70
Age at 8-Year Assessment, Months			
Mean (SD)	8.7 (.6)	8.4 (.4)	4(70) = 2.04 = 0.5
Range	8.0-11.1	8.0-9.5	t(79) = -2.04, p = .05

## Table 1Child Demographic Characteristics

## Table 2Parent Demographic Characteristics

	ABC	DEF	
Mother Characteristics	(n = 50)	(n = 57)	
Sex, No. (%)	(	(1 01)	
Male	0 (0)	0 (0)	
Female	50 (100.0)	50 (100.0)	
Race/Ethnicity, No. (%)	~ /	· · · ·	
White	7 (14.0)	6 (10.5)	
African American	31 (62.0)	36 (63.2)	<sup>2</sup> (2) M (107) 02 02
Hispanic	9 (18.0)	13 (22.8)	$\chi^2$ (3, N = 107) = .92, p = .82
Biracial	3 (6.0)	2 (3.5)	
Age at 24-Month Assessment, Years			
Mean (SD)	28.8 (7.4)	26.7 (7.8)	(105) 1.42 16
Range	17.6-46.1	16.4-45.6	t(105) = -1.43, p = .16
Education			
Less than high school	30 (60.0)	37 (64.9)	
High school graduate	16 (32.0)	16 (28.1)	$^{2}$ (2 N 107) 2.05 40
Some college	2 (4.0)	4 (7.0)	$\chi^2$ (3, N = 107) = 2.95, p = .40
College graduate	2 (4.0)		
Income			
Less than \$10,000	34 (68.0)	44 (77.2)	
\$10,000 - \$19,000	4 (8.0)	8 (14.0)	
\$20,000 - \$29,000	8 (16.0)	2 (3.5)	$\chi^2$ (4, N = 107) = 7.99, p = .10
\$30,000 - \$39,000	2 (4.0)	3 (5.3)	
\$40,000 - \$59,000	2 (4.0)		
Marital Status			
Married	4 (8.0)	3 (5.3)	
Separated	2 (4.0)		
Divorced	3 (6.0)		$\chi^2$ (4, N = 107) = 7.03, p = .13
Living together	11 (22.0)	11 (19.3)	
Single	30 (60.0)	43 (75.4)	

## Procedure

Families were referred to the study by CPS workers if children were younger

than 2 years old, and remained living with a biological parent following CPS

involvement. Parents were contacted and invited to participate in the study, with

written informed consent obtained from parents if they agreed to participate. After consent, a project coordinator randomly assigned participants to the experimental intervention (Attachment and Biobehavioral Catch-up, ABC; n = 50) or control intervention (Developmental Education for Families, DEF; n = 57) using a randomly generated number sequence (with group assignment based on even versus odd digits). On average, children were 9.9 months old (SD = 5.8) at the start of the interventions. Approval for the conduct of this research was obtained from the University of Delaware Institutional Review Board.

Follow-up assessments were planned to include a post-intervention home visit approximately one month after the completion of the intervention, and yearly postintervention research visits around the time of the child's birthday continuing until children reached 48 months old (i.e., a 24-month-old visit, a 36-month-old visit, and a 48-month-old visit). Additional follow-up visits were conducted when children were 8, 9, and 10 years old. Efforts were made to conduct research visits with children during the follow-up phase even if families did not complete the intervention. A total of 211 children were enrolled in the study and were randomized to receive either the ABC or control intervention. Of these 211 children, 107 participated in the 24-monthold assessment, and 81 of these children participated in the 8-year-old visit.

Outcome data for the present study were collected during the laboratory postintervention visit that occurred when children were approximately 24 months old (M = 25.2, SD = 3.5) and 8 years old (M = 8.5, SD = 0.4). Parents completed a demographic questionnaire when they first enrolled in the study and when the children

were 8 years old. In addition, parents participated in a calendar-based interview regarding the presence of certain risk factors through the child's life when the child was 8 years old. Additional questionnaires regarding child temperament and parent mental health were completed at the initial visit and at the 24-month assessment.

To assess whether differential attrition threatened the validity of the 24-monthold or 8-year-old assessments, characteristics of included and excluded children were compared. No significant differences between the groups were found with regard to child age at the beginning of the intervention, child gender, child ethnicity, parent age, parent gender, parent ethnicity, parent income, parent education, or parent marital status (all *p* values > 0.05).

#### Interventions

The experimental and control interventions were similar in structure, frequency, and duration. Both interventions consisted of 10 training sessions conducted in the families' homes and were based on structured manuals.

Attachment and Biobehavioral Catch-up Intervention (ABC) The ABC intervention had three primary targets: a) to increase parents' sensitivity and following their children's lead (e.g., parent clapping blocks together after child claps blocks together), b) to increase parents' nurturing behavior in response to children's distress (e.g., hugging child when he or she is upset), and c) to decrease parents' frightening or intrusive behaviors (e.g., yelling at a child or grabbing him or her roughly). During sessions, parent coaches presented a rationale for target behaviors based on research evidence, provided feedback to parents about their interactions with their children using video clips from previous sessions, and guided parents in considering how their own experiences influenced their parenting. A key component of the ABC intervention was the parent coaches' provision of "in the moment" comments about the parents' interactions with children during sessions (Caron, Bernard, & Dozier, 2016). These comments provided in-vivo feedback about parent behaviors consistent with the intervention targets.

#### Developmental Education for Families (DEF) The DEF intervention was adapted from a home-visiting program developed

by Ramey and colleagues (e.g., Ramey, Yeates, & Short, 1984), that was effective in enhancing children's intellectual functioning when provided intensively and for a long duration (Brooks-Gunn, Klebanov, Liaw, & Spiker, 1993; Ramey et al., 1984). Components that involve parental sensitivity to child cues were excluded in this study in order to distinguish it from ABC. Instead, the DEF intervention focused on enhancing children's motor, cognitive, and language skills directly. Parent coaches discussed methods to help children reach developmental milestones and practiced these skills with the parents and children. Video feedback was also used to review skills and demonstrate children's gains throughout the intervention. In this way, the DEF intervention served as an active control for non-specific effects of therapy, receiving parent coaching in the home, and monetary compensation for participation.

#### Measures

Parent-child mutual positive affect at 24 months old Parent-child co-regulation was assessed through a semi-structured play interaction when children were approximately 24 months old. During this task, parents were asked to play with their child with either blocks or a rattle, stacking cups, and squeaky toy. Coding of emotion expression utilized the D.O.T.S. Emotion Coding System (Cole, Wiggins, Radzioch, & Pearl, 2007). Two teams of independent coders, blind to other study information, coded child emotion expression and parent emotion expression second-by-second using Noldus Observer XT 11. Both systems were time-sensitive and time-linked with each other. Both teams of coders established acceptable levels of inter-rater reliability on training videos prior to coding for the present study. For parent emotion expression coding, twenty percent of the videos were double coded to assess inter-rater reliability ( $\kappa = 0.82$ ). For child emotion expression, all videos were double-coded and conferenced to reach consensus ( $\kappa =$ 0.76).

Child emotion regulation at 8 years old Child emotion regulation was measured through parent report with the Emotion Regulation Checklist (Shields & Cicchetti, 1997) at the 8-year-old assessment. The checklist has 24 items rated on a 4-point Likert scale indicating how frequently the behaviors occur (1 = almost always to 4 = never). Two scales were generated: a) emotion lability/negativity, and b) positive emotion regulation. Items assessing emotion lability/negativity focused on emotional lability, anger reactivity, and negative emotion intensity, whereas items measuring positive emotion regulation examined emotion understanding and empathy.

## Cumulative risk index

Cumulative risk indices were developed across three domains: child, parent, instability, and calculated for two time periods: a) 0-24 months old, and b) 8-10 years old. The method of developing these cumulative risk indices was drawn from previous literature (Appleyard et al., 2005; Brown & Ackerman, 2011). Information for the cumulative risk indices were obtained from demographic questionnaires completed at both time points, as well as questionnaires regarding parental mental health and child temperament. A life events interview utilizing a calendar-based method was conducted with the parent when the child was 8 years old. This interview queried the presence of a range of risk factors throughout the child's life. Information from all sources was consolidated, and each risk factor was given a score of zero (0) if absent and a score of one (1) if present. Whenever possible, contemporaneous information was used to make these score determinations, the retrospective interview was primarily used to confirm or supplement previously gathered data. Table 3 includes descriptive information regarding each index for both developmental periods. Information regarding specific risk factors are included below.

Table 3	Risk Factors and	Cumulative	Risk	Scores	by Group

	A	BC	DEF	
	0-24  mo ( <i>n</i> = 50)	8-10 yo ( <i>n</i> = 38)	0-24  mo ( <i>n</i> = 57)	8-10 yo ( <i>n</i> = 42)
Child Risk Factors, No. (%)	· · ·			
Low Birth Weight	8 (16.0)		11 (19.3)	
Prenatal Substance Exposure	19 (38.0)		15 (26.3)	
Difficult Temperament	6 (12.0)		6 (10.5)	
Parent Risk Factors, No. (%)			× ,	
Low income (Income-to-needs ratio < 1)	40 (80.0)	24 (48.0)	52 (91.2)	33 (57.9)
Mental health concerns	32 (64.0)	20 (40.0)	36 (63.2)	21 (36.8)
Low education (Less than high school)	26 (52.0)	10 (20.0)	28 (49.1)	13 (22.8)
Unemployed	33 (66.0)	18 (36.0)	41 (71.9)	22 (38.6)
Criminal justice system involvement	10 (20.0)	1 (2.0)	5 (8.8)	3 (5.3)
Adolescent parent (Less than 18yo)	22 (44.0)	14 (28.0)	29 (50.9)	21 (36.8)
Single parent	28 (56.0)	25 (50.0)	36 (63.2)	27 (47.4)
Substance abuse	22 (44.0)	38 (76.0)	22 (38.6)	4 (7.0)
Instability Risk Factors, No. (%)		( )	~ /	× ,
Residential (At least one move)	33 (66.0)	20 (40.0)	40 (70.2)	26 (45.6)
Relationship (Status change)	18 (36.0)	23 (46.0)	29 (50.9)	17 (29.8)
Homelessness	10 (20.0)	2 (4.0)	15 (26.3)	2 (3.5)
Child separation (More than 2 weeks)	6 (12.0)	9 (18.0)	5 (8.8)	8 (14.0)
Other children removed	18 (36.0)	13 (26.0)	18 (31.6)	15 (26.3)
Child Cumulative Risk Index				
Mean (SD)	.68 (.87)		.59 (.78)	
Range	0 - 3		0 - 2	
Parent Cumulative Risk Index				
Mean (SD)	4.56 (1.89)	3.24 (1.57)	4.71 (1.68)	3.42 (1.69
Range	1 – 8	0 - 6	1 – 8	0 - 8
Instability Cumulative Risk Index				
Mean (SD)	1.76 (1.29)	1.76 (1.17)	1.96 (1.19)	1.60 (1.07
Range	0 - 5	0 - 4	0 - 4	0 - 4

## Child cumulative risk

*Child low birth weight.* Parents reported the child's birth weight on the demographic questionnaires. Children who were reported to have a birth weight greater than 2500 gm were given a score of zero (0), whereas those reported to have a birth weight less than 2500 gm were given a score of one (1).

*Prenatal substance or alcohol exposure.* Parents reported prenatal alcohol or substance use on demographic questionnaires. In addition, parents were asked about their alcohol and substance use on the life events interview, and when they learned that they were pregnant. Children whose parents reported using no alcohol or substances during pregnancy were given a score of zero (0), whereas those whose parents reported using alcohol or substances during pregnancy were given a score of zero (1).

*Difficult temperament.* Parents completed the Infant Behavior Questionnaire -Revised (IBQ-R, Gartstein & Rothbart, 2003), which is designed to assess temperament in young children. Two scales were used to assess children's temperament: the Distress to Limitations scale, which measures the child's reactions to limitations such as delays in feeding and being placed in a confining position such as a car seat, and the Soothability scale, which assesses the child's reduction of fussing, crying, or distress when the parent uses soothing techniques. Children whose parents scored them less than one standard deviation away from the average were given a score of zero (0), whereas children whose parents scored them more than one standard deviation away from the average were given a score of one (1).

#### Parent cumulative risk

*Income.* On the demographic questionnaires, the parent reported yearly family income from all sources (e.g., employment, child support, TANF, etc.). The number of family members living in the residence was also reported on the demographic

questionnaires and through the life events interview. An income-to-needs ratio based on the federal standard for the poverty line was calculated using this information. Parents who reported a ratio greater than 1.0 (above the poverty line) were given a score of zero (0), while those who reported a ratio lower than 1.0 (below the poverty line), were given a score of one (1).

Parent mental health. Parent mental health was measured using the Psychiatric Diagnostic Screening Questionnaire (PDSQ), a 125 item self-report checklist designed to assess the presence of psychopathological symptoms (Zimmerman & Mattia, 2001). Parents who reported symptoms that exceeded the "clinical cutoff" score for depression, anxiety, or posttraumatic stress disorder on the PDSQ or who reported significant mental health concerns on a life events interview were given a score of one (1). Those who did not report significant mental health concerns on the PDSQ or interview were given a score of zero (0).

*Parent education.* Parents completed demographic information forms at both time points listing their education level. Parents who completed high school or beyond (or obtained a GED) were given a score of zero (0). Those who did not complete high school were given a score of one (1).

*Parent employment.* Demographic forms were completed by parents at both time points, and the life events interview assessed periods of employment. Parents who were employed during the relevant time period were given a score of zero (0), whereas those who were employed were given a score of one (1).

*Parent criminal justice involvement.* The life events interview and the demographic questionnaires inquired about parental involvement with the criminal justice system. Parents with no criminal justice system involvement during the relevant time period were given a score of zero (0), whereas those with criminal justice system involved during the time period were given a score of one (1).

*Age first became parent.* Demographic questionnaires completed by parents at the first time point inquired about the parent's date of birth, as well as the dates of birth of all of their children. Based on this information, the age at which parent first gave birth was calculated. Parents who were 18 years or older when they first became a parent were given a score of zero (0), whereas those who were 17 years old or younger when they first became a parent were given a score of one (1).

*Single parent.* Information regarding the parent's marital status was collected through demographic questionnaires at both time points. In addition, the life events interview inquired about partners that helped with 50% or more of the child care responsibilities. Parents who reported having a partner who assisted with 50% or more of the child care responsibilities during the relevant time period were given a score of zero (0), whereas those who reported no partner during the time period were given a score of one (1).

*Parent substance abuse.* The demographic questionnaire given at the first time period assessed for substance abuse, and parents were also asked about a history of substance abuse during the life events interview. Parents who reported no substance

abuse during the relevant time period were given a score of zero (0), whereas those who reported substance abuse during the time period were given a score of one (1).

#### Instability cumulative risk

*Residential moves.* During the life events interview the parent described each residence since the child was born and when residential moves occurred. If no residential moves occurred during the relevant time period, the parent was given a score of zero (0). Parents who reported residential moves occurring during the relevant time period were given a score of one (1).

*Changes in romantic partners.* Parents reviewed their romantic relationships during the life events interview, including periods when relationships began or ended. If the parent reported no changes in romantic relationships during the relevant time period, the parent was given a score of zero (0). Parents who reported the beginning or end of a romantic relationship during the relevant time period were given a score of one (1).

*Homelessness*. Information regarding homelessness was gathered from the initial referral information, as well as through the interview utilizing a calendar method which was conducted with the parent when children were eight years old. Parents who reported no homelessness during the relevant time period were given a score of zero (0). Those who reported being homeless at any time during the relevant time period were given a score of one (1).

*Significant separations between child and parent.* Parents described any significant separations (for one month or more) between child and parent in the life events interview. Parents who reported no significant separations during the relevant time period were given a score of zero (0), whereas those that reported a significant separation during the time period were given a score of one (1).

*Removal of other children by CPS.* Parents reported on the removal of other children by CPS on the first demographic form, and also in the life events interview. Parents who reported no children removed by CPS were given a score of zero (0), whereas parents who reported other children removed by CPS were given a score of one (1).

#### Chapter 3

## RESULTS

## **Preliminary Analyses**

Calculating mutual positive affect at 24 months old To construct a temporally-sensitive measure of parent-child mutual positive affect, the second-by-second coding completed by two independent teams of coders using Noldus Observer XT 11 was exported to ObsTxtSds 3.0 (Bakeman & Quera, 2008), which converted the data to code compatible with Generalized Sequential Querier 5.1 (Bakeman & Quera, 1995; 2011). Generalized Sequential Querier 5.1 was used to analyze the time both child and mother exhibited positive affect at the same moment. These analyses created a variable representing the percentage of time that child and parent both displayed positive affect simultaneously.

Intervention group differences on demographic and risk variables Participants were first compared on demographic variables and composite risk scores. There were no significant differences in demographic variables between children or mothers randomly assigned to the ABC versus the DEF intervention groups. In addition, there were no differences between the intervention groups on the cumulative risk indices: child cumulative risk, t(104) = -0.57, p = 0.57; parent cumulative risk at 0-24 months old, t(104) = 0.44, p = 0.66; parent cumulative risk at 8-10 years old, t(79) = 0.50, p = 0.62; instability cumulative risk at 0-24 months, t(104) = 0.85, p = 0.40; instability cumulative risk, t(79) = -0.64, p = 0.53.

# **Primary Analyses**

Risk across developmental periods Differences in risk across the two developmental periods (0-24 months old and 8-10 years old) were examined. The child risk index did not vary across time due to the nature of the included risk factors (low birthweight, prenatal exposure to substances, and difficult infant temperament). However, the risk factors in the parent and instability risk indices varied across developmental periods (Table 3). In general, the parent risk index was higher at 0-24 months old (M = 4.77, SD = 1.76) than at 8-10 years old (M = 3.33, SD = 1.63; t(80) = 8.24, p < 0.01. Similarly, the instability risk index was higher at 0-24 months old (M = 2.05, SD = 1.25) than at 8-10 years old (M= 1.68, SD = 1.12; t(80) = 2.44, p < 0.01. Table 4 shows Pearson correlations between the target variables, including the correlations between risk indices and mutual positive affect at 24 months old. Mutual positive affect at 24 months old was negatively associated with child risk, r = -0.19, p = 0.04, and also negatively associated with parent risk at 24 months old at a level that approached significance, r= -0.17, p = 0.09.

### Table 4 Bivariate Correlations Between Primary Variables

	1	2	3	4	5	6	7	8	9	10	11
1. ABC Intervention											
2. Mutual Positive Affect, 24mo	.21*										
3. Positive Emotion Regulation, 8yo	.04	.28*									
4. Emotion Lability/Negativity, 8yo	05	14	36**								
5. Child Risk	.06	19*	.17	.10							
6. Parent Risk, 0-24yo	04	17	27*	.27*	.26**						
7. Parent Risk, 8-10yo	06	23*	35**	.15	.07	.58**					
8. Instability Risk, 0-24mo	08	.07	09	09	.03	.36**	.06				
9. Instability Risk, 8-10yo	.07	.02	22*	07	.02	.40**	.34**	.34**			
10. Child Gender	.09	.10	.09	.12	16	.04	.12	.04	.23*		
11. Child Age, 24mo Assessment	04	03	.13	.06	.01	.03	.12	.02	02	02	
12. Child Age, 8yo Assessment	.23*	.05	13	.11	01	.05	11	.08	.06	.15	002

*Note.* p < 0.10, \* p < 0.05, \*\* p < 0.01. *Note:* ABC intervention was coded 1 for participation in ABC and 0 for participation in DEF. Child gender was coded 1 for male and 0 for female.

Intervention effects for mutual positive affect at 24 months The effects of the ABC intervention on parent-child mutual positive affect at 24 months old were examined by regressing mutual positive affect at 24 months old on the intervention. Results showed that parent-child dyads who received the ABC intervention when children were infants displayed significantly more time in mutual positive affect at 24 months old than parent-child dyads who received the control intervention, F(1, 104) = 4.73, p = 0.03 (Table 5, Model 1). Given the association between risk and mutual positive affect, child, parent, and instability risk were added to the model to evaluate their influence. Controlling for child, parent, and instability risk from 0-24 months old, parent-child dyads who received the ABC intervention still displayed significantly more mutual positive affect at 24 months than parent-child dyads who received the control intervention, F(4, 101) = 3.31, p = 0.01 (Table 5, Model 2).

Variable	В	SE	t	р
Step 1				
ABC Intervention	2.62	1.20	2.17	0.03
(Constant)	4.17	0.83	5.04	< 0.01
Step 2				
ABC Intervention	2.79	1.18	2.37	0.02
Child Risk	-1.27	0.75	-1.71	0.09
Parent Risk, 0-24mo	-0.59	0.37	-1.60	0.11
Instability Risk, 0-24mo	0.75	0.51	1.46	0.15
(Constant)	6.23	1.18	3.44	< 0.01

Table 5Linear Regression Model for Parent-Child Mutual Positive Affect, 24<br/>Months Old

Table 5: Table - *Note*.  $R^2 = 0.04$  for Block 1 (p > 0.05);  $R^2 = 0.12$  for Block 2 (p < 0.05). Intervention was coded ABC = 1, DEF = 0.

Intervention effects for positive emotion regulation at 8 years old No significant differences were found when child positive emotion regulation

at 8 years old was regressed onto intervention, F(1, 79) = 0.10, p = 0.75 (Table 6, Model 1). However, when parent-child mutual positive affect at 24 months old was added to the model, mutual positive affect at 24 months old was found to significantly contribute to child positive emotion regulation at 8 years old, F(2, 78) = 3.11, p < 0.05(Table 6, Model 2). This association held even when controlling for child risk, parent risk at 0-24 months old, and instability risk at 0-24 months old, F(5, 75) = 4.69, p <0.01 (Table 6, Model 3), as well as parent risk at 8-10 years old and instability risk at 8-10 years old, F(7, 73) = 3.79, p < 0.01 (Table 6, Model 4). In addition, child risk was found to be positively associated with child positive emotion regulation at 8 years old and parent risk at 0-24 months old was found to be negatively associated with child positive emotion regulation at 8 years old.

Variable	В	SE	t	р
Step 1				
ABC Intervention	0.37	1.17	0.32	0.75
(Constant)	28.63	0.80	35.87	< 0.01
Step 2				
ABC Intervention	-0.24	1.16	-0.21	0.83
Mutual Positive Affect, 24mo	0.25	0.10	2.47	0.02
(Constant)	27.67	0.87	32.00	< 0.01
Step 3				
ABC Intervention	-0.77	1.09	-0.71	0.48
Mutual Positive Affect, 24mo	0.31	0.10	0.34	< 0.01
Child Risk	2.20	0.68	3.25	< 0.01
Parent Risk, 0-24mo	-0.95	0.35	-2.73	< 0.01
Instability Risk, 0-24mo	-0.05	0.48	-0.11	0.92
(Constant)				
Step 4				
ABC Intervention	-0.65	1.09	-0.59	0.55
Mutual Positive Affect, 24mo	0.28	0.10	2.77	< 0.01
Child Risk	1.99	0.69	2.89	< 0.01
Parent Risk, 0-24mo	-0.52	0.44	-1.17	0.25
Parent Risk, 8-10yo	-0.54	0.42	-1.28	0.21
Instability Risk, 0-24mo	-0.11	0.51	-0.22	0.83
Instability Risk, 8-10yo	-0.43	0.54	-0.80	0.42
(Constant)	31.59	1.79	17.61	< 0.01

Table 6Linear Regression Model for Child Positive Emotion Regulation, 8 YearsOld

Table 6: Table - *Note.*  $R^2 = 0.04$  for Block 1 (p = 0.75);  $R^2 = 0.27$  for Block 2 (p < 0.05),  $R^2 = 0.49$  for Block 3 (p < 0.01),  $R^2 = 0.52$  for Block 4 (p < 0.01). Intervention was coded ABC = 1, DEF = 0.

Intervention effects for emotion lability/negativity at 8 years old No significant differences were found when child emotion lability/negativity at

8 years old was regressed onto intervention, F(1, 79) = 0.19, p = 0.67 (Table 7, Model

1). In addition, parent-child mutual positive affect at 24 months old did not

significantly contribute to child emotion lability/negativity at 8 years old, F(2, 78) = 0.81, p < 0.45 (Table 7, Model 2). When child, parent, and instability risk were added into the model, only parent risk at 0-24 months old significantly contributed to child emotion lability/negativity at 8 years old, F(7, 73) = 1.87, p = 0.09 (Table 7, Model 4).

Variable	В	SE	t	р
Step 1				
ABC Intervention	-0.65	1.52	-0.43	67
(Constant)	23.05	1.04	22.19	< 0.01
Step 2				
ABC Intervention	-0.25	1.55	-0.16	0.87
Mutual Positive Affect, 24mo	-0.16	0.14	-1.20	0.24
(Constant)	23.67	1.16	20.44	< 0.01
Step 3				
ABC Intervention	-0.53	1.52	-0.35	0.73
Mutual Positive Affect, 24mo	-0.05	0.14	-0.37	0.71
Child Risk	-0.12	0.95	-0.13	0.91
Parent Risk, 0-24mo	1.41	0.49	2.90	< 0.01
Instability Risk, 0-24mo	-1.27	0.67	-189	0.06
(Constant)	19.23	2.40	8.01	< 0.01
Step 4				
ABC Intervention	-0.29	1.53	-0.19	0.85
Mutual Positive Affect, 24mo	-0.07	0.14	-0.48	0.64
Child Risk	-0.31	0.96	-0.32	0.75
Parent Risk, 0-24mo	1.80	0.62	2.91	< 0.01
Parent Risk, 8-10yo	-0.30	0.59	-0.51	0.61
Instability Risk, 0-24mo	-1.17	0.71	-1.65	0.10
Instability Risk, 8-10yo	-0.91	0.75	-1.21	0.23
(Constant)	19.82	2.51	7.90	< 0.01

Table 7Linear Regression Model for Child Emotion Lability/Negativity, 8 Years<br/>Old

*Note.*  $R^2 = 0.05$  for Block 1 (p = 0.67);  $R^2 = 0.14$  for Block 2 (p = 0.45),  $R^2 = 0.36$  for Block 3 (p = 0.06),  $R^2 = 0.39$  for Block 4 (p = 0.09). Intervention was coded ABC = 1, DEF = 0.

#### Chapter 4

#### DISCUSSION

This study sought to evaluate the impact of ABC on early parent-child mutual positive affect and later child emotion regulation capabilities through a randomized clinical trial, controlling for the effects of early risk. Results showed that CPS-involved parent-child dyads randomly assigned to ABC displayed a significantly higher percentage of mutual positive affect at 24 months old than parent-child dyads assigned to DEF. Controlling for risk did not affect these significant intervention effects. At the 8-year-old follow-up, no significant intervention effects were found for child emotion lability/negativity or positive emotion regulation. However, early parent-child mutual positive affect at 24 months old was significantly associated with child positive emotion regulation skills at 8 years old, controlling for early and concurrent risk.

The influence of risk and early parent-child mutual positive affect at 24 months old on later child emotion regulation at 8 years old was also explored. For emotion lability/negativity, the primary significant contributor was early parent risk at 0-24 months. This early parent risk continued to be a significant contributor to later emotion lability/negativity at 8 years old, even controlling for concurrent parent risk at 8-10 years old and early mutual positive affect at 24 months old. Neither concurrent parent risk at 8-10 years old or early mutual positive affect at 24 months old were significantly associated with later emotion lability/negativity. These results suggest

that early parent risk plays a particularly important role in the development of later child emotional dysregulation.

This study offers a significant contribution to the assessment of early preventative interventions for at-risk children. Previous studies had found that ABC had positive results for children and parents independently, compared with a control intervention. For example, foster parents who received the ABC intervention were found to interact with their children in more sensitive ways than parents in a control intervention (Bick & Dozier, 2013), and CPS-involved children who received ABC as infants displayed lower levels of negative affect during a frustrating task as toddlers, compared with children who received a control intervention (Lind et al., 2014). However, these studies examined the outcomes for children and parents independently. In contrast, the temporally sensitive measure of parent-child mutual positive affect in the current study allows for the assessment of the dynamics between the parent-child dyad. Importantly, this variable of mutual positive affect captures the process of co-regulation that has been deemed to be critical throughout the literature. Thus, this study offers evidence that ABC enhances parent-child interaction and mutual positive affect compared with a control intervention.

A seemingly contradictory finding in this study is the significant intervention effects for early parent-child mutual positive affect at 24 months but no significant intervention effects on child emotion regulation at 8 years old (despite the fact that higher levels of early parent-child mutual positive affect at 24 months was significantly associated with higher child positive emotion regulation capabilities at 8

years old). Several factors may have contributed to these results. First, there was a significant amount of time elapsed between the intervention and the 8-year-old visit. Children were infants when then received either ABC or the control intervention, and an average of 7.4 years had passed since the intervention at the 8-year follow-up assessment (SD = 0.6). Second, the measure of child emotion regulation at 8 years old relied on a parent-report measure, rather than observational coding. Difficulties with parent-report have been reported throughout the literature (Achenbach, Krukowski, Dumenci, & Ivanova, 2005; Achenbach, McConaughy, & Howell, 1987). Rater bias can interfere with a parent's ability to "accurately" report on the child's behavior. Factors such as family stress (Collishaw, Goodman, Ford, Rabe-Hesketh, & Pickles, 2009; Lavigne, Dahl, Gouze, Lebailly, & Hopkins, 2015; Youngstrom, Loeber, & Stouthamer-Loeber, 2000), parent depression (Boyle & Pickles, 1997; Briggs-Gowan, Carter, & Schwab-Stone, 1996; Gartstein, Bridgett, Dishion, & Kaufman, 2009), awareness of developmentally appropriate behaviors (Mesman & Koot, 2000; Wakschlag et al., 2005), and relationship quality with child (Seifer, Sameroff, Dickstein, Schiller, & Hayden, 2004; Treutler & Epkins, 2003) have all been found to be linked to bias and discrepancies in parent reports of child functioning. It would be helpful to code child and parent emotion expression in a similar task conducted at the 8-year-old assessment. Additionally, observational coding of a task that involved child emotion expression and child regulatory behaviors would provide measurement of child emotion regulation capabilities. These measures would allow for more direct

comparison of emotion expression and regulation between the two time points, and may allow for the observation of intervention differences.

Bias in parent report may also contribute to another one unexpected finding, the unexpected direction of association between child risk and later positive emotion regulation. Results showed that higher levels of child risk were associated with higher positive emotion regulation capabilities. It is possible that some of the risk factors included in the child index may have predisposed parents to certain reporting biases. For example, a child that had a difficult temperament as an infant may appear to have better coping skills as they mature and gain slightly better regulation skills.

Another issue for future study involves the lack of data regarding preintervention parent-child mutual positive affect. It would be helpful to show that the intervention groups did not differ with regard to co-regulation before the intervention. However, the random assignment of parent-child dyads to the intervention groups make significant pre-intervention differences unlikely.

In conclusion, this study suggests than an early preventative intervention conducted in infancy can enhance parent-child mutual positive affect during toddlerhood in CPS-involved families. This adds a critical component to the research regarding ABC, as it shows that ABC can reach beyond the influence on children and parents individually and impact the dyadic relationship. In addition, this study shows the critical role of early parent risk in predicting later child emotion lability/reactivity and the contribution of early parent-child co-regulation to later child positive emotion regulation.

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# Appendix A

# IRB-APPROVED PROTOCOL FOR TAILORING SERVICES TO INFANTS AND BIRTH PARENTS NEEDS

HUMAN SUBJECTS PROTOCOL University of Delaware

Protocol Title: Tailoring Services to Infants and Birth Parents' Needs (The Infant Caregiver Project)

Principal Investigator Name: Mary Dozier Department/Center: Psychological and Brain Sciences Contact Phone Number: 302-831-2286 Email Address: mdozier@udel.edu

Advisor (if student PI): Name: Contact Phone Number: Email Address:

Other Investigators:

Investigator Assurance:

By submitting this protocol, I acknowledge that this project will be conducted in strict accordance with the procedures described. I will not make any modifications to this protocol without prior approval by the IRB. Should any unanticipated problems involving risk to subjects occur during this project, including breaches of guaranteed confidentiality or departures from any procedures specified in approved study documents, I will report such events to the Chair, Institutional Review Board immediately.

# 1. Is this project externally funded? □ YES X NO

If so, please list the funding source:

# 2. Research Site(s)

X University of Delaware □ Other (please list external study sites)

Is UD the study lead?  $\Box$  YES  $\Box$  NO (If no, list the institution that is serving as the study lead)

# 3. Project Staff

Please list all personnel, including students, who will be working with human subjects on this protocol (insert additional rows as needed):

NAME	ROLE	HS TRAINING COMPLETE?
Mary Dozier	Data analysis	Yes
Lindsay Zajac	Data analysis	Yes
Julie Hoye	Data analysis	Yes
Kristin Bernard	Data analysis	Yes
Lisa Berlin	Data analysis	Yes
Elizabeth Allen	Data analysis	Yes

### 4. Special Populations

Does this project involve any of the following:

Research on Children? Yes

Research with Prisoners? No

If yes, complete the Prisoners in Research Form and upload to IRBNet as supporting documentation

Research with Pregnant Women? No

Research with any other vulnerable population (e.g. cognitively impaired, economically disadvantaged, etc.)? please describe No

5. **RESEARCH ABSTRACT** Please provide a brief description in LAY language (understandable to an 8<sup>th</sup> grade student) of the aims of this project.

The purpose of the study is to assess the effectiveness of an intervention for birth parents that have neglected their children. The intervention targets several critical areas. First, parents are helped to re-interpret their children's behavioral signals. Second, parents are taught to "over-ride" their own propensities to respond in inconsistent or rejecting ways to the children. Third, parents are helped to provide an interpersonally responsive environment, which helps children develop regulatory responses.

Research measures are collected from children and their birth parents before the intervention and at ages 2, 3, 4 years. Parents who choose to participate in subsequent follow up sub-studies also participate in data collection when children are 5, 6, 7, and 8. High risk birth families were referred to the project by the Department of Human Services of the City of Philadelphia under the program Servicing Children in their Own Homes (SCOH). Meanwhile, research measures were also collected at ages 4 and 5 from a sub-group of children attending the Early Learning Center at the University of Delaware. Additionally, research measures were collected from a sub-group of low-risk children at ages 4, 5, and 6 for comparison.

We are interested in studying the behavioral and biobehavioral outcomes associated with the intervention and with high-risk living conditions more generally.

6. **PROCEDURES** Describe all procedures involving human subjects for this protocol. Include copies of all surveys and research measures.

We aimed to recruit 125 children living in high-risk birth homes in the original study. The Department of Human Services of the City of Philadelphia referred families to the study. Families were then contacted and recruited by phone. Parents completed preand post-intervention visits consisting of questionnaires, video-recorded interactions, and assessments of children's theory of mind, inhibitory control, and receptive language. We also asked parents to collect saliva samples from children in the morning and before bed for three consecutive days to assess children's cortisol levels. Additionally, families participating in the original study completed 10 in-home training sessions in between the pre- and post-intervention visits. For families who consented to teacher participation, teachers were asked to complete questionnaires about child behavior in daycare and school settings when children were 3- and 4-years old. Families participated in the original study until they had completed the 4-year old post-visit.

We also recruited a sub-group of children from the Early Learning Center (ELC) at the University of Delaware in order to obtain comparison data. These children completed the same assessments of theory of mind, inhibitory control, and receptive language as the high-risk children enrolled in the original study. Children from the ELC were assed at 4- and 5-years old.

After the 4-year follow up visit, a sub-group of 50 high-risk participants from the original study were recruited from the original sample for additional follow-up when children were between 4- and 6-years old. Parents who were enrolled in the original study were contacted by phone about participating in two intervention booster sessions to review intervention skills as well as the 4- to 6-year old follow up visits, consisting of one home visit and one lab visit described below.

The 4- to 6-year old home visit consisted or activities similar to those completed in the original study. We digitally recorded a parent-child play interaction, divided attention task, and unstructured time. Parents also completed questionnaires about demographic information, maternal depression, and responses to children's distress. We asked children to provide 2-5 droplets of blood via a finger-prick to assess C-reactive protein. We also asked parents to collect saliva samples from children in the morning and before bed for three consecutive days to assess children's cortisol levels. We used buccal swabs to collect cheek cells from inside children's mouths to assess telomere length. Finally, we measured children's physical growth as a control variable.

The 4- to 6-year lab visit consisted of event-related potential (ERP) tasks designed to assess parents' responses to their own children. During the first ERP task, parents were asked to categorize crying, laughing, and neutral faces in order to determine brain reactions to distress. During the second ERP task, parents looked at images of their own child, a familiar child, and an unfamiliar child in order to assess their reaction to each stimulus.

We also recruited a sub-group of low-risk children as a comparison for the 4- to 6-year old post-visits. We aimed to recruit 50 low-risk children from previous studies conducted in the Infant Caregiver Project lab, community daycare centers, local moms' groups, and through announcements posed on a University website. Research staff called parents to briefly describe the research protocol of the study. If parents were interested, the home visit and lab visit were scheduled. Comparison families participated in the same home and lab visit measures described above.

Also when original study participants were between 4- and 6-years old, we recruited a separate sub-sample of original participants to participate in a second home visit as part of a different follow up study. During this visit, we interviewed parents about significant life events that had happened during their pregnancy with their participating child and until the child was 5-years old. Parents were also asked to complete questionnaires about their own and their children's functioning, similar to those completed during the original study's follow-up visits.

When original study participants were between 6- and 8-years old, we recruited another sub-sample of participants for additional follow up measures. During this follow-up portion, we recruited original study participants by phone. Families who were interested in completing the 6- to 8-year old follow-up were invited to participate in one lab visit, described below.

The 6- to 8-year old lab visit consisted of an interview about significant life events occurring in the parents' lives between pregnancy with the enrolled child and the present date, as described in the 4- to 6-year old home visit protocol above. Child attention and cognitive abilities were also assed during a computerized go-no go computer game as well as an assessment of receptive vocabulary. We also measured child emotion regulation during laboratory assessments designed to elicit child disappointment and frustration. Children were videotaped completing a series of cartoon vignettes designed to assess hostile attribution biases. Children were also videotaped while completing a face-matching activity designed to assess children's emotion recognition. Parents and children were digitally recorded during semi-structured interaction tasks in order to measure parenting behaviors. Finally, parents were asked to collect saliva samples in the morning and before bed to assess biomarkers for stress and immune function.

### 7. STUDY POPULATION AND RECRUITMENT

Describe who and how many subjects will be invited to participate. Include age, gender and other pertinent information.

In the original high-risk birth parents study, we aimed to enroll 125 children living with neglecting birth parents. Consent was obtained for parents' participation from their own parents or from DHS if the teen parent was in foster care. Parents over 18-years old consented for their own and for their infant's participation.

When children were ages 4 to 6 and again when they were ages 6 to 8, sub-groups of high-risk participants were recruited for additional follow-up. All participants were recruited from the original study sample. In both sub-studies, we aimed to follow up with 50 participants who had participated previously.

Finally, two sub-groups of low-risk children were recruited for comparison data. For the first sub-group we aimed to recruit 50 children ages 4 and 5 from the Early Learning Center (ELC) at the University of Delaware. For the second sub-group we aimed to recruit 50 children ages 6, 7, and 8 from the community living in low-risk homes.

Attach all recruitment fliers, letters, or other recruitment materials to be used. If verbal recruitment will be used, please attach a script.

Recruitment for this study is complete.

Describe what exclusionary criteria, if any will be applied.

None

Describe what (if any) conditions will result in PI termination of subject participation.

None

## 8. RISKS AND BENEFITS

List all potential physical, psychological, social, financial or legal risks to subjects (risks listed here should be included on the consent form).

The study poses minimal risk to participant children and families. During intervention sessions, parents may feel uncomfortable discussing challenging topics about parenting and watching back video of themselves interacting with their children. Parents may feel uncomfortable being digitally recorded or responding to questions, such as those about their own mental health symptoms. During collection of biological samples from children, including buccal cheek swabs and a finger-stick, sample collection may cause discomfort or distress. Finally, during EEG recording a gel will be applied to parents' scalps. Parents with sensitive skin may feel a stinging sensation, though these effects are mild and temporary. The EEG cap and gel may also displace parents' hairstyles. Steps taken to minimize risks are described below.

In your opinion, are risks listed above minimal\* or more than minimal? If more than minimal, please justify why risks are reasonable in relation to anticipated direct or future benefits.

(\*Minimal risk means the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily *life or during the performance of routine physical or psychological examinations or tests)* 

The risks listed above are minimal.

What steps will be taken to minimize risks?

Parents will be assured that their involvement is voluntary, and will be assured that no information will be shared with others. In order to minimize discomfort that parents may feel during the intervention sessions, parent trainers will remain supportive and empathic when discussing difficult topics or reviewing videotapes. In order to minimize discomfort that parents may feel during videotaped activities, research staff will place the camera at a distance and attempt to be unobtrusive during filming. With regard to videotapes and questionnaires, parents will be reminded that their information will be kept confidential and labeled with an ID number. Additionally, parents will be informed that their participation is voluntary and that they can choose not to answer any questions or complete any activities that make them uncomfortable.

Regarding biological sample collection from children, during the consent process we will ask parents to let us know if their children have any fears, phobias, or negative past experiences related to sharp objects or seeing blood. We will also ask parents if they are aware of any medical conditions that their children have that might make the finger-prick unsafe. Children will be excluded from participating if we have reasons to suspect that they would be exposed to greater than minimal risk. All participants will given the option to refuse blood drop collection even after they have consented. Site oozing, if any, will be controlled with direct pressure until complete hemostasis is achieved during the visit. Mild physical or emotional discomfort will be minimized by using a "tell-show-do" approach, using conversational distraction, and allowing the parent to help the child as she normally would. The risk for fainting will be minimized by having the children sit during the procedure and for 5 minutes afterwards.

Regarding assessment of parents' brain activity, during the consent process and prior to the laboratory visits, parents will be reminded that the EEG recording will require them to wear an electrode cap and have gel put in their hair. Parents will have an opportunity to fix their hair after the procedure at the laboratory. Additionally, parents will be reminded that their participation is voluntary and they can choose to stop participating at any point during the procedure.

Describe any potential direct benefits to participants.

None

Describe any potential future benefits to this class of participants, others, or society.

Participation of parents and their children is expected to benefit future parents and children by helping researchers evaluate the effectiveness of interventions for infants and their parents. The research study is expected to provide valuable information about how the parenting intervention may improve social, emotional, behavioral, and biological outcomes of children who have faced early neglect/maltreatment. The results could also have implications for understanding challenges faced by young children who have experienced adversity in developing executive functions and theory of mind.

If there is a Data Monitoring Committee (DMC) in place for this project, please describe when and how often it meets.

Not applicable

## 9. COMPENSATION

Will participants be compensated for participation?

Yes

If so, please include details.

During the initial intervention and follow-up visits at ages 2, 3, and 4, participating parents were compensated for completing all forms, interviews, and other procedures. Parents were paid \$25 for each assessment before and after the intervention, and were also paid \$100 for completion of the series of in-home training sessions. Teachers who completed questionnaires about child behavior were paid \$10.

During the 4- to 6-year old follow up sub-study for both previous participants and the comparison sample participating in home and lab visits, parents were compensated \$200 total. This included \$100 for the home visit assessments (\$50 for the behavioral assessments, \$25 for blood sample and buccal swab, and \$25 for cortisol collection homework) and \$100 for the lab visit assessments.

During the 4- to 6-year old follow up sub-study of previous participants completing the single home visit participants were compensated \$25 for the visit.

During the 6- to 8-year old follow up sub-study of previous participants completing the single lab visit participants were compensated \$100 total. This included \$75 for the lab visit assessments and \$25 for saliva sample collection.

# 10. **DATA** Will subjects be anonymous to the researcher?

No

If subjects are identifiable, will their identities be kept confidential? (If yes, please specify how)

Yes, see below.

How will data be stored and kept secure (specify data storage plans for both paper and electronic files. For guidance see <a href="http://www.udel.edu/research/preparing/datastorage.html">http://www.udel.edu/research/preparing/datastorage.html</a> )

Parents participating in the study are assured of full confidentiality. We protect participant by storing data and consent forms in locked cabinets. Video recordings, which are electronic files, are downloaded to a secure server that is stored in a locked room on campus. The computer file, developed for data management and analysis, will not identify participants by name. The longitudinal nature of the study requires a master list, linking respondents, ID numbers, addresses and phone numbers and this list will be kept in a locked filing cabinet to assure confidentiality. Blood spot samples will be temporarily stored in freezers that have been used for storing saliva samples collected as part of the original protocol. For assay, however, these samples will be shipped to a lab in the Department of Anthropology at Northwestern University. Samples will only be labeled with ID numbers, such that no participant information will be shared with staff performing the assay for C-reactive protein levels.

How long will data be stored?

Paper data and saliva samples will be stored indefinitely. After blood spot samples are assayed for C-reactive protein levels, they will be destroyed.

Will data be destroyed? X YES  $\Box$  NO (if yes, please specify how the data will be destroyed)

Blood spot samples will be destroyed after analysis according to Northwestern University biological safety procedures in an appropriate landfill.

Will the data be shared with anyone outside of the research team?  $\Box$  YES X NO (if yes, please list the person(s), organization(s) and/or institution(s) and specify plans for secure data transfer)

How will data be analyzed and reported?

We will examine whether there are main effects of risk status or interactions of risk status with intervention group in predicting child outcomes. We will also consider the effects of variables such as gender, ethnicity, and child theory of mind, and child receptive vocabulary in preliminary analyses. Pre-intervention measures of child behaviors will also be considered. Analyses will be conducted to examine development over time in inhibitory control, emotion regulation, peer relations, and cortisol production as a function of intervention. Multilevel or hierarchical linear models (HLM; Raudenbush & Bryk, 2002) will be the primary method for analyzing intervention effectiveness.

## 11. CONFIDENTIALITY

Will participants be audiotaped, photographed or videotaped during this study?

Yes

How will subject identity be protected?

Parents participating in the study are assured of full confidentiality. We protect participant confidentiality by storing data and consent forms in locked cabinets. Video recordings, which are electronic files, are downloaded to a secure server that is stored in a locked room on campus. The computer file, developed for data management and analysis, will not identify participants by name. The longitudinal nature of the study requires a master list, linking respondents, ID numbers, addresses and phone numbers and this list will be kept in a locked filing cabinet to assure confidentiality.

Is there a Certificate of Confidentiality in place for this project? (If so, please provide a copy).

A Certificate of Confidentiality issued by the National Institutes of Health will protect data from being revealed to non-research interests by court subpoena in any federal, state, local civil, administrative, legislative or other proceedings.

# 12. CONFLICT OF INTEREST

(For information on disclosure reporting see: http://www.udel.edu/research/preparing/conflict.html)

Do you have a current conflict of interest disclosure form on file through UD Web forms?

No

Does this project involve a potential conflict of interest\*?

\* As defined in the <u>University of Delaware's Policies and Procedures</u>, a potential conflict of interest (COI) occurs when there is a divergence between an individual's private interests and his or her professional obligations, such that an independent observer might reasonably question whether the individual's professional judgment, commitment, actions, or decisions could be influenced by considerations of personal gain, financial or otherwise.

No

If yes, please describe the nature of the interest:

### 13. CONSENT and ASSENT

\_X\_\_ Consent forms will be used and are attached for review (see Consent Template under Forms and Templates in IRBNet)

\_X\_\_Additionally, child assent forms will be used and are attached.

Waiver of Documentation of Consent (attach a consent script/information sheet with the signature block removed).

\_ Waiver of Consent (Justify request for waiver)

### 14. Other IRB Approval

Has this protocol been submitted to any other IRBs?

If so, please list along with protocol title, number, and expiration date.

Not applicable

## 15. Supporting Documentation

Please list all additional documents uploaded to IRBNet in support of this application.

- 1. Assent for 6 to 8YR Visits
- 2. Assent for Dependent Teen Parents
- 3. Consent for 6 to 8YR Lab Visit
- 4. Consent for 4 to 6YR Home and Lab Visits
- 5. Consent for Booster Intervention Sessions
- 6. Consent for Birth Parent Original DHS Protocol
- 7. Consent for Comparison Group for 4 to 6YR Visits
- 8. Consent for 4 to 6YR Home Visit Only
- 9. Consent for Birth Parent Original NIMH Protocol
- 10. Consent for Dependent Teen Parents
- 11. Continuing Review Request Protocol Closure 2017

No



**RESEARCH OFFICE** 

210 Hullihen Hall University of Delaware Newark, Delaware 19716-1551 Ph: 302/831-2136 Fax: 302/831-2828

DATE:

December 31, 2009

to: From:	Mary Dozier, PhD University of Delaware IRB
STUDY TITLE: IRB REFERENCE #: SUBMISSION TYPE:	[143902-2] Specialized Services for Birth Parents
	Amendment/Modification
ACTION:	APPROVED
APPROVAL DATE:	December 30, 2009
EXPIRATION DATE:	February 24, 2010
REVIEW TYPE:	Full Committee Review

Thank you for your submission of Amendment/Modification materials for this research study. The University of Delaware IRB has APPROVED your submission. This approval is based on an appropriate risk/benefit ratio and a study design wherein the risks have been minimized. All research must be conducted in accordance with this approved submission.

This submission has received Full Committee Review based on the applicable federal regulation.

Please remember that <u>informed consent</u> is a process beginning with a description of the study and insurance of participant understanding followed by a signed consent form. Informed consent must continue throughout the study via a dialogue between the researcher and research participant. Federal regulations require each participant receive a copy of the signed consent document.

Please note that any revision to previously approved materials must be approved by this office prior to initiation. Please use the appropriate revision forms for this procedure.

All SERIOUS and UNEXPECTED adverse events must be reported to this office. Please use the appropriate adverse event forms for this procedure. All sponsor reporting requirements should also be followed.

Please report all NON-COMPLIANCE issues or COMPLAINTS regarding this study to this office.

Please note that all research records must be retained for a minimum of three years.

Based on the risks, this project requires Continuing Review by this office on an annual basis. Please use the appropriate renewal forms for this procedure.

## Appendix B

## IRB-APPROVED PROTOCOL FOR INTERVENING EARLY: KEY MIDDLE CHILDHOOD OUTCOMES

For HUMAN SUBJECTS PROTOCOL University of Delaware

Protocol Title: Intervening Early: Key Middle Childhood Outcomes

#### **Principal Investigator**

Name: Mary Dozier Department/Center: Psychology Department Contact Phone Number: (302) 831-2286 Email Address: mdozier@udel.edu

Advisor (if student PI): Name: Contact Phone Number: Email Address:

Other Investigators:

Investigator Assurance:

By submitting this protocol, I acknowledge that this project will be conducted in strict accordance with the procedures described. I will not make any modifications to this protocol without prior approval by the IRB. Should any unanticipated problems involving risk to subjects, including breaches of guaranteed confidentiality occur during this project, I will report such events to the Chair, Institutional Review Board immediately.

1. Is this project externally funded? If so, please list the funding source: National Institute of Mental Health (RO1 MH074374)

#### 2. Project Staff

Please list personnel, including students, who will be working with human subjects on this protocol (insert additional rows as needed):

NAME	ROLE	HS TRAINING
		COMPLETE?
Mary Dozier	Principal Investigator	Yes
Julie Hubbard	Co-Investigator	Yes
Robert Simons	Co-Investigator	Yes
Caroline Roben	Senior Scientist	Yes
Kristiana Rios	Graduate RA	Yes
Elisabeth Neely	Graduate RA	Yes
Julie Hoye	Graduate RA	Yes
Lindsay Zajac	Graduate RA	Yes
Alison Goldstein	Graduate RA	Yes
Heather Yarger	Graduate RA	Yes
Lexie Tabachnick	Graduate RA	Yes
Alyssa Griffith	Research Assistant	Yes
Kirsten Johnson	Graduate RA	Yes
Megan Bookhout	Graduate RA	Yes
Christina Moore	Graduate RA	Yes
Chelsea Mondock	Research Assistant	Yes
Kadisha Mack	Undergraduate RA	Yes
Bridget Amponsah	Graduate RA	Yes

#### 3. Special Populations

Does this project involve any of the following:

Research on Children? Yes

Research with Prisoners? No

Research with any other vulnerable population (please describe)? No

4. **RESEARCH ABSTRACT** Please provide a brief description in LAY language (understandable to an  $8^{th}$  grade student) of the aims of this project.

Experiences of early neglect have problematic effects on young children's developing brain and behavioral systems. An intervention for neglecting parents, Attachment and Biobehavioral Catch-up, was developed to help parents follow their children's lead, and behave in nurturing and non-frightening ways with their infants and toddlers. As expected, this intervention proved effective in a randomized clinical trial in enhancing attachment security, emotion expression, and physiological regulation among young children. This extension of the Specialized Services for Birth Parents study is highly significant in several ways. At this point, effects of the ABC intervention have been demonstrated among children and parents three years after the intervention. The aims of the proposed project would

extend these findings into school-aged years when children are operating largely out of their parents' direct influence. Support for a brief early intervention that affects children's ability to regulate behaviors, emotions, and physiology in middle childhood would have high public health significance. Second, whereas most developmental studies relating early experience to later outcomes have relied on correlational designs (e.g., Doan et al., 2012), the random assignment to intervention condition allows an experimental assessment of the effects of early experience on developmental outcomes. What is particularly exciting here is that parents have been randomly assigned to condition, allowing causal statements about the effects of parental synchrony, for example, on later outcomes. Third, children's behavioral and neurobiological functioning is studied in ways that are theoretically and empirically compelling.

5. **PROCEDURES** Describe all procedures involving human subjects for this protocol. Include copies of all surveys and research measures.

#### Overview:

We will follow parents who were initially enrolled in a randomized clinical trial, as well as low-risk parents who will serve as a comparison group.

Data will be collected in individually administered laboratory tasks, parent-child interaction tasks, and through parent-, teacher-, and child-report. Cortisol will be collected through diurnal sampling.

As with previous IRB protocols submitted with this population, we will also collect several questionnaires from parents concerning demographics, parental mental health, and child behaviors.

Specific procedures:

Research staff will call parents who had previously participated in the initial study for neglecting parents. Staff will briefly describe the research protocol of the present study extension. If parents are interested, a research visit to the family's home will be scheduled. At the home visit, research staff will explain the present study in detail and obtain consent before beginning the procedures described below.

\*Note 1: All consent forms are the same general consents we have used in the past with this population, with changes pertaining only to the specific tasks being completed at visits relevant to this study.

\* Note 2: The same procedures will occur for the comparison group, except that they will be new recruits. See below in "Study Population and Recruitment" section.

\* Note 3: Some comparison group members will be recruited from a study of the Attachment and Biobehavioral Catch-Up intervention with adoptive families.

Adoptive families will also participate in the same procedures. See below in "Study Population and Recruitment" section.

\*Note 4: Some local children will be recruited, not to participate in the full study, but as "back-up" children to assist with play groups when a participant is no longer able to attend his or her scheduled lab visit. We have a separate consent form for our back-up children. These children will not participate in any other tasks.

Primary tasks assess inhibitory control, emotion regulation, and peer relations, as described below.

With respect to the items below that refer to teacher reports or participation: Parents will sign two copies of a release form giving the Infant Caregiver Project permission to contact the child's teacher. One form will remain with the Infant Caregiver Project, for our records, and the other copy will be sent to the child's teacher by ICP staff along with a letter explaining their role and blank copies of the questionnaires they will be asked to fill out. Teachers will be compensated with a \$10 electronic gift card following their participation. We will ask for e-mail confirmation that they have received payment.

### **Inhibitory Control Assessments**

*Prior to conducting the event-related potential (ERP) tasks assessing inhibitory control,* we will collect approximately 7 minutes of resting electroencephalogram (EEG) data prior to conducting the ERP tasks (not including instructions). During this time, the child will sit without engaging in a specific task while the computer asks the child to open or close his or her eyes for a given length of time (approximately 1 minute periods). Once these data have been collected, the ERP tasks will begin.

<u>Simon Task:</u> The Simon Task targets interference control, or the ability to resist the interference created by competing response tendencies. On each trial, children are asked to make a response based on the color of an arrow presented on a computer monitor while ignoring the direction in which the arrow is pointing. The task is composed of 384 trials arranged into 6 blocks of 64 trials each. Behavioral data for this task are accuracy and reaction times; the ERP data of primary interest are the event-related negativity (ERN). These data will be collected at 2 of the 3 time points (ages 8 and 10).

<u>Stop-Signal Task</u>: The Stop Signal Reaction Time Task assesses children's ability to stop a response once it has started (Barch et al., 2009). This task has two different trial types. The stop trials are identical to the go trials, but when the go stimulus is on the screen a red circle appears superimposed on the arrow at varying delay intervals. Subjects are instructed to inhibit their response to the go stimulus as soon as the stop

signal is presented. The Stop-Signal task will consist of four blocks of 100 trials each. Behavioral data for this task are both stop and go reaction times, and ERP data of primary interest are frontal N200 and P300. These data will be collected at 2 of the 3 time points (ages 8 and 10).

<u>Teacher- and parent-report:</u> Teachers and parents will complete the Child Behavior Checklist (CBCL), as well as the Social Competence subscale from Harter's Teacher Rating Scale of Child's Actual Behavior. Both scales have good test-retest reliability and internal consistency (Cole et al., 1996; Harter, 1985). These data will be collected at all 3 time points (ages 8, 9, and 10).

### **Emotion Regulation**

Impossibly Perfect Circle/ Impossible Maze Task: In order to observe how children regulate their emotions when frustrated, we will ask children to complete the Impossibly Perfect Circle task at age 8. The Impossibly Perfect Circle Task was drawn from the Laboratory Temperament Assessment Battery (Lab-TAB; Goldsmith & Rothbart, 1996). In the Impossibly Perfect Circle task, the experimenter asks the child to draw a "perfect" circle, critiquing each circle with specific statements that do not include suggestions for correcting the problem. After 3.5 minutes of critiques, the examiner leaves, after which a second examiner enters and praises the child's final circle. At ages 9 and 10, a maze will be used instead of perfect circles, and will be administered similarly (Cole et al., 2006). In the Impossible Maze Task, the experimenter asks the child to complete a maze, critiquing each attempt with specific statements that do not include suggestions for improving performance. After 3.5 minutes of critiques, the examiner leaves, after which a second examiner enters and praises the child's final attempt. Although frustrating, this task is similar to experiences in many everyday situations at school or with peers. These data will be collected at all 3 time points (ages 8, 9, and 10).

**Disappointing Gift:** The Disappointing Gift task (also adapted from Lab-TAB, Goldsmith & Rothbart, 1996) has been used by a number of investigators to assess children's handling of disappointment (e.g., Dennis et al., 2011; Simonds et al., 2007). In this version of the Disappointing Gift, the child will be asked to rank prizes from favorite to least favorite at the beginning of the session by one experimenter. At the end of the session, a different examiner will give the child a wrapped package containing the least favorite gift (e.g., a broken toy). The child will then be with the experimenter for 30s, alone for 30s, interviewed about the experience by a second researcher, and reunited with his or her mother for 2 minutes. Finally, the experimenter will return with the desired gift while apologizing for making a mistake. Again, although disappointing, such challenges are not unlike those experienced often as part of everyday life. These data will be collected at 1 time point (age 8).

<u>Teacher- and parent-report:</u> Teachers and parents will be asked to complete the Emotion Regulation Checklist (ERC: Shields & Cicchetti, 2001). The ERC has good construct and discriminant validity. These data will be collected at all 3 time points (ages 8, 9, and 10).

#### **Peer Relations and Aggression**

<u>Peer group tasks</u>: Groups of 3-5 same-sex unfamiliar children will be invited to the lab to allow direct assessments of children's behavior with peers. To the extent possible, groups will be balanced by including children who vary in terms of level of emotion regulation (as assessed in the previous year's emotion regulation tasks), as well as children in the ABC, DEF, and low-risk comparison conditions. Children will participate in "round robin" interactions involving dyads. Compared with larger playgroups, the dyads will make us less vulnerable to problems associated with children arriving at the lab at different times or failing to show up. Further, group interactions limit the effective sample size to the number of groups, whereas dyads make the number of children the effective sample size.

The dyads will each complete two tasks together. The first task will be challenging (e.g., working on a maze with no solution, and opening a box for which the keys do not work) and the second will be a success task (e.g., designing a dream school for children). Children will be left alone in dyads while completing the assigned tasks. Their interactions will be observed in real time and research staff will intervene if needed (e.g., a child becomes aggressive or distressed). Before starting the tasks, children will be shown a prize booth with three levels of prizes to win, based on the number of tickets accumulated. All children will win enough tickets for the highest level of prize, regardless of how well they actually perform. (Please note that this protocol has been approved by the IRB in work by Julie Hubbard, Investigator on this application.)

Peer groups will occur at 1 of the 3 time points (age 9). Please see "Study Population and Recruitment" section for information about a subset of children who will be recruited to assist with peer groups in the event that a participant needs to reschedule at the last minute.

<u>Peer simulation task:</u> When children are 10 years old, they will participate in a computer game designed to simulate an interaction with a peer. Simulated peer interactions have been used successfully to elicit aggressive responses in a number of studies (including those conducted by co-Investigator Hubbard and Consultant Dodge). An adapted version of Cherek's Point Subtraction Aggression Paradigm, used by Carre, Dodge and colleagues (2013), will be used here. This paradigm has been used extensively with children, adolescents, and adults (e.g. Casat et al., 1995; Cherek, 2006; Reijntnes et al., 2013). In this version of the task, children play a computer game against a fictitious peer. Children will earn points by catching shooting stars. They catch shooting stars by pressing buttons on a video game controller. If they press a foot pedal, they can "zap" the fictitious peer's astronaut and prevent him or her from catching stars and earning points. The children are told that the fictitious peer can also press a foot pedal and keep them from catching stars. In the first part of the computer game, the opponent does not press the foot pedal, and the child wins a prize. The number of times children press the foot pedal serves as a measure of proactive aggression. In the second part of the computer game, the children are told that they will earn points that are exchangeable for money. The opponent presses the foot pedal at random times during this part of the game. The number of times the children press the foot pedal serves as a measure of reactive aggression. Following the game, children will be awarded \$4 and debriefed.

<u>Teacher- and parent-report</u>: Parents and teachers will complete a questionnaire assessing reactive and proactive aggression. Parents will complete the questionnaire at 1 time point (age 10) and teachers will complete the questionnaire at all 3 time points (ages 8, 9, and 10).

In addition, parents will be interviewed with the P-ChIPS (the Parent version of the Children's Interview for Psychiatric Symptoms; Weller, Weller, Rooney, & Fristad, 2013) when children are 10. Although identifying itself as a psychiatric interview, the P-ChIPS is very similar to the BASC in asking parents whether their children have various symptoms. There are 155 items that parents respond to with a yes or no. (For example, "your child pays no attention to detail," and "Your child has stolen more than 1 time.") We chose this measure because it is not associated with the participant burden of full psychiatric interviews such as the Kiddie-SADS.

<u>Child self-report measures</u>: Children will complete a self-report measure of peer rejection, the 6-item Social Competence subscale of the Self-Perception Profile for Children (SPPC; Harter, 1985). The subscale has demonstrated strong convergent, concurrent, and discriminant validity (Harter, 1985). These data will be collected at all 3 time points (ages 8, 9, and 10).

<u>Children will complete a questionnaire assessing reactive and proactive aggression. Children will complete the questionnaire at 1 time point (age 10).</u>

<u>Child interview measures:</u> Hostile attributional biases and positive outcome expectations for aggression will be assessed through children's responses to vignettes developed by Dodge et al. (1986) and modified for video presentation by Kupersmidt (2014). The vignettes will be presented as videos depicting interactions between children. All vignettes present an interaction that results in a negative outcome for the protagonist, but in which the intention of the peer is ambiguous. Children will be asked openended questions about why the peer acted as he or she did, the children's likely response, and likely outcomes. These data will be collected at 1 time point (age 8).

#### **Assessment of Salivary Analytes**

<u>Diurnal salivary analytes:</u> Saliva samples will be taken from children two times daily over a 3-day period through passive drool. The two samples each day will include when the child first wakes up and at bedtime. The normative pattern of cortisol, dehydroepiandosterone (DHEA), and testosterone, is a high wake-up level, decreasing throughout the day, with the lowest level in the evening (Ankarberg & Norjavaara, 1999; Larson et al., 1998; Rosenfeld et al., 1975). Saliva samples will be collected at all 3 time points (ages 8, 9, and 10). Diurnal cortisol will be assayed at all 3 time points (ages 8, 9, and 10). Diurnal DHEA and testosterone will only be assayed at one time point (age 9).

The bottle containing the Salivabio device (used for collecting passive drool with a straw) will have an automated time/date stamp that records the time the container is opened. The use of the time-date stamping caps has been found to enhance compliance (Broderick et al., 2004; Kudielka et al., 2003). A sleep, feeding, health, medication, and behavior diary will be completed by parents for the days that saliva is collected. These data will be available for assessment of confounding factors. If the child is sick or having other acute physical problems, assessments will be delayed for one week or until the child's health has recovered. Analyses will exclude children taking steroids (e.g., prednisone, inhalers) or other medications known to affect cortisol, DHEA, or testosterone levels.

**Parent-child interaction**: To provide a current assessment of parenting, the child and primary parent will participate in digitally recorded interactions annually. These tasks were adapted from Rubin and Burgess (2006). At age 8, the tasks will include discussion of three issues that the child and parent often disagree on (e.g., chores, homework) and the child's "perfect birthday party." At age 9, the tasks will include discussion of an interpersonal issue that the child is concerned about (chosen with the help of research staff) and a "perfect day-trip." At age 10, the tasks will include discussion of an ambiguous interpersonal conflict (i.e., the child approaches a group of peers who are talking about a party that the child was not invited to) and the child's "perfect birthday party."

Autonomic Nervous System (ANS) activity: Information related to parents' and children's autonomic nervous system (ANS) activity will be continuously collected during the parent-child discussion tasks. In order to measure perspiration rate, a research assistant will attach two sensors to the palmar surface of the last phalanxes of the second and fourth fingers of each individual's non-dominant hand. In order to measure heart rate, a research assistant will instruct and demonstrate how to attach three electrode stickers to each individual's torso: under the right clavicle, under the left rib cage, and on the sternum. The participants will attach the electrode stickers themselves. These data will be collected at 1 time point (age 9). Prior to beginning the autonomic nervous system (ANS) activity data collection, the parent will complete a "Health Behaviors Questionnaire". This questionnaire will provide researchers with information relevant to understanding the parent's and child's physiological functioning.

<u>**Cumulative risk index**</u>: Early childhood and middle childhood risk indices will be computed, as specified by Appleyard et al. (2005), and adapted from a rich literature using risk indices (e.g., Sameroff et al., 1987). The factors will include disruptions in care, maltreatment, parent jailed or hospitalized for more than 2 weeks, exposure to violence, high maternal stress, and poverty, and will be assessed through interviews with parents (Appleyard et al., 2005). These interviews will be audio recorded. These data will be collected at all 3 time points (ages 8, 9, and 10).

<u>Child IQ</u>: Research staff will administer the Letter-Word Identification, Applied Problems, and Spelling sub-tests from the Woodcock-Johnson III Tests of Achievement as well as the Verbal Comprehension, Fluid Reasoning, and Processing Speed sub-tests from the Woodcock-Johnson III Tests of Cognitive Abilities. These data will be collected once (age 9).

<u>Child growth and development</u>: Research staff will collect information related to each child's height and weight. Each child will also complete the Pubertal Development Scale, a well-validated self-report questionnaire designed to assess children's physical development related to puberty (Petersen et al., 1988). These data will be collected at 2 of the 3 time points (ages 9 and 10).

<u>**Parent measures and interviews:</u>** While the child is completing the inhibitory control assessments (e.g., Simon Task and Stop Signal Task) and the peer relations assessments (e.g., peer group tasks, peer simulation task, and child interview measures), the parent will complete the Attachment Script Assessment (ASA) and a social support interview. These interviews will be audio recorded.</u>

<u>Attachment Script Assessment (ASA)</u>: The ASA uses a word-prompt outline to help parents generate short stories with attachment-related themes. Parents will complete the ASA at 1 time point (age 8).

<u>Social Support Interview:</u> This interview concerns the availability and the mother's satisfaction with the support she is receiving from the child's biological father, other romantic partners, her own parents or other family members, friends, and agency-based support services. This interview is incorporated to elicit information about the quality and extent of the parent's social support system and will be collected at all 3 time points (ages 8, 9, and 10).

The parent will also complete the Adverse Childhood Experiences (ACE) Questionnaire (Felitti et al., 1998) at 1 time point (age 10). This survey has been used extensively with high-risk populations.

At two time points (ages 9 and 10), the parent will complete the following brief surveys:

- Quality of Marriage Index (QMI; Norton, 1983) 6 items assessing parent romantic relationship quality, to be completed only by parents in romantic relationships.
- Ambivalent Sexism Inventory (ASI; Glick & Fiske, 1996): 22 items assessing benevolent and hostile sexism, to be completed by all parents.
- Marital Conflict Scale (MSC; Braiker &Kelley, 1979) 5 items assessing romantic relationship conflict, to be completed only by parents in romantic relationships.
- Significant Others Scale (SOS; Power, Champion, & Arias, 1988) Ideal 10 items assessing ideal instrumental and emotional support received by romantic partner, to be completed by all parents.
- Significant Others Scale (SOS; Power, Champion, & Arias, 1988) Actual 10 items assessing instrumental and emotional support received by romantic partner, to be completed only be parents in romantic relationships.

These surveys are well-validated and have been used extensively with adult populations.

**Child measures and interviews:** Children will complete a child version of the ASA, the middle childhood attachment script assessment (MC-ASA), at 2 time points (ages 9 and 10). Similar to the ASA, the MC-ASA uses a word-prompt outline to help children generate short stories with attachment-related themes.

Children will complete the Kerns Security Scale (KSS) at 2 time points (ages 9 and 10). This questionnaire will provide a measure of the child's thoughts and feelings about the relationship with his or her primary caregiver in middle childhood. We will

supplement the KSS with an Attachment Hierarchy interview designed to further assess children's attachment relationships with their parents and friends.

Children will be interviewed with the ChIPS (the Child version of the Children's Interview for Psychiatric Symptoms; Weller, Weller, Rooney, & Fristad, 2013) at 1 time point (age 10). We chose this measure because it is not associated with the participant burden of full psychiatric interviews such as the Kiddie-SADS.

Children will also complete a brief money task at 1 time point (age 10). For this task, children will be asked whether they would like to receive one dollar today or three dollars in three days. If the child selects to receive a dollar, he or she will receive the dollar immediately. If the child chooses to receive three dollars in three days, the child will be mailed three dollars to his or her home. We will contact the family to confirm the child received payment.

#### 6. STUDY POPULATION AND RECRUITMENT

Describe who and how many subjects will be invited to participate. Include age, gender and other pertinent information. Attach all recruitment fliers, letters, or other recruitment materials to be used.

We expect that we will be able to enroll at least 220 participants. These will include some parents who have participated in the study since their children were infants and some who are low-risk who have been enrolled more recently.

Most high-risk parents are expected to be single mothers, minority, and living in poverty. Most low-risk parents are expected to be married and middle class, and minority.

We will recruit parents from previous participants. We will call parents and ask their permission to participate in this new project that is a follow-up from a study they already participated in. As needed, we will recruit additional low-risk parents from the community using recruitment flyers. Fliers will be placed in nearby businesses including libraries, parks, and shopping malls. Finally, we will also recruit low-risk participants from a previous Attachment and Biobehavioral Catch-Up study of adoptive families.

We will also recruit local children who will serve as "back-ups" for our 9 year play groups. When participants need to reschedule at the last minute, we would still like to be able to hold play groups. These "back up" children will come in so that our participants are able to complete the laboratory tasks as planned. They will only participate in play groups, and not other tasks. Parents of these back-up children will be consented and children will provide verbal assent. We will be inviting children (boys and girls, any race/ethnicity) between the ages of 8 and 10 to participate as back-ups in our project. We will recruit back-up participants at local Boys & Girls Clubs and the YMCA. (We established community partnerships with these agencies to recruit participants for our "low-risk" comparison sample.) We will also recruit children by posting ads on UD classifieds and through word of mouth.

Describe what exclusionary criteria, if any will be applied.

None.

Describe what (if any) conditions will result in PI termination of subject participation.

For our back-up participants:

- Children can be "on call" to be a back-up participant as many times as they like. However, once children participate in the peer group activities, they are no longer eligible to be a back-up participant.
- Consented children will no longer be able to participate as back-up children when they are older than 11 years and 1 month.

### 7. RISKS AND BENEFITS

Describe the risks to participants (risks listed here should be included in the consent document). If risk is more than minimal, please justify.

This study poses minimal risk to participant children and families. Below we describe issues identified as possible risks, and procedures developed to minimize risk.

**Assessment of demographic information and parenting behaviors:** Parents may feel uncomfortable responding to questions (such as those about their own mental health symptoms). Parent may also feel uncomfortable being digitally recorded interacting with their children. Steps to minimize these risks are described below.

**Laboratory activities:** Children may become frustrated, upset, angry, or embarrassed as a result of lab procedures. Children may also feel uncomfortable wearing the EEG cap. As part of the EEG (brain activity) recording, a non-harmful gel will be applied to children's scalp. Children with sensitive skin may feel a minor stinging sensation, though these effects are mild and temporary. The electrode cap and gel may displace children's hairstyles, which may cause mild distress. Steps to inform parents and children for this risk are described below. Children and their parents may feel uncomfortable wearing the sensors on their chest and fingers. However, they will not feel any sensations or pain from the sensors. Steps to inform parents and children for this risk are described below.

Children may feel embarrassed when they find that they had been misled about interacting with a peer in the peer simulation task. Children will be fully debriefed with reasons for the deception explained fully. Previous experience has suggested that nearly all children will not be distressed.

What steps will be taken to minimize risks?

Assessment of parenting behaviors and demographic information: In order to minimize discomfort that parents may feel during digitally recorded activities, research staff will place the camera at a distance and attempt to be unobtrusive during filming. During audio recorded activities, research staff will place the audio recorder in an unobtrusive location during recording. With regard to digital recordings, audio recordings, and questionnaires, parents will be reminded that their information will be kept confidential and labeled with an ID number instead of their name (more information regarding confidentiality below). Additionally, parents will be informed that their participation is voluntary and that they can choose not to answer any questions or complete any activities that make them uncomfortable without affecting their participation as a whole.

Laboratory activities: Activities are not expected to elicit more negative emotion than everyday activities similar to those that would occur in a school environment. All activities are explained to parents in detail prior to completion. Additionally, children sign a written assent form prior to each visit and each activity is verbally explained to the child before it is completed. As part of this assent, children are reminded before every task that they are able to decline participation from any measure **at any time**.

During all activities parents are able to watch their children from behind a one-way mirror and are permitted to terminate the procedure at any point.

We are aware that some children and parents may be uncomfortable with the sensors on their chest and fingers; however, most children and adults get used to the sensors and actually forget that they are wearing them within a few minutes. A research assistant will attach the sensors to the participant's fingers, but children and parents will have the opportunity to put the sensors on themselves. Parents and children will also be reminded that their participation is voluntary and that they can ask us to stop participating at any point during the procedure.

We are aware that some children may be uncomfortable with the EEG sensors; however, prior experience suggests that discomfort with the physiological equipment is unlikely to occur. Most children habituate to the equipment and actually forget they are wearing it within a few minutes. During the consent process, and prior to the laboratory visits, parents will be reminded that the EEG recording will require their child to wear an electrode cap and have gel put in their hair. Parents will have an opportunity to fix their child's hair after the procedure at the laboratory. Additionally, parents will be reminded that their child's participation is voluntary and that they can ask us (and so can the child themselves) to stop participating at any point during the procedure.

Describe any direct benefits to participants.

None.

Describe any future benefits to this class of participants.

The research is expected to provide valuable information about how an intervention targeting parenting behaviors in infancy enhances children's long-term outcomes. In addition, it is expected to provide information about how disruptions in care, maltreatment, extended parental absence due to incarceration or illness, exposure to violence, high maternal stress, and poverty (among other things) play a role in child outcomes.

If there is a Data Monitoring Committee (DMC) in place for this project, please describe when and how often it meets.

Yes. There is a DMC that meets annually, and more often as needed. The committee considers the following issues immediately: concerns about the possibility of maltreatment; concerns with participant safety (e.g., severe depression, suicidality); reactions to experimental procedures that did not abate before leaving the lab; concerns with debriefing following peer simulation; problems with participant confidentiality. Dr. Dozier is responsible for reporting any evidence or suspicion of maltreatment. In instances where concerns are raised but she determines that evidence does not meet threshold for reporting, she will consult immediately with the board to verify her decision. In annual meetings, the Board will review risks to participants, reasons for any drop-out, safeguarding of data, and any adverse events. This Board will report to the University of Delaware IRB and NIH as appropriate.

#### 8. COMPENSATION

Will participants be compensated for participation?

Yes.

If so, please include details.

Families will be compensated \$25 for their initial consent visit, which includes consent form review. Following the initial consent visit, families will be compensated \$100 for all other lab visits during their participation. Additionally, families will receive \$25 for each saliva collection kit that they complete. This totals \$150 in year 1 (age 8), \$125 in year 2 (age 9) and \$125 in year 3 (age 10). Children will be given ICP printed t-shirts each year at the end of the lab visit and a toy of their choosing. The child's teacher will also receive a \$10 electronic gift card for filling out forms about the child each year. Finally, families will be compensated for taxi or bus transportation costs to our lab facility.

#### For our back-up participants:

On days when we do not need them to come to lab to participate in peer groups, back-up participants will receive \$10 for making themselves available. On days when we need them to come to lab to participate in peer groups, back-up participants will be compensated \$50. Additionally, children will earn a prize.

#### 9. DATA

Will subjects be anonymous to the researcher?

No.

If subjects are identifiable, will their identities be kept confidential?

Yes. (See confidentiality section for additional information.)

How and how long will data be stored?

Data will be stored indefinitely, except cortisol samples which will be stored for a maximum of 5 years before being destroyed. Questionnaires will be stored in cabinets that are in locked offices at the University of Delaware. All identifying information will be removed from the questionnaires (e.g., names) and replaced with ID numbers. Digital and audio recordings will be downloaded to a password protected sever that is stored in a locked office at the University of Delaware. Saliva samples will be labeled only with an ID number and will be stored in freezers in locked laboratories at the University of Delaware.

How will data be destroyed?

After a maximum of 5 years, cortisol samples will be autoclaved and disposed of according the University's biological safety procedures in an appropriate landfill.

How will data be analyzed and reported?

Analyses: The focus of this study is to follow neglected children from a randomized clinical trial begun in children's infancy into middle childhood. Intervention effects on inhibitory control, emotion regulation, peer relations, and cortisol production are of primary interest, and we expect that these effects will be mediated by parental behavior. We will assess whether parenting during early or middle childhood best predicts outcomes for children during middle childhood, accounting for across-time stability in both child and parent behaviors. We will first examine whether there are main effects of risk status or interactions of risk status with intervention group in predicting middle childhood parenting or child outcomes. We will also consider the effects of variables such as gender, ethnicity, and child intelligence in preliminary analyses. Such variables will be included in primary analyses as moderators or covariates when indicated in preliminary analyses. Pre-intervention measures of child behaviors can also be considered for inclusion in analyses where appropriate. These pre-intervention data will not always provide direct assessments of constructs of interest (e.g., there will be no pre-intervention measure of peer relations), but will provide checks on the equivalence of groups at baseline. Also, post-intervention outcomes from early childhood will be evaluated as possible predictors, mediators, or moderators of later outcomes, as appropriate. A low-risk comparison group is included to ensure that differences that we consider preferable are consistent with findings from a low-risk comparison group.

Analyses will be conducted to examine development over time in inhibitory control, emotion regulation, peer relations, and cortisol production as a function of intervention. Multilevel or hierarchical linear models (HLM; Raudenbush & Bryk, 2002) will be the primary method for analyzing intervention effectiveness. We will also extend the multilevel analyses into a structural equation modeling (SEM) framework in order to accommodate latent variables with multiple indicators and to conduct mediation analyses (Bollen & Curran, 2006). This data analytic framework can accommodate time-varying covariates, data that are missing at random (or ignorable missing data), and unequal time intervals between repeated measurements.

#### **10. CONFIDENTIALITY**

Will participants be audiotaped, photographed or videotaped during this study?

Yes.

How will subject identity be protected?

Parents participating in the study are assured of full confidentiality. Participant confidentiality will be protected by storing data and consent forms in data cabinets that are stored in locked offices at the University of Delaware. Digital and audio recordings, which are electronic files, are downloaded to a secure server that is stored in a locked room on campus. The computer file, developed for data management and analysis, will not identify participants by name. The longitudinal nature of the study requires a master list linking respondents, ID numbers, addresses and phone numbers. The master list will be stored on password-protected computers that are stored in locked offices at the University of Delaware.

#### For our back-up participants:

We will need to store contact information for our back-up participants in order to call and schedule them. Of note, we will not store their contact information in the database we use for participants for our full study. We will store their contact information in a password-protected spreadsheet that is saved on our lab's secure server.

Participants in our full study have an ID label. We must assign ID labels in some way to our back-up children so we can put them into the coding system. However, we will not have any document linking child name to an ID label. Instead, we will link ID label with the date of the playgroup.

Is there a Certificate of Confidentiality in place for this project? (If so, please provide a copy).

No.

#### 11. CONSENT and ASSENT

\_X\_\_\_ Consent forms will be used and are attached for review.

\_X\_\_Additionally, child assent forms will be used and are attached.

Consent forms will not be used (Justify request for waiver).

## 12. Other IRB Approval

Has this protocol been submitted to any other IRBs?

No.

If so, please list along with protocol title, number, and expiration date.

### 13. Supporting Documentation

Please list all additional documents uploaded to IRBNet in support of this application.

- 1) Consent forms
  - a. Previous Participants
  - b. Comparison Sample
  - c. Adoption Participants
  - d. Back-Up Participants
  - e. Back-Up Participants who Completed Play Groups
  - f. Computer Game Activity for all Participants
- 2) Child assent forms
  - a. Participants in full study
  - b. Back-Up Participants
- 3) Survey Instruments
  - a. Parent
    - i. Demographics Questionnaire
    - ii. Brief Symptom Inventory (BSI)
    - iii. Child Behavior Checklist (CBCL)
    - iv. Health Behaviors Questionnaire
    - v. Harter
    - vi. Reactive and Proactive Aggression Questionnaire
    - vii. Adverse Childhood Experience (ACE) Questionnaire
    - viii. Emotion Regulation Checklist
    - b. Child
      - i. Pubertal Developmental Scale (PDS; boy and girl versions)
      - ii. What am I Like (SPPC)
      - iii. Kerns Security Scale
      - iv. Reactive and Proactive Aggression Questionnaire
      - v. Money Task Form
      - vi. Woodcock-Johnson Tests of Achievement Protocols
      - vii. Woodcock-Johnson Tests of Cognitive Abilities Protocols
    - c. Teacher
      - i. Harter (TRS)
      - ii. Teacher Report Form (TRF teacher version of the CBCL)
      - iii. Emotion Regulation Checklist (same as parent version)
      - iv. Reactive and Proactive Aggression Questionnaire
- 4) Interviews
  - a. Parent
    - i. Attachment Script Assessment (ASA)

- ii. Social Support Interview (SSI)
- iii. Cumulative Risk Interview [Life Event Calendar(LEC)]
- iv. The Parent version of the Children's Interview for Psychiatric Symptoms (P-ChIPS) Scoring Form
- b. Child
  - i. Attachment Hierarchy Interview
  - ii. Middle Childhood Script Assessment (MC-ASA)
  - iii. The Child version of the Children's Interview for Psychiatric Symptoms (ChIPS) Scoring Form
- 5) Parent-Child Interaction Scripts
  - a. Age 8
  - b. Age 9
  - c. Age 10 (boy and girl versions)
- 6) Photo and Video Release
- 7) Teacher Release
- 8) Letter to Teachers
- 9) Peer Simulation Debriefing
- 10) Text for Back-up Participant Ad



**RESEARCH OFFICE** 

210 Hullihen Hall University of Delaware Newark, Delaware 19716-1551 Ph: 302/831-2136 Fax: 302/831-2828

DATE:

May 31, 2017

TO. Mary Dozier, PhD FROM: University of Delaware IRB STUDY TITLE: [547621-13] Intervening Early with Neglected Children: Key Middle Childhood Outcomes SUBMISSION TYPE: Amendment/Modification APPROVED ACTION: APPROVAL DATE: May 31, 2017 EXPIRATION DATE: February 14, 2018 **REVIEW TYPE:** Expedited Review per 45 CFR 46. 110 (b) (2)

Thank you for your submission of Amendment/Modification materials for this research study. The University of Delaware IRB has APPROVED your submission. This approval is based on an appropriate risk/benefit ratio and a study design wherein the risks have been minimized. All research must be conducted in accordance with this approved submission.

This submission has received Expedited Review based on the applicable federal regulation.

Please remember that <u>informed consent</u> is a process beginning with a description of the study and insurance of participant understanding followed by a signed consent form. Informed consent must continue throughout the study via a dialogue between the researcher and research participant. Federal regulations require each participant receive a copy of the signed consent document.

Please note that any revision to previously approved materials must be approved by this office prior to initiation. Please use the appropriate revision forms for this procedure.

All SERIOUS and UNEXPECTED adverse events must be reported to this office. Please use the appropriate adverse event forms for this procedure. All sponsor reporting requirements should also be followed.

Please report all NON-COMPLIANCE issues or COMPLAINTS regarding this study to this office.

Please note that all research records must be retained for a minimum of three years.

Based on the risks, this project requires Continuing Review by this office on an annual basis. Please use the appropriate renewal forms for this procedure.