

PENN STATE BRANDYWINE
JANE E. COOPER HONORS PROGRAM

DIVISION OF HEALTH AND HUMAN DEVELOPMENT

A DIGITAL WORLD: DO SCREENS INFLUENCE PARENT-CHILD
INTERACTION?

ALLYSON MOORE
SPRING 2020

A thesis
submitted in partial fulfillment
of the requirements
for a baccalaureate degree
in Psychology
with honors in Human Development and Family Studies

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ABSTRACT

As technology continues to grow in prevalence, it is important to investigate the impacts of technology on children during their most impressionable time. By 2016, children were spending more time with media and technology than they spent on any other activity besides sleeping (Rideout, 2017). In the limited studies of parent-child interaction around screens, findings show that increased technology use may decrease the quality of parent-child interactions through behaviors of both children and parents (Radesky, Silverstein, Zuckerman, & Christakis, 2014), but it is not entirely clear exactly *how* technology use may change parent-child interactions. For example, in studies of electronic versus non-electronic toys, Wooldridge and Shapka (2012) found that mothers were less responsive to their children when engaged in a play session with an electronic toy compared to a matched traditional toy. In this project, we aimed to uncover the types of parent-child interactions that are and are not impacted by screen use relative to more traditional, non-electronic toys.

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ACKNOWLEDGEMENTS

I would like to thank my thesis supervisor, Dr. Jennifer Zosh. Without her guidance and support, this thesis would not have been possible. I would also like to thank my academic advisor, Dr. Laura Evans for her role in this thesis project. I would like to thank all of the student researchers involved with the Brandywine Child Development Lab for helping to get this project started. Additionally, I would like to thank the Cooper Honors Program for awarding me with the Honors Research Grant and allowing me to fund this research. Most importantly, I would like to thank my mom, siblings, friends, and boyfriend for supporting me and encouraging me throughout this research.

Chapter 1

Introduction

Early child development largely determines a child's success in middle and late childhood (Rosenbaum, 1975) and even adulthood (Raby, Roisman, Fraley, & Simpson, 2014); however, many aspects can influence the quality of early development in either positive or negative directions. *Risk factors* are influences during early child development that increase the likelihood of a child experiencing adverse outcomes. Walker and colleagues (2011) explain risk factors affecting the quality of early development such as poverty, lack of stimulation, and excessive stress. Children's physical and cognitive development is also sensitive to environmental toxins such as lead exposure or lack of clean water (Walker et al., 2011). *Protective factors* are the influences throughout early development that promote a child's growth and combat the negative effects of risk factors; some well-known protective factors include parental education and socio-emotional stimulation (Walker et al., 2011). High quality parent-child interactions seem to be a strong and effective protective factor that is necessary for healthy development (Luthar, 2006). There are many facets to high quality parent-child interactions (e.g., eye contact, attachment) throughout childhood that help a child to develop cognitively and socio-emotionally.

While some environmental factors (e.g., pollutants) and contextual factors (e.g., parental education) have clearly positive or negative impacts on child development, many are not so well defined. This thesis explores the role of a quickly changing aspect of child development; namely, technology and its impact on parent-child interaction during play.

Parent-child Interactions

The relationship between children and their parents begins at birth and is formed throughout the early years of childhood. Healthy relationships and interactions between children and parents are essential to child development (Eliot, 1999; Galinsky, 2010). Children develop and learn best when they have warm, comforting, and understanding relationships with their caregivers/parents (Bronson & Merryman, 2009; Galinsky, 2010).

A number of behaviors seem to help build strong and positive relationships between parents/caregivers and children. For example, infants as young as three months begin to gaze in the direction of their parents or others who are speaking to them (Brooks & Meltzoff, 2002). As children grow, the matched gaze between child and caregiver develops into joint attention, where infants follow the gaze of their caregiver and learn more about objects or events as they are identified (Brooks & Meltzoff, 2002). Further, parents often speak to infants using infant-directed speech; they speak slowly in a high-pitched, warm tone of voice (Kuhl, 1983). Ramirez-Esparza, Garcia-Sierra, and Kuhl (2014) explain that this infant-directed speech is linked to increased babbling and higher vocabulary as the infant grows. Whether it be verbal or non-verbal communication, one key factor to high quality interactions is contingent responses between the child and the caregiver. Children learn the rules of communication early on through contingent interactions with the adults in their lives; in other words, caregivers must respond when the child attempts to communicate through speech or non-verbal communication (e.g., reaching for an object, crying; Rosenbaum, 1975). All of the behaviors that influence parent-child interactions help to develop the child's form of attachment with that caregiver. High quality parent-child interactions will help to develop a secure attachment between parent and child, and vice versa. However, it should be noted that attachment style is not determined solely by quality of parent-child interactions; it is possible for children to develop insecure attachment even when parents are engaging in high quality interactions (Hong & Park, 2012).

One aspect of early social and emotional development is the attachment children form with their parents (Osofsky & Fitzgerald, 2000). There is variability in styles of attachment that children may exhibit. Attachment styles include secure, avoidant, anxious, and disorganized. Children with secure attachments often have a better sense of autonomy, while children with anxious, avoidant, or disorganized attachment styles appear to be more preoccupied and dismissive. Children with a secure attachment tend to have higher quality social and emotional interactions with their caregivers than those children with an avoidant or disorganized attachment style. Parents play an important role in children's attachment styles. Parents who attend to their children's behaviors and respond to them accordingly are more likely to develop a secure attachment with their children (Myers & DeWall, 2015). These interactions must be contingent upon one another; children whose parents respond only sometimes are less likely to develop secure attachment (Myers & DeWall, 2015). While attachment is important to child development, it is not the only factor to consider when thinking about parent-child interactions.

Researchers are also interested in exploring the quality of parent-child interaction across multiple dimensions. One could imagine that some parents are highly focused on teaching their children but are less likely to be warm in their caregiving. Alternatively, some parents may be focused on providing warmth and encouragement, but spend less effort on teaching behaviors. The PICCOLO coding tool considers four important domains that can be observed during parent-child interaction. These four domains include affection, encouragement, responsiveness, and teaching. Parental affection, encouragement, and responsiveness have been positively linked to child's increased self-esteem and behavior control (Suchodoletz, Trommsdorff, & Heikamp, 2011), while parental teaching focus has been linked to higher comprehension and vocabulary retention (DeLoache et al., 2010). For instance, affection may be presented when the caregiver smiles at the child or speaks in a warm tone of voice (see Table 1-1). Encouragement may be seen when a caregiver offers suggestions to help the child or encourages the child to handle toys (see

Table 1-2). Responsiveness may be seen as caregivers changing pace to meet the child's interests or replying to the child's utterances (see Table 1-3). Additionally, teaching behaviors may include caregivers engaging in pretend play with the child or asking the child for information during play (see Table 1-4). PICCOLO includes a checklist of 29 observable items that prove beneficial to early development; each of these individual behaviors help to support the protective factor of high-quality parent-child interaction.

While there is an abundance of research about parent-child interactions and relationships, it is not yet well defined as to exactly how technology influences these essential interactions during early development. Research is beginning to explore these impacts although much work remains to be done. Parish-Morris, Mahajan, Hirsh-Pasek, Golinkoff, & Collins (2013) explored parent-child story reading as well as child comprehension of the book when using electronic books in comparison to traditional books. This study found that both dialogic reading (prompting the child to extend the story and expanding on their response) between parents and children as well as the child's comprehension were negatively impacted when reading electronic books (Parish-Morris et al., 2013). Play with toys and/or books involving technology decreases the quality of language that a child hears (Zosh et al., 2015), as well as decreases conversations between parent and child during play (Chiong, Ree, Takeuchi, & Erickson, 2012). Additionally, play involving tablets encourages social control behaviors and increases more solitary play instead of joint play when compared to traditional toys (Hiniker, Lee, Kientz, & Radesky, 2018; Munzer, Miller, Weeks, Kaciroti, & Radesky, 2019). This paper further explores the effects of technology during play on the parent-child dyad.

Technology Use

Technology use, by both children and parents, is continuing to increase as technology is more easily accessible (Rideout, 2017). In addition to technology use growing over time, children are also being exposed to technology at a much younger age than in previous decades. In 1970,

children were being exposed to television around age four; currently, children are exposed to screens as early as four months of age (Chassiakos, Radesky, Christakis, Moreno, & Cross, 2016). It is currently recommended to avoid technology and screen time for children under two years of age, with the exception of video chat calls (American Academy of Pediatrics, 2018). Video chat calls allow for a similar contingent conversation and interaction as would happen during face-to-face conversations. Further, the American Academy of Pediatrics (2018) recommends limiting screen time for children aged two- to five-years old to just one hour per day. Although these recommendations are in place, it is clear that they are not always followed. Children and parents spend an average of nine hours with technology each day, not including time used for homework and work (Felt & Robb, 2016). Further, children spent an average of 48 minutes per day on just mobile devices in 2017 (Rideout, 2011; Rideout, 2017). Rideout (2017) reports to Common Sense Media that 95% of children under eight years have access to a mobile device in the home and one in three internet users is a child or young teen.

Parent-child interaction with technology

Given the importance of parent-child interaction, it is perhaps unsurprising that at least a few researchers have begun to examine the impact of technology on the quality of parent-child interaction. This section will explore the impact of various types of technology (television, screens/tablets, and toys) on the quality of parent-child interaction.

Television

Many parents allow their children to use technology or watch television in order for them to get chores done or relax; however, this is not beneficial when children learn best from observing parental behaviors (Plowman, McPake, & Stephen, 2008). One study investigated whether a parent's focus on teaching influences a child's retention of new words while watching educational television (TV). Fender and colleagues (2010) assessed each child's knowledge of the vocabulary from the program prior to testing (i.e., if the child knew the meaning of the word, if

the child could say the word) and then recorded each parent-child dyad while they watched the film. Researchers paid attention to the child's engagement during the film as well as how the parents used words from the film and encouraged their child to use the words. Children remained engaged in the film and showed a more positive affect when parents spoke to them about the film and spoke to them frequently (Fender et al., 2010). Additionally, children retained more of the new vocabulary when parents showed a higher focus on teaching and keeping the child engaged (DeLoache et al., 2010). When watching educational TV programs, it is not enough to let the child watch alone; parents must be engaged with the child and keep them engaged with the program. One thing to note, however, is that today's tablet-based technology is more contingent than television, leading to open questions about the role of parents in traditional toy play versus tablet-play.

Tech Toys

While there has been an increased focus on play involving screens (e.g., tablets, television), research in the area of electronic toys is limited. Electronic toys, or tech toys, can be defined as toys that use batteries and provide light and audio feedback during play. Zosh and colleagues (2015) investigated the amount and quality (i.e., unique words, the focus of the speech) of language children hear when playing with an electronic or traditional shape sorter. This research found that while children heard more words in the electronic toy condition (due to increased speech from the toy), the quality of speech they heard decreased (Zosh et al., 2015). This study suggests that play involving electronic toys decreases the amount of learning that takes place during play as well as the quality of parent-child interactions during play. Wooldridge and Shapka (2012) produce a similar finding regarding the effect of electronic toys on play. Mothers and children were observed playing with both a traditional and a matched electronic toy; the videos were coded using the PICCOLO coding system which assesses parental affection, encouragement, teaching, and responsiveness (Wooldridge & Shapka, 2012). Maternal

responsiveness, teaching, and encouragement were all significantly lower when playing with electronic toys compared to traditional toys. Although electronic toys precede the development of screen-based play, this area of technology usage is less explored in the area of early development and parent-child interactions.

Tablets and Applications

Tablets are used during play in forms other than reading electronic books; tablets are often loaded with applications (apps) targeted for young children. One area of research focuses on discovering how play involving apps influences interactions between parents and children. Hiniker, Lee, Kientz, and Radesky (2018) attempt to understand how play with apps affects parent-child interactions in comparison to play with traditional toys through observation of play sessions. This study found that children are more likely to play by themselves when playing with a tablet compared to the joint play often seen when playing with traditional toys (Hiniker et al., 2018). The research of Munzer and colleagues (2019) produced a similar finding: the design of tablets and tablet play encourages solitary play and less joint engagement between parent and child. When children and parents have less physical interaction, and are overall less engaged with one another, during play there are less opportunities for educational interactions. However, it is still unknown what the impacts might be if a parent and child willingly engage in play with a tablet together versus with a traditional toy. While some research finds that there is a cost to parent-child interaction when reading e-books versus traditional books (Chiong et al., 2012), more work is needed to explore possible effects of technology based play relative to non-technology play on different aspects (e.g., responsiveness, warmth, teaching) of parent-child interaction.

The Current Study

This study investigates the quality of the parent-child interaction when parent-child dyads play with a traditional (non-electronic toy or book) compared to play with a screen-based version

of that same toy/book. In this study, each parent-child dyad was asked to participate in a play session with a given toy (randomly assigned electronic or traditional) as they normally would at home. Each play session was recorded for video and audio and coded with a validated scale that quantifies the quality of the parent-child interaction (see below). Upon completion of play sessions, we compared the PICCOLO scores of parent-child dyads that played with screens vs. non-technology based versions of the same toy/book.

Chapter 2

Methods

Participants

Participants were 14 children (7 male) and their parents from families who visited the Delaware Children's Museum in Wilmington, DE, the on-campus Child Development Laboratory at The Pennsylvania State University Brandywine campus, and the Middletown Free Library in Media, PA; the participants took part in this study at one of these three locations. Eleven children engaged in the play session with only their mothers; two children engaged in play with both their mother and father; the remaining child engaged in play with their father. The families reported English as the primary language spoken at home. The children ranged in age from 26.6 months to 69.6 months ($M = 49.03$ months or 4.09 years).

PICCOLO Coding Protocol

The PICCOLO coding tool includes 29 observable parenting behaviors to look for during a play session. This coding scheme quantifies the quality of an interaction by assigning a numerical value that corresponds with how frequently each behavior was observed. PICCOLO separates these behaviors into four domains (e.g., affection, encouragement, responsiveness, teaching) as follows.

Table 1-1

Indicators of Affection as Classified on the PICCOLO Coding Scheme

Parent...	Observation Guidelines	Absent	Barely	Clearly
Speaks in a warm tone of voice	Parent's voice is positive in tone and may show enthusiasm or tenderness. A parent who speaks little but very warmly should be coded highly.	0	1	2
Smiles at child	Parent directs smiles toward child, but parent and child do not need to be looking at each other when smile occurs. Includes small smiles.	0	1	2
Praises child	Parent says something positive about child characteristics or about what child is doing. A "thank you" can be coded as praise.	0	1	2
Is physically close to child	Parent is within easy arm's reach of child, comfortably able to sooth or help. Consider context: Expect more closeness for book reading than for playing house.	0	1	2
Uses positive expressions with child	Parent says positive things or uses words like "honey," "kiddo," or an affectionate nickname. (<i>Note:</i> Emphasis on verbal expressions.)	0	1	2
Is engaged in interacting with child	Parent is actively involved together <i>with</i> child, not just with activities or with another adult.	0	1	2
Shows emotional warmth	Parent shows enjoyment, fondness, or other positive emotion about child and directed to child. (<i>Note:</i> Includes verbal but emphasis on nonverbal).	0	1	2

Table 1-2

Indicators of Encouragement as Classified on the PICCOLO Coding Scheme

Parent...	Observation Guidelines	Absent	Barely	Clearly
Waits for child's response after making a suggestion	Parent pauses after saying something the child could do <i>and</i> waits for child to answer or do something, whether child actually responds or not.	0	1	2
Encourages child to handle toys	Parent offers toys or says positive things when child shows obvious interest in toys. (Does not include preventing children from mouthing toys.)	0	1	2
Supports child in making choices	Parent allows child to choose activity or toy <i>and</i> gets involved with activity or toy child chooses.	0	1	2
Supports child in doing things on his or her own	Parent shows enthusiasm for things child tries to do without help, lets child choose how things are done, <i>and</i> lets child try to do things before offering help or suggestions. Parent can be engaged in activities child does "on his/her own."	0	1	2
Verbally encourages child's efforts	Parent shows verbal enthusiasm, offers positive comments, <i>or</i> makes suggestions about child's activity.	0	1	2
Offers suggestions to help child	Parent gives hints or makes comments to make thing <i>easier</i> for child without interfering with child's play.	0	1	2
Shows enthusiasm about what child is doing	Parent makes positive statements, claps hands, or shows other clear positive response to what child is doing, including quiet enthusiasm such as patting child, nodding, smiling, or asking child questions about activities.	0	1	2

Table 1-3

Indicators of Responsiveness as Classified on the PICCOLO Coding Scheme

Parent...	Observation Guidelines	Absent	Barely	Clearly
Pays attention to what child is doing	Parent looks at and reacts to what child is doing by making comments, showing interest, helping, or otherwise attending to child's actions.	0	1	2
Changes pace or activity to meet child's interests or needs	Parent tries a new activity or speeds up or slows down an activity in response to where child looks, what child reaches for, what child says, or emotions child shows.	0	1	2
Is flexible about child's change of activities or interests	Parent accepts a child's choice of a new activity or toy <i>or</i> shows agreeableness about the change or about child playing in unusual ways with or without toys.	0	1	2
Follows what child is trying to do	Parent both responds to <i>and</i> gets involved with child's activities.	0	1	2
Responds to child's emotions	Parent reacts to child's positive or negative feelings by showing understanding or acceptance, suggesting a solution, reengaging the child, labeling or describing the feeling, showing a similar feeling, or providing sympathy for negative feelings.	0	1	2
Looks at child when child talks or makes sounds	When child makes sounds, parent clearly looks at child's face or (if eyes or child's face are not visible) parent's position and head movement face toward child.	0	1	2
Replies to child's words or sounds	Parent repeats what child says or sounds child makes, talks about what child says or could be saying, or answers child's questions.	0	1	2

Table 1-4

Indicators of Teaching as Classified on the PICCOLO Coding Scheme

Parent...	Observation Guidelines	Absent	Barely	Clearly
Explains reasons for something to child	Parent says something that could answer a “why” question, whether child asks a question or not.	0	1	2
Suggests activities to extend what child is doing	Parent says something child could do to add to what child is already doing but does not interrupt child’s interests, actions, or play.	0	1	2
Repeats or expands child’s words or sounds	Parent says the same words or makes the same sounds child makes <i>or</i> repeats what child says while adding something that adds to the idea.	0	1	2
Labels objects or actions for child	Parent names what child is doing, playing with, or looking at.	0	1	2
Engages in pretend play with child	Parent plays make belief in any way-for example, by “eating” pretend food.	0	1	2
Does activities in a sequence of steps	Parent demonstrates or describes the order of steps or does an activity in a way that a definite order of steps is clear even if parent does not say exactly what the steps are. Book reading counts <i>only</i> if parents makes the steps explicit by exaggerating or explaining the steps while reading.	0	1	2
Talks to child about characteristics of objects	Parent uses words or phrases that describe features such as color, shape, texture, movement, function, or other characteristics.	0	1	2
Asks child for information	Parent asks any kind of question or says, “tell me,” “show me,” or other command that requires a yes/no response, short answer, or longer answer-whether or not child replies. Does not include questions to direct attention (“See?”) or suggest activities (“Wanna open the bag?”).	0	1	2

Stimuli and Procedure

Materials

Each parent-child dyad was randomly assigned to play with either a non-electronic traditional toy or book, or an electronic toy or book on the laboratory's iPad. Children who read either a traditional or electronic book read *The Pokey Little Puppy*; children also played with traditional blocks or a block building app as well as Fruit Ninja on the laboratory's iPad. While the traditional and electronic book fall under education toys, the non-electronic toy was considered non-educational. The non-electronic toy (blocks) as well as the paper book and matched e-book were age appropriate for the children.

Procedure

Parents and children were randomly assigned to play with an electronic or non-electronic toy. After presenting the toy, the researcher instructed the caregiver to play with the child as they would at home. The researcher left the room for the duration of the play session and started the timer. Each play session was timed using the timer on an iPhone standard clock application. The researcher observed and recorded the play session via audio and video recordings using the laboratory cameras. After ten minutes of play, the researcher returned and asked the parent-child dyad if they had a fun time playing. The researcher thanked the parent and child as well as gave the child a personalized certificate.

The video recordings of each play session were later reviewed for coding. There were four variables of interest using the PICCOLO coding tool: affection, responsiveness, encouragement, and teaching. The toy that the parents and children interacted with was also recorded.

Chapter 3

Results

This study investigated how electronic toys influenced parent-child interactions in comparison to traditional toys. This question was investigated using the observed play session and the PICCOLO coding tool.

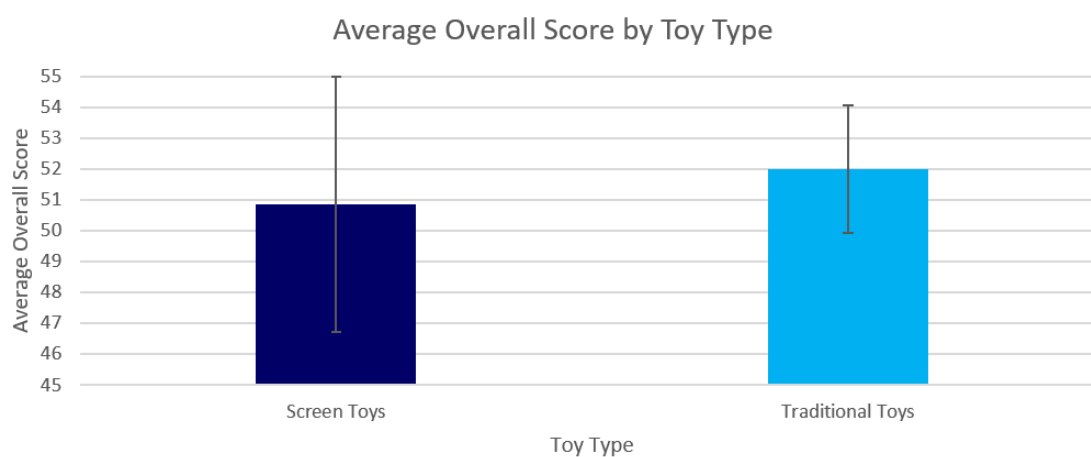
First, we examined overall parent-child interaction by summing all total scores across the four domains (see Figure 1). This analysis revealed essentially no difference between the overall interactions regardless of whether the parent and child were interacting with screens ($M = 50.86$; $SD = 4.14$) or traditional toys/books ($M = 52$; $SD = 2.08$). This overall score does not tell us, however, whether the interaction was similar or different across each of the four domains, or within specific individual items within each domain. To compare the domains to one another, we then calculated the overall sum of behaviors for each domain by summing the seven (affection, engagement, and responsiveness) or eight (teaching) items that made up each domain. This analysis found relatively no difference in all domains other than teaching (see Figure 2). From this analysis, we found that average overall teaching scores were less when dyads were playing with screen-based toys ($M = 11$; $SD = 1.63$) or traditional toys/books ($M = 12.86$; $SD = 1.86$). Next, we calculated the overall average within each of these domains to better understand parent-child. Again, this analysis showed minimal difference in all domains other than teaching (see Figure 3). Similar to previous analyses, this showed that parent-child interactions related to teaching behaviors suffer when playing with screens ($M = 1.38$; $SD = 0.20$), compared to play with traditional toys ($M = 1.61$; $SD = 0.23$). To conduct a more fine-grained analysis, we next created average scores for each individual item within each domain (see Figure 4). The results of

this analysis agreed with previous analyses in that parent-child interaction suffered in the teaching domain when playing with screen toys compared to traditional toys.

Finally, we investigated differences between toy type for each individual item within each domain. This analysis revealed many more similarities than differences; however, some differences did exist. We then conducted a closer examination of individual items in which there was a difference of more than 0.2 between the average score for an individual item based on condition (see Figure 5). This showed that there were no individual items in the Responsiveness domain that differed between play with traditional toys/books or screen-based versions. Further, the two domains which were most influenced by toy type were encouragement and teaching. Each of these domains differed on three specific items. Under the encouragement domain, parents were more likely to support their child in doing things by themselves when playing with a screen-based toy ($M_{\text{Screen}} = 2$; $M_{\text{Traditional}} = 1.71$). Ironically, parents were also more likely to offer suggestions to help the child when playing with screen-based toys. On the other hand, parents were more likely to verbally encourage their child's efforts when playing with traditional toys in comparison to screen-based toys. When looking at the teaching domain, parents were more likely to explain reasons for something, engage in pretend play, and talk about characteristics of objects when playing with traditional toys in comparison to screen-based toys. Outside of these two domains, there was one individual item that differed in the affection domain. This analysis found that parental use of positive expressions towards their children (e.g., 'sweetie' or a nickname) was more frequent when playing with screen-based toys than when playing with traditional toys.

Figure 1

Average Overall Score by Toy Type

**Figure 2**

Average Total Score of All Domains by Toy Type

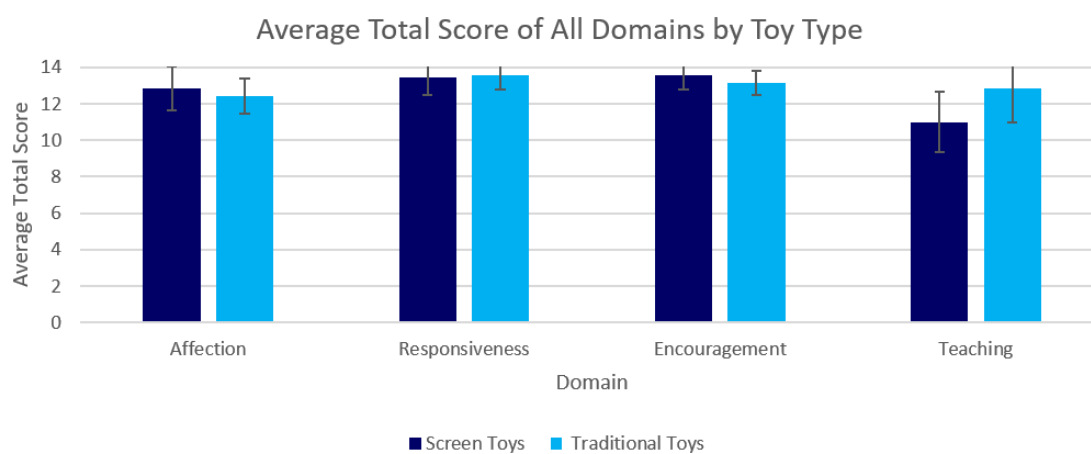
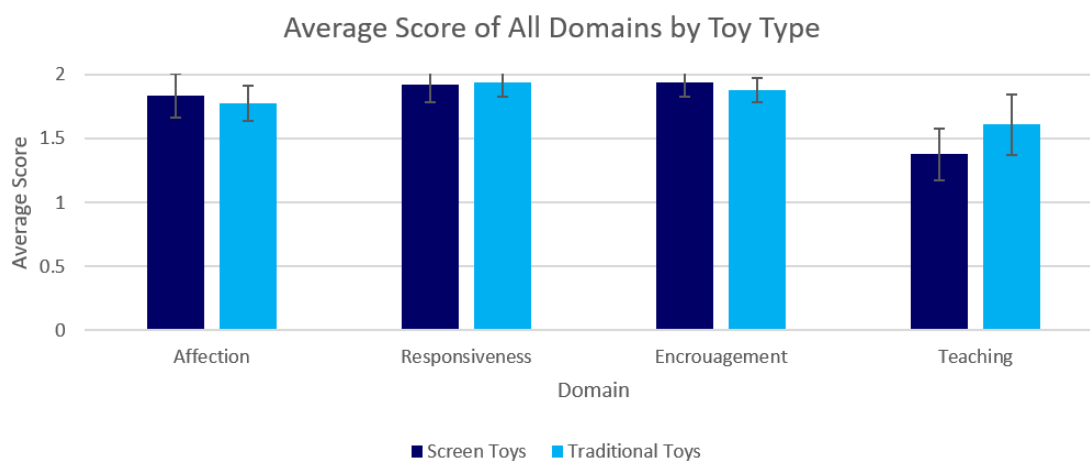
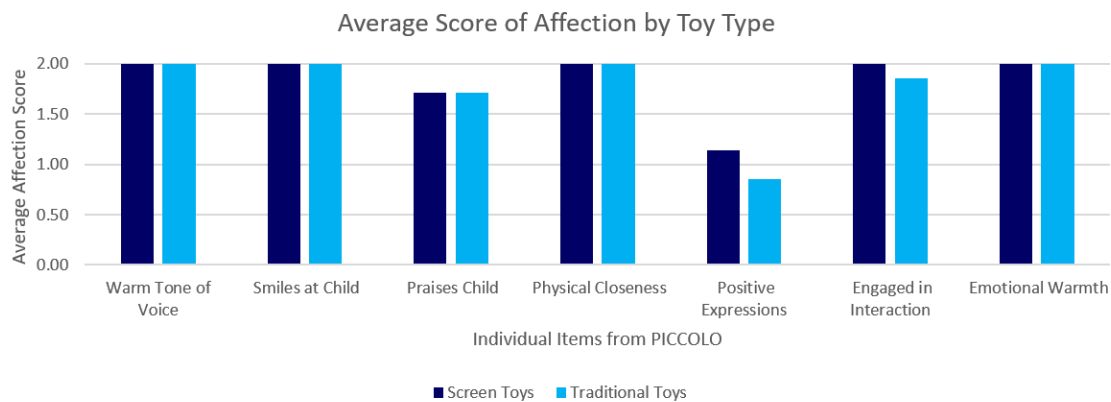
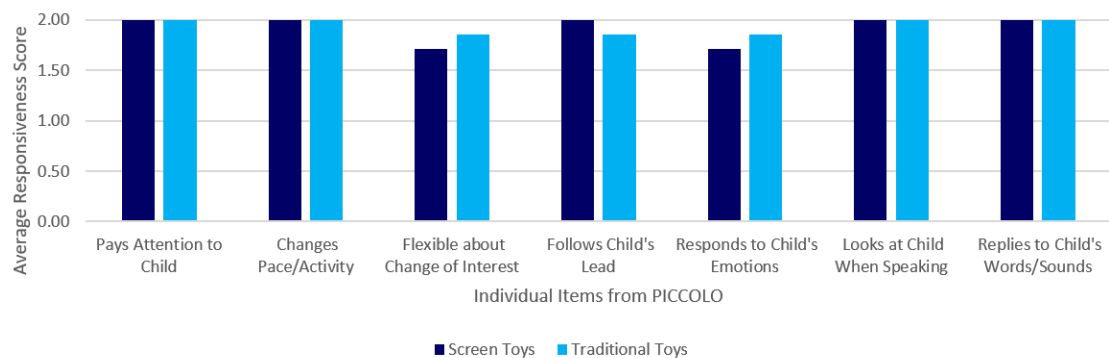
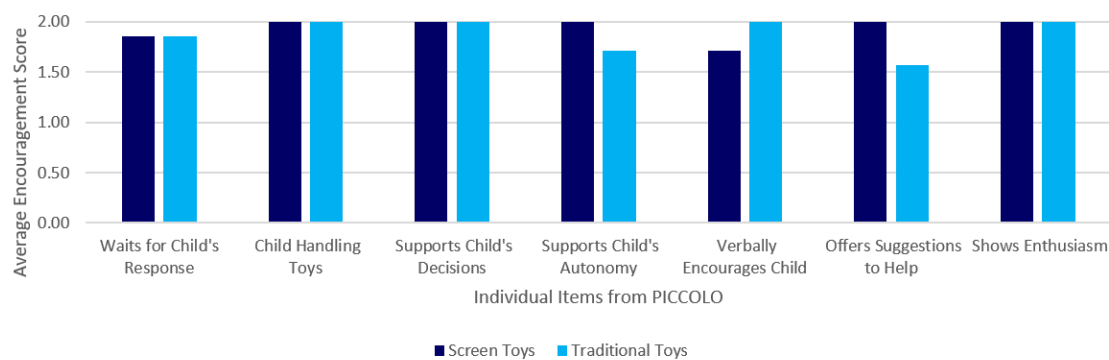


Figure 3*Average Score of All Domains by Toy Type***Figure 4***Average Scores of Each Domain*

Average Score of Responsiveness by Toy Type



Average Score of Encouragement by Toy Type



Average Score of Teaching by Toy Type

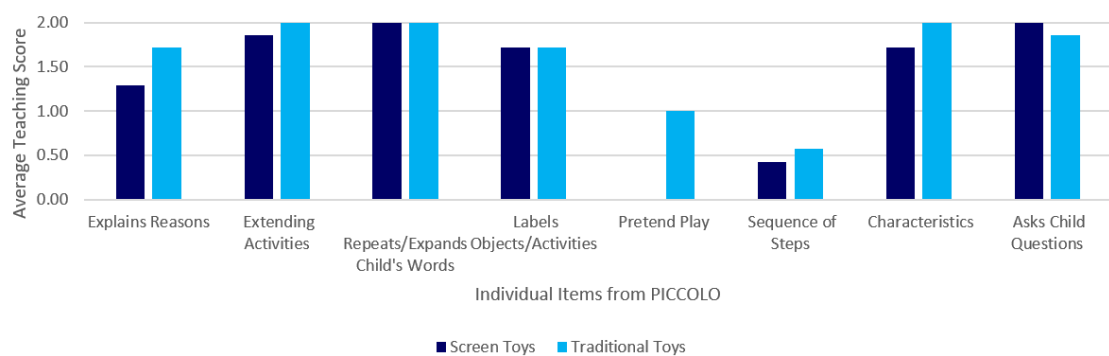
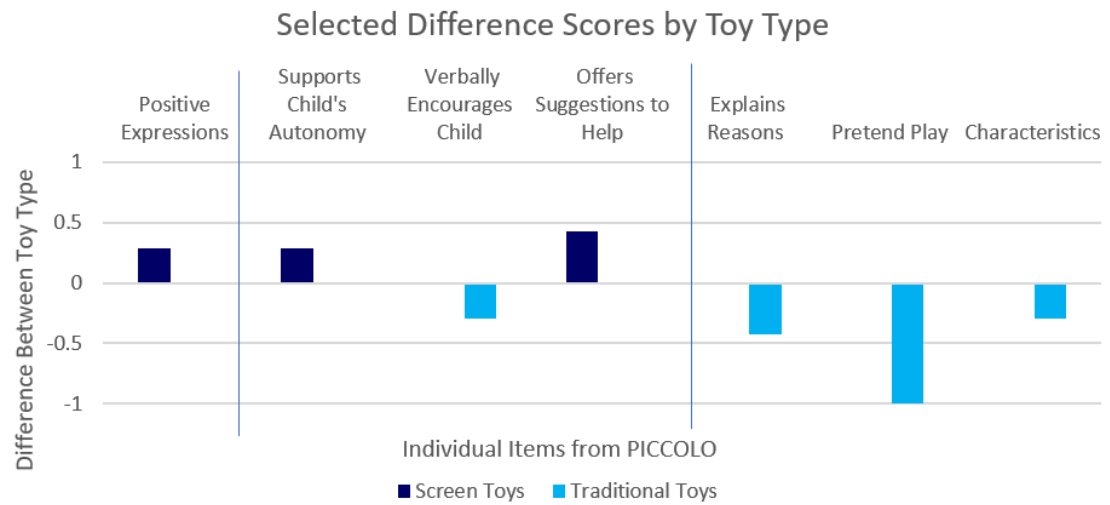


Figure 5*Selected Difference Scores by Toy Type*

Chapter 4

General Discussion

This research aimed to determine the effect of screen-based toys on parent-child interaction during play in comparison to play with traditional, non-electronic toys. While our analyses showed fewer differences than expected, there were some differences to be noted. Overall, parent-child interactions involving teaching decreased when play involved a screen-based toy. Further, we found more variability in parental behaviors when playing with a screen-based toy compared to a traditional, non-electronic toy. There was little difference in other areas of parent-child interaction overall (affection, responsiveness, encouragement), but there was notable difference on specific behaviors within these areas. From our analyses, many areas of parent-child interaction were relatively unchanged when playing with screen-based toys versus traditional toys, but other aspects of parent-child interaction may be impacted (in both positive and negative ways). This suggests that parents need not be overly worried, but should be aware of potential impacts to parent-child interaction based on the types of toys they are playing with together.

While this study gave us insight into parent-child interaction when playing together with a toy, it is important to note that many parents themselves are using technology when around their children (Radesky et al., 2014) and often turn to technology to babysit or entertain their child while doing other things (Radesky et al., 2014). Below, these two areas are explored more deeply. Finally, the prevalence of technology in service of educational goals is explored.

Parental Technology Use

Parents and caregivers are spending increasing amounts of time using technology devices (e.g., cell phones), which can change the way they are interacting with children. Parents may implement technology as a way to distract their children or keep the peace, but they also use technology in order to stay in touch with relatives and friends, keep up with work, or schedule their daily activities (Plowman, McPake, & Stephen, 2008; Radesky et al., 2016). In one study conducted by Radesky and colleagues (2014), researchers observed parental technology use when out to eat with young children and found that the more absorbed the parent was in their device, the less they focused on their children. Further, parents are more focused on their devices when texting or swiping than when making a phone call; this is likely due to the fact that parents can make eye contact with their children and respond to bids for attention nonverbally when only engaged on a phone call (Radesky et al., 2014). Researchers found that when parents were highly absorbed in their devices, children would engage in disruptive behaviors and parents would respond to these bids by swatting children's hands away, scolding the child, or giving the child their own device to engage with. Another study showed that mothers were less likely to show encouraging behaviors when using a mobile device. Radesky and colleagues (2015) assessed both verbal and nonverbal encouraging behaviors as children tried different foods and found that the most notable decrease in encouragement occurred when mothers used a mobile device while a child was introduced to an unfamiliar food. The experience of being introduced to an unfamiliar food is similar to the many novel experiences young children have; it is essential for children to have parental support and guidance in unfamiliar situations. Although parental technology use decreased the amount of verbal and non-verbal responses from parents, shared viewing of the same device and minimal parental viewing decreased these effects.

Future directions include conducting an experiment that teases about parent and child technology use and its impact on parent-child interactions. Due to the COVID-19 pandemic, this

designed study was unable to be completed for this thesis (see Appendix A for the IRB-approved protocol).

Parental Views about Technology and Their Role

With the growing use of technology and the increase of technology-based toys, it is no surprise that ‘play time’ for children and parenting styles are changing to accommodate the new style of toys and games for children. In one case study that aimed to determine how and why parents use technology with children, it was found that parents are not teaching their children how to use technology and believe that kids just ‘pick it up’ from observing adults and older siblings in their lives (Plowman, McPake, & Stephen, 2008). Researchers also found that parents do not introduce technology for educational purposes; they often allow children to use technology or watch television to distract them so that parents have uninterrupted time for chores or relaxation (Plowman, McPake, & Stephen, 2008). Children may view technology as a reward; in this sense, parents are rewarding their children for leaving them alone. Additionally, parents often allow their children to use technology at the same time they are using their own because it is more peaceful and prevents conflict (Radesky et al., 2016). In a follow-up study, researchers found that parents often allow children free reign when playing with technology because they are unsure how to set boundaries and guidelines for tech play (Plowman, McPake, & Stephen, 2010). An important aspect of early development and parent-child interactions is scaffolded play. When parents are aware of their children’s behaviors and learning potential during play, they are better equipped to help their child learn more than they could when playing by themselves (Fender, Richert, Robb, & Wartella, 2010). The findings from the previous studies support the idea that parents are unaware of how to scaffold play when it involves technology. Research is growing in the area of technology as play; however, with the many types of technology available previous research includes many forms of tech play.

Learning from Apps

While this study suggests that there may not be a cost to most aspects of parent-child interaction, the question of what children learn from screens versus traditional toys/books is still a highly controversial topic. Few apps on the market are designed with children's learning in mind; apps that claim to be educational may not be designed with consideration for how children really learn (Hirsh-Pasek et al., 2015). Many children's apps are not reviewed before being placed on the market, and with the growing technology parents are not always sure how to implement and regulate technology use in their children's lives (Hirsh-Pasek et al., 2015; Plowman, McPake, & Stephen, 2010). Researchers analyzed the educational benefits in educational apps on the market and found that they are not always as beneficial as they appear. Hirsh-Pasek and colleagues (2015) analyzed these apps through the lens of the 'four pillars': active learning, engagement, meaningful experiences, and social interactions. Researchers argued that while all screen-time is not bad, apps can be created in a more effective way to meet expectations in all four pillars while also being of educational benefit to children using them (Hirsh-Pasek et al., 2015).

In sum, this study represents the first step towards understanding how parent-child interactions are influenced during play with screen-based toys in comparison to technology-based toys. Further research is needed to draw firm conclusions on how technology influences parent-child interactions during play. This study is a start to understanding how this new electronic culture will impact early development through parent-child interactions.

Appendix A

Protocol for Original IRB-approved Study

HRP-591 - Protocol for Human Subject Research

Protocol Title:

Provide the full title of the study as listed in item 1 on the “Basic Information” page in CATS IRB (<http://irb.psu.edu>).

Investigating the impact of technology on parents and children during toy play

Principal Investigator:

Name: Jennifer M. Zosh

Department: Human Development and Family Studies

Telephone: 610-892-1438

E-mail Address: jzosh@psu.edu

Version Date:

Provide the date of this submission. This date must be updated each time the submission is provided to the IRB office with revisions. DO NOT revise the version date in the footer of this document.

[Type text here]

Clinicaltrials.gov Registration #:

Provide the registration number for this study, if applicable. See “HRP-103- Investigator Manual, When do I have to register my project at ClinicalTrials.gov?” for more information.

[Type text here or indicate as not applicable]

Important Instructions for Using This Protocol Template:

This template is provided to help investigators prepare a protocol that includes the necessary information needed by the IRB to determine whether a study meets all applicable criteria for approval.

1. GENERAL INSTRUCTIONS:

- Prior to completing this protocol, ensure that you are using the most recent version by verifying the protocol template version date in the footer of this document with the current version provided in the CATS IRB Library.
- Do not change the protocol template version date located in the footer of this document.

- Some of the items may not be applicable to all types of research. If an item is not applicable, please indicate as such or skip question(s) if indicated in any of the instructional text.
- **GRAY INSTRUCTIONAL BOXES:**
 - Type your protocol responses below the gray instructional boxes of guidance language. If the section or item is not applicable, indicate not applicable.
 - **Penn State College of Medicine/Penn State Health researchers:** Delete the instructional boxes from the final version of the protocol prior to upload to CATS IRB (<http://irb.psu.edu>).
 - **Penn State researchers at all other campuses:** Do NOT delete the instructional boxes from the final version of the protocol.
- Add the completed protocol template to your study in CATS IRB (<http://irb.psu.edu>) on the “Basic Information” page.

2. CATS IRB LIBRARY:

- Documents referenced in this protocol template (e.g. SOP’s, Worksheets, Checklists, and Templates) can be accessed by clicking the Library link in CATS IRB (<http://irb.psu.edu>).

3. PROTOCOL REVISIONS:

- When making revisions to this protocol as requested by the IRB, please follow the instructions outlined in the Study Submission Guide available in the Help Center in CATS IRB (<http://irb.psu.edu>) for using track changes.
- Update the Version Date on page 1 each time revisions are made.

If you need help...	
University Park and other campuses: Office for Research Protections Human Research Protection Program The 330 Building, Suite 205 University Park, PA 16802-7014 Phone: 814-865-1775 Fax: 814-863-8699 Email: irb-orp@psu.edu	College of Medicine and Penn State Health: Human Subjects Protection Office 90 Hope Drive, Mail Code A115, P.O. Box 855 Hershey, PA 17033 (Physical Office Location: Academic Support Building Room 1140) Phone: 717-531-5687 Email: irb-hspo@psu.edu

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1.0 Objectives

1.1 Study Objectives

Describe the purpose, specific aims or objectives. State the hypotheses to be tested.

This study will investigate the impact of technology use by both parents and children during a naturalist play session with toys. Children will play with either traditional (non-battery operated) or technology-based (e.g., battery operated, enhanced with sounds) toys under a parent's supervision (see attached materials for toy examples). During the play session parents will be assigned to one of two groups: they will either be required to keep their cellphone outside of the observation room, or required to have their cellphone present and visible to their child. This study has two specific aims.

Specific Aim 1: By observing children and their parents in their assigned conditions, this study aims to examine if certain types of play (*i.e.*, playing with an electronic toy or a traditional toy) affect the interactions between parent and child during play.

Specific Aim 2: Secondly, we seek to examine whether the presence of parental technology (*i.e.*, cellphones) affects the child's engagement with the toy as well as the interactions between parent and child during play.

1.2 Primary Study Endpoints

State the primary endpoints to be measured in the study.

Clinical trials typically have a primary objective or endpoint. Additional objectives and endpoints are secondary. The endpoints (or outcomes), determined for each study subject, are the quantitative measurements required by the objectives. Measuring the selected endpoints is the goal of a trial (examples: response rate and survival).

-
- The study will be complete after a sufficient number of subjects have been run to test the above hypothesis.

1.3 Secondary Study Endpoints

State the secondary endpoints to be measured in the study.

Not applicable.

2.0 Background

2.1 Scientific Background and Gaps

Describe the scientific background and gaps in current knowledge.

For clinical research studies being conducted at Penn State Health/Penn State College of Medicine, and for other non-PSH locations as applicable, describe the treatment/procedure that is considered standard of care (i.e., indicate how patients would be treated in non-investigational setting); and if applicable, indicate if the study procedure is available to patient without taking part in the study.

Research studies investigating technology use are gaining in frequency, but still rather limited. Two studies heavily analyzed parental attitudes and family practices in relation to children's use of technology. Plowman, McPake, and Stephen (2010) used a case study method for 24 participants to determine what factors have the greatest impact on children's technology use. The researchers visited each family a total of five times and collected qualitative data regarding parental attitudes towards technology, the intended use of technology in the home, the actual use of technology in the home, and perceived educational benefits of technology (Plowman, McPake, & Stephen, 2010). This study was fueled by an earlier study from Plowman, McPake, and Stephen conducted in 2008 that also attempted to determine the factors that influenced children's technology use. In the earlier study, the researchers concluded that children's individual preferences had the greatest impact on what technology they used and how they learned from it (Plowman, McPake, & Stephen, 2008). Alternatively, the later study determined that the most important factor in children's technology use is actually parental beliefs about technology and parental regulation of technology use (Plowman, McPake, & Stephen, 2010). These results explained that parents are often confused about how to implement technology in the lives of their children and therefore, cannot properly regulate children's use of technology (Plowman, McPake, & Stephen, 2010). These two studies attempted to determine why children use technology; the remaining studies attempt to understand how technology use affects developmental and relational outcomes in children.

Several studies attempted to determine how technology use influences developmental outcomes in children. Li and Atkins (2004) collected information from 122 parents about how often their preschool aged children used technology and what types of technology the children were using. The researchers tested each child on a variety of tests including the Bender Visual Motor Gestalt test, the Boehm Test of Basic Concepts (third edition preschool), the second edition of the Test of Gross Motor Development, and a shorter, revised form of the Wechsler Preschool and Primary Scale of Intelligence (Li & Atkins, 2004). The

researchers compared the children's performance on the tests with the information about their technology use to conclude that female participants performed better on the tests and that children with access to a computer actually performed better on the tests as well (Li & Atkins, 2004). In another study, researchers tested children to determine the effect of television on their executive function (Lillard & Peterson, 2011). The study included three treatment conditions including fast-paced television, educational television, and drawing; each child performed their treatment condition for nine minutes prior to testing (Lillard & Peterson, 2011). The results of this study suggested that children who spend time watching fast-paced television programs have worse control over their executive functioning when compared to the other two groups; children who were assigned to the drawing condition performed significantly better than the other two groups (Lillard & Peterson, 2011). These two studies attempted to determine the effect of technology on developmental outcomes in children; however, they produced conflicting results. While different factors were being analyzed, the results directly conflict with each other as to whether technology helps or harms developmental outcomes.

The remaining studies took different approaches when attempting to determine the impact of technology on parent-child interaction and relationships. Fender, Richert, Robb, and Wartella (2010) analyzed parental teaching focus when their child is watching an educational DVD. The researchers observed 64 parent-child dyads and analyzed the parent's focus on teaching while the child watched the DVD (Fender, Richert, Robb, & Wartella, 2010). Fender and colleagues (2010) concluded that children were more engaged and displayed a more positive affect when their parents had a high-teaching focus as opposed to children with parents who were not focused on teaching their child. Another study prepared for the Joan Ganz Cooney Center (2012) observed 32 parent-child dyads while they read both a traditional print book and electronic book (e-book). The results of this study showed that children were more engaged when the parent was reading the traditional book than the e-book, likely due to less distraction from the technology enhancements (Joan Ganz Cooney Center, 2012). The final two studies compare different types of play and the impact they have on parent-child interaction. Hiniker, Lee, Kientz, & Radesky (2018) recorded and observed 15 parent-child dyads during play sessions and analyzed parental and child engagement and parental acknowledgement of child's bids. The researchers concluded that although children may enjoy using tablets during play, this type of play is not beneficial to them as it encourages the child to play on their own instead of involving the parent as well (Hiniker, Lee, Kientz, & Radesky, 2018). The researchers mention that if children's apps were created to include two players or a parental component, this type of play could be less damaging to the parent-child interaction (Hiniker, Lee, Kientz, & Radesky, 2018). Another similar study observed 25 mother-child dyads during a play session involving traditional and electronic toys (Wooldridge & Shapka, 2012). Wooldridge and

Shapka (2012) analyzed the recordings of these play sessions using the PICCOLO coding scheme to conclude that parental responsiveness, teaching, and encouragement decrease significantly when play involves electronic toys. Zosh, Verdine, Filipowicz, Golinkoff, Hirsh-Pasek, and Newcombe (2015) conducted a study that examined the effects of electronic toys on language during play. This study observed 24 parent-child dyads during a play session using either a traditional shape sorter or a technology-enhanced shape sorter (Zosh et al., 2015). Each parent-child dyad played with their assigned toy as they would at home and the researchers recorded and analyzed the play sessions; the researchers specifically focused on the quality of speech the child heard during the play session (Zosh et al., 2015). Zosh and others (2015) concluded that children heard more words when playing with the electronic toy, due to the speech from the toy itself, but that the overall quality of speech heard by the child decreased when playing with the technology-enhanced toy. These studies all focused on parent-child interaction in relation to technology use and they all produced results suggesting that different types of technology can decrease the quality of parent-child interaction.

Current research in this area has produced conflicting results about the impact of technology use on developmental and relational outcomes in children and has focused heavily on technology in the form of screens (e.g., tablets, television). The goal of my research project is to compare play involving traditional toys and technologically enhanced toys (e.g., lights, audio feedback) to determine how this form of technology affects parent-child interaction. Most research in this area has focused on how technology use impacts children's behavior or developmental outcomes, while less research has focused on the relationship between parent and child when engaging in play with technology. The studies that have been done have not examined the interaction between child technology use with parent technology use.

2.2 Previous Data

Describe any relevant preliminary data.

This study and its design will be informed by the designs of similar studies conducting in the PI's lab and other labs across the country.

2.3 Study Rationale

Provide the scientific rationale for the research.

Most of the research about technology-based toys is conducted with the use of electronic devices such as tablets, phones, computers, etc. One relatively unexplored area in this line of research is the comparison of traditional toys with matched electronically enhanced versions of the same toy. Additionally, the impact of the presence of parental technology on parent-child interactions during play has yet to be established.

3.0 Inclusion and Exclusion Criteria

Create a numbered list below in sections 3.1 and 3.2 of criteria subjects must meet to be eligible for study enrollment (e.g., age, gender, diagnosis, etc.).

Vulnerable Populations:

Indicate specifically whether you will include any of the following vulnerable populations in this research. You MAY NOT include members of these populations as subjects in your research unless you indicate this in your inclusion criteria because specific regulations apply to studies that involve vulnerable populations.

The checklists referenced below outline the determinations to be made by the IRB when reviewing research involving these populations. Review the checklists as these will help to inform your responses throughout the remainder of the protocol.

- **Children** –Review “HRP-416- Checklist - Children”
- **Pregnant Women** – Review “HRP-412- Checklist - Pregnant Women”
- **Cognitively Impaired Adults**- Review “HRP-417- Checklist - Cognitively Impaired Adults”
- **Prisoners**- Review “HRP-415- Checklist - Prisoners”
- **Neonates of uncertain viability or non-viable neonates**- Review “HRP-413- Checklist - Non-Viable Neonates” or “HRP-414- Checklist - Neonates of Uncertain Viability”

3.1 Inclusion Criteria

- Create a numbered list of the inclusion criteria that define who will be included in your final study sample (e.g., age, gender, condition, etc.)

1. All typically-developing children between the ages of 2 years and 4 years of age are eligible for this study.
2. Only children who are proficient in English will be able to participate in this study.

3.2 Exclusion Criteria

- Create a numbered list of the exclusion criteria that define who will be excluded in your study.

1. Participants with severely abnormal vision or diagnosed cognitive impairments will be excluded from the study. However, we will not ask families any screening questions. Typically, parents of children with special needs will ask about their child’s eligibility. If asked, we will say that since

our studies are examining a new question related to cognitive development and we are not medical doctors nor trained to work with special populations, we are currently only conducting studies with ‘typically developing’ children. If parents report this when they are already at the lab or after the study, the child will still be able to participate but the participant’s data will not be included in the analysis.

2. We will also exclude any children whose parents report that they are not proficient in English.

3.3 Early Withdrawal of Subjects

3.3.1 Criteria for removal from study

- Insert subject withdrawal criteria (e.g., safety reasons, failure of subject to adhere to protocol requirements, subject consent withdrawal, disease progression, etc.).

The study will be immediately stopped if a parent requests that it will be stopped or if a child has any issues (starts crying strongly, needs a diaper change and is upset, etc.).

3.3.2 Follow-up for withdrawn subjects

- Describe when and how to withdraw subjects from the study; the type and timing of the data to be collected for withdrawal of subjects; whether and how subjects are to be replaced; the follow-up for subjects withdrawn from investigational treatment.

Since this is a 1-time behavior test, no-follow up will be given. If sufficient data is generated, the subject will be included in the final sample of children. If not, they will still be compensated with a certificate and sticker and will incur no differences in their experience than that of children who lasted the entire study.

4.0 Recruitment Methods

- Upload recruitment materials for your study in CATS IRB (<http://irb.psu.edu>). **DO NOT** include the actual recruitment wording in this protocol.
- StudyFinder: If StudyFinder (<http://studyfinder.psu.edu>) is to be used for recruitment purposes, separate recruitment documents do not need to be uploaded in CATS IRB. The necessary information will be captured from the StudyFinder page in your CATS IRB study.
- Any eligibility screening questions (verbal/phone scripts, email, etc.) used when contacting potential participants must be uploaded to your study in CATS IRB (<http://irb.psu.edu>).

[Do not type here]

4.1 Identification of subjects

Describe the source of subjects and the methods that will be used to identify potential subjects (e.g., organizational listservs, established recruitment databases, subject pools, medical or school records, interactions during a clinic visit, etc.). If not recruiting subjects directly (e.g., database query for eligible records or samples) state what will be queried, how and by whom.

StudyFinder:

- If you intend to use StudyFinder (<http://studyfinder.psu.edu>) for recruitment purposes, include this method in this section.
- Information provided in this protocol needs to be consistent with information provided on the StudyFinder page in your CATS IRB study.

For Penn State Health submissions using Enterprise Information Management (EIM) for recruitment, and for non-Hershey locations as applicable, attach your EIM Design Specification form on in CATS IRB (<http://irb.psu.edu>). See “HRP-103- Investigator Manual, What is appropriate for study recruitment?” for additional information. **DO NOT** include the actual recruitment material or wording in this protocol.

Infant and child participants will be recruited by using a general lab database of interested families. These families will be contacted via phone or email (if this is mentioned by the parent as the preferred contact method). The script for the telephone call and email are included with this submission. Also, a description will be listed on the lab website (also included with this submission).

At off-site locations, members of the lab team will be visible and available to interested families. Signs may be posted recruiting for participants generally (not for this specific study) and they may approach families to see if they are interested in hearing about what kinds of studies the lab does generally. If the parent expresses interest and has a child the correct age for this specific study, they will be asked if they would like to hear more and they will be told about the specific study using the script provided.

4.2 Recruitment process

Describe how potential subjects first learn about this research opportunity or indicate as not applicable if subjects will not be prospectively recruited to participant in the research. Subject recruitment can involve various methods (e.g., approaching potential subjects in person, contacting potential subjects via email, letters, telephone, ResearchMatch, or advertising to a general public via flyers, websites, StudyFinder, newspaper, television, and radio etc.). **DO NOT** include the actual recruitment material or wording in this protocol.

On-campus recruitment: (taken directly from approved [STUDY00012507](#))

General interest recruitment procedure: A member of the laboratory will be responsible for approaching and responding to potential participants throughout the entire process.

Existing participants: The lab maintains a database of families interested in hearing about potential research studies. A member of the research team will call or email families of children in the correct age range to see if they are interested in participating in this study. If they are not interested in participating in this study or any future study, we will thank them for their time and put them on a list of families that are NOT to be contacted again (using any method) in the future. If they are interested in participating in the future but not right now, they will remain in the laboratory database.

New families: If a parent responds via a phone call, flier, website response, or email to our general lab recruitment information, we will collect contact information about their family (name, address, telephone number, email address in order to email directions and appointment confirmation) as well as information about any children in the family that might be able to participate (name, birthdate, sex). If any of their children are in the appropriate age range for a currently running study, we will tell the parent that we currently have a study running that their child is eligible for and ask them if they would like to participate. If there is not a study currently running that their child will be eligible for, we will tell them that we will contact them again when we have a study for them to participate in.

Recruitment for this specific study: The default contact method will be via telephone and email. We will call the family and use the script that is included with this application. Additionally, we will send an email (also included with this application). Finally, a description of this project will be included on the website (also included with this application).

4.3 Recruitment Materials

We will maintain a website that will be hosted on the PSU Brandywine Servers (bcdl.bw.psu.edu)

General lab recruitment: We will recruit families to be in our general lab database through a variety of methods including word-of-mouth, fliers, etc. After a family decides they want to be in our lab database we will recruit them for a specific study. The scripts are attached to this application.

Recruitment for this specific study: The use of a general lab database will allow us to have access to a number of families that have children in the correct age group for this study. The ongoing recruitment

process outlined above will allow us to have a constant source of interested families to participate in this study. To recruit for this specific study, we will utilize the website, a telephone script, and an email. All of this information is included in this application under “recruitment materials.”

Scripts used to talk to parents at off-site locations are included with this application.

4.4 Eligibility/screening of subjects

There is no screening for this study. If a parent volunteers that their child has a disability and cannot participate due any reason, we will tell the parent that we will keep their child in mind for future studies. Because this is not a clinical study, we do not collect clinical information. If a parent self-reports that their child is not proficient in English, we will not have them participate in this study.

5.0 Consent Process and Documentation

Refer to the following materials:

- The “HRP-090- SOP - Informed Consent Process for Research” outlines the process for obtaining informed consent.
- The “HRP-091– SOP - Written Documentation of Consent” describes how the consent process will be documented.
- The “HRP-314- Worksheet - Criteria for Approval” section 7 lists the required elements of consent.
- The “HRP-312- Worksheet - Exemption Determination” includes information on requirements for the consent process for exempt research. In addition, the CATS IRB Library contains consent guidance and templates for exempt research.
- The CATS IRB library contains various consent templates for expedited or full review research that are designed to include the required information.
- Add the consent document(s) to your study in CATS IRB (<http://irb.psu.edu>). Links to Penn State’s consent templates are available in the same location where they are uploaded. **DO NOT** include the actual consent wording in this protocol.

[Do not type here]

5.1 Consent Process:

Check all applicable boxes below:

- ☒ Informed consent will be sought and documented with a written consent form *[Complete Sections 5.2 and 5.6]*

- ☐ Implied or verbal consent will be obtained – subjects will not sign a consent form (waiver of written documentation of consent) *[Complete Sections 5.2, 5.3 and 5.6]*
- ☐ Informed consent will be sought but some of the elements of informed consent will be omitted or altered (e.g., deception). *[Complete section 5.2, 5.4 and 5.6]*
- ☐ Informed consent will not be obtained – request to completely waive the informed consent requirement. *[Complete Section 5.5]*

The following checkbox is for all locations EXCEPT Penn State Health and College of Medicine:

- ☐ **Exempt Research at all Locations Except Penn State Health and the College of Medicine:** If you believe that the research activities outlined meet one or more of the criteria outlined in “HRP-312- Worksheet- Exemption Determination.” Please verify by checking this box that if conducting an exempt research study, the consent process will disclose the following (all of which are included in “HRP-590- Consent Guidance for Exempt Research”):

Penn State affiliation; name and contact information for the researcher and advisor (if the researcher is a student); the activities involve research; the procedures to be performed; participation is voluntary; that there are adequate provisions to maintain the privacy interests of subjects and the confidentiality of the data; and subjects may choose not to answer specific questions.

Note: If this box has been checked, skip the remainder of section 5 and proceed to section 6 of this protocol. If the investigator’s assessment is inaccurate, an IRB Analyst will request revision to the protocol and that an informed consent form be submitted for review and approval. Except for exemptions where Limited IRB Review (see “HRP-312- Worksheet- Exemption Determination”) is required or where otherwise requested by the IRB, informed consent forms for research activities determined to be exempt without Limited IRB Review are generally not required to be submitted for review and approval by the University Park IRB.

5.2 Obtaining Informed Consent

5.2.1 Timing and Location of Consent

Describe where and when the consent process will take place.

If a parent agrees to participate during recruitment, a member of the laboratory (either the P.I. Jennifer Zosh or IRB-trained research

assistants) explains the purpose of the study. We will explain the method and the purpose of the project. We also explain the right of the parent or child to stop the study at any time, and answer any questions that the family may have. The lab member then allows the family to read the form while either playing with the child or setting up for the study so that the parent can read the form without feeling any pressure.

5.2.2 Coercion or Undue Influence during Consent

Describe the steps that will be taken to minimize the possibility of coercion or undue influence in the consent process.

The researcher will allow the family to read the consent form while either playing with the child or setting up for the study so that the parent can read the form without feeling any pressure.

5.3 Waiver of Written Documentation of Consent

Review "HRP – 411 – Checklist – Waiver of Written Documentation of Consent."

5.3.1 Indicate which of the following conditions applies to this research:

- ☐ The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.
- OR
- ☐ The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern. *(Note: This condition is not applicable for FDA-regulated research. If this category is chosen, include copies of a consent form and /or parental permission form for participants who want written documentation linking them to the research.)*
- OR
- ☐ If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained. *(Note: This condition is not applicable for FDA-regulated research.)*

Describe the alternative mechanism for documenting that informed consent was obtained:

Not applicable.

5.3.2 **Indicate what materials, if any, will be used to inform potential subjects about the research (e.g., a letter accompanying a questionnaire, verbal script, implied consent form, or summary explanation of the research)**

Not applicable.

5.4 **Informed consent will be sought but some of the elements of informed consent will be omitted or altered (e.g., deception).**

Review "HRP-410-Checklist -Waiver or Alteration of Consent Process" to ensure that you have provided sufficient information.

5.4.1 **Indicate the elements of informed consent to be omitted or altered**

Not applicable.

5.4.2 **Indicate why the research could not practicably be carried out without the omission or alteration of consent elements**

Not applicable.

5.4.3 **Describe why the research involves no more than minimal risk to subjects.**

Not applicable.

5.4.4 **Describe why the alteration/omission will not adversely affect the rights and welfare of subjects.**

Not applicable.

5.4.5 **If the research involves using identifiable private information or identifiable biospecimens, describe why the research could not be practicably be carried out without using such information or biospecimens in an identifiable format.**

Not applicable.

5.4.6 Debriefing

Explain whether and how subjects will be debriefed after participation in the study. If subjects will not be debriefed, provide a justification for not doing so. Add any debriefing materials to the study in CATS IRB.

Not applicable.

5.5 Informed consent will not be obtained – request to completely waive the informed consent requirement

Review “HRP-410-Checklist -Waiver or Alteration of Consent Process” to ensure that you have provided sufficient information.

5.5.1 Indicate why the research could not practicably be carried out without the waiver of consent

Not applicable.

5.5.2 Describe why the research involves no more than minimal risk to subjects.

Not applicable.

5.5.3 Describe why the alteration/omission will not adversely affect the rights and welfare of subjects.

Not applicable.

5.5.4 If the research involves using identifiable private information or identifiable biospecimens, describe why the research could not be practicably be carried out without using such information or biospecimens in an identifiable format.

Not applicable.

5.5.5 Additional pertinent information after participation

Explain if subjects will be provided with additional pertinent information after participation. If not applicable, indicate “not applicable.”

Not applicable.

5.6 Consent – Other Considerations

5.6.1 Non-English-Speaking Subjects

Indicate what language(s) other than English are understood by prospective subjects or representatives.

If subjects who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those subjects will be in that language. Indicate the language that will be used by those obtaining consent.

Indicate whether the consent process will be documented in writing with the long form of the consent documentation or with the short form of the consent documentation. Review “HRP-091 –SOP- Written Documentation of Consent” and “HRP-103 -Investigator Manual” to ensure that you have provided sufficient information.

We will not be recruiting non-English speaking participants.

5.6.2 Cognitively Impaired Adults

Refer “HRP-417 -CHECKLIST- Cognitively Impaired Adults” for information about research involving cognitively impaired adults as subjects.

5.6.2.1 Capability of Providing Consent

Describe the process to determine whether an individual is capable of consent.

Not applicable.

5.6.2.2 Adults Unable to Consent

Describe whether and how informed consent will be obtained from the legally authorized representative. Describe who will be allowed to provide informed consent. Describe the process used to determine these individual’s authority to consent to research.

For research conducted in the state of Pennsylvania, review “HRP-013 -SOP- Legally Authorized Representatives, Children and Guardians” to be aware of which individuals in the state of Pennsylvania meet the definition of “legally authorized representative.”

For research conducted outside of the state of Pennsylvania, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective subject to their participation in the procedure(s) involved in this research. One method of obtaining this information is to have a legal counsel or authority review your protocol along with the definition of “children” in “HRP-013 -SOP- Legally Authorized Representatives, Children, and Guardians.”

Not applicable.

5.6.2.3 Assent of Adults Unable to Consent

Describe the process for assent of the subjects. Indicate whether assent will be required of all, some or none of the subjects. If some, indicate which subjects will be required to assent and which will not.

If assent will not be obtained from some or all subjects, provide an explanation of why not.

Describe whether assent of the subjects will be documented and the process to document assent. The IRB allows the person obtaining assent to document assent on the consent document and does not routinely require assent documents and does not routinely require subjects to sign assent documents.

Not applicable.

5.6.3 Subjects who are not yet adults (infants, children, teenagers)

-

5.6.3.1 Parental Permission

Describe whether and how parental permission will be obtained. If permission will be obtained from individuals other than parents, describe who will be allowed to provide permission. Describe the process used to determine these

individual's authority to consent to each child's general medical care.

For research conducted in the state of Pennsylvania, review "HRP-013-SOP- Legally Authorized Representatives, Children and Guardians" to be aware of which individuals in the state of Pennsylvania meet the definition of "children."

For research conducted outside of the state of Pennsylvania, provide information that describes which persons have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which research will be conducted. One method of obtaining this information is to have a legal counsel or authority review your protocol along with the definition of "children" in "HRP-013-SOP- Legally Authorized Representatives, Children, and Guardians."

Parents or a legal guardian will sign the consent forms on behalf of the child participants. A member of the laboratory (either the P.I. Jennifer Zosh or IRB-trained research assistants) will explain the study when the original appointment is scheduled. When the family comes into the laboratory, one of the lab members (either the P.I. or a research assistant) will again explain the study generally, including the paradigm, the right of the parent or child to stop the study at any time, and answer any questions that the family may have. The lab member will then allow the family to read the form while either playing with the child or setting up for the study so that the parent can read the form without feeling any pressure. The person giving consent will be given a copy of the consent form to take home. They will also be offered a copy of the consent form before or after an appointment is scheduled.

5.6.3.2 Assent of subjects who are not yet adults

Indicate whether assent will be obtained from all, some, or none of the children. If assent will be obtained from some children, indicate which children will be required to assent. When assent of children is obtained describe whether and how it will be documented.

The children in this study are too young to provide assent. If a child is upset or a parent wants to stop, the study will stop immediately.

6.0 HIPAA Research Authorization and/or Waiver or Alteration of Authorization

This section is about the access, use or disclosure of Protected Health Information (PHI). PHI is individually identifiable health information (i.e., health information containing one or more 18 identifiers) that is transmitted or maintained in any form or medium by a Covered Entity or its Business Associate. A Covered Entity is a health plan, a health care clearinghouse or health care provider who transmits health information in electronic form. See “HRP-103 -Investigator Manual” for a list of the 18 identifiers.

If requesting a waiver/alteration of HIPAA authorization, complete sections 6.2 and 6.3 in addition to section 6.1. The Privacy Rule permits waivers (or alterations) of authorization if the research meets certain conditions. Include only information that will be accessed with the waiver/alteration.

[Do not type here]

6.1 Authorization and/or Waiver or Alteration of Authorization for the Uses and Disclosures of PHI

Check all that apply:

- ☒ **Not applicable, no identifiable protected health information (PHI) is accessed, used or disclosed in this study.** *[Mark all parts of sections 6.2 and 6.3 as not applicable]*
- ☐ **Authorization will be obtained and documented as part of the consent process.** *[If this is the only box checked, mark sections 6.2 and 6.3 as not applicable]*
- ☐ **Partial waiver is requested for recruitment purposes only (Check this box if patients’ medical records will be accessed to determine eligibility before consent/authorization has been obtained).** *[Complete all parts of sections 6.2 and 6.3]*
- ☐ **Full waiver is requested for entire research study (e.g., medical record review studies).** *[Complete all parts of sections 6.2 and 6.3]*
- ☐ **Alteration is requested to waive requirement for written documentation of authorization (verbal authorization will be obtained).** *[Complete all parts of sections 6.2 and 6.3]*

6.2 Waiver or Alteration of Authorization for the Uses and Disclosures of PHI

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6.2.1 Access, use or disclosure of PHI representing no more than a minimal risk to the privacy of the individual

6.2.1.1 Plan to protect PHI from improper use or disclosure

Include the following statement as written – DO NOT ALTER OR DELETE unless this section is not applicable because the research does not involve a waiver of authorization. **If the section is not applicable, remove the statement and indicate as not applicable.**

Not applicable.

6.2.1.2 Plan to destroy identifiers or a justification for retaining identifiers

Describe the plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research. Include when and how identifiers will be destroyed. If identifiers will be retained, provide the legal, health or research justification for retaining the identifiers.

•

Not applicable.

6.2.2 Explanation for why the research could not practicably be conducted without access to and use of PHI

Provide an explanation for why the research could not practicably be conducted without access to and use of PHI.

•

Not applicable.

6.2.3 Explanation for why the research could not practicably be conducted without the waiver or alteration of authorization

Provide an explanation for why the research could not practicably be conducted without the waiver or alteration of authorization.

Not applicable.

6.3 Waiver or alteration of authorization statements of agreement

By submitting this study for review with a waiver of authorization, you agree to the following statement – DO NOT ALTER OR DELETE unless this section is not applicable because the research does not involve a waiver or alteration of authorization. **If the section is not applicable, remove the statement and indicate as not applicable.**

Not applicable.

7.0 Study Design and Procedures

Data collection materials that will be seen or used by subjects in your study must be uploaded to CATS IRB (<http://irb.psu.edu>). **DO NOT** include any actual data collection materials in this protocol (e.g., actual survey or interview questions)

7.1 Study Design

Describe and explain the study design.

Observing how parent and child interaction while playing with technological toys and traditional toys can help us to understand how contextual factors, specifically technology, affect child interaction with caregivers around them and vice versa. Additionally, we will observe how parent and child interaction changes when the parent/caregiver has technology devices present during play. This will help us to develop a better understanding of the effects technological advances may have on developmental outcomes.

7.2 Study Procedures

Provide a step by step description of all research procedures being conducted (broken down by visit, if applicable) including such information as below (where and when applicable); describe the following:

- HOW: (e.g., data collection via interviews, focus groups, forms such as surveys and questionnaires, medical/school records, audio/video/digital recordings, photographs, EKG procedures, MRI, mobile devices such as electronic tablets/cell phones, observations, collection of specimens, experimental drug/device testing, manipulation of behavior/use of deception, computer games, etc.)
- WHERE: (e.g., classrooms, labs, internet/online, places of business, medical settings, public spaces, etc.)

7.2.1 Visit 1 or Day 1 or Pre-test, etc.

Provide a description of what procedures will be performed on visit 1 or day 1 or pre-test in order of how these will be done. If your study only involves one session or visit, use this section only and indicate 7.2.2 as not applicable.

1. Recruitment: Children will be recruited using the methods outlined in this IRB application.
2. Arrival: Families will be greeted at the assigned parking spaces for the Brandywine Child Development Lab. This parking space is close to the building where the laboratory is located. A member of the lab will walk with the family into the Commons Building at Penn State Brandywine's campus and will assist the family into the lab, located on the second floor of this building (using either the stairwell or elevator). There is a waiting area for families that is adjacent to the testing room.
3. Initial Paperwork: Upon entering the Center, an IRB-approved laboratory member will sit down with the family to confirm the information that we have in our database as well as thoroughly explain the goals of the study. The researcher will also explain the methodology to the parents as well as answer any questions that the family may have. During this time, the researcher will also interact with the child so that the child feels comfortable and secure in this new setting. The parent will be told that he/she can elect to stop the study at any time. At this point, the parent will be given a choice of rewards for their child (i.e., a choice of snacks or stickers).
4. Entering testing space (Room 201): Once the family says that they are ready, the researcher will bring the family into the testing room (located adjacent to the waiting area). The researcher will ask the parent(s) to sit on a chair or on the floor next to the child and will be instructed to act naturally. The parent(s) will be with the child the entire time and will be reminded that they can stop the study at any time.
5. Apparatus: Toddlers will be seated on the floor, on the play mat, or at the table in the room, depending on age and preference. Parents will either sit on the floor or in a chair nearby, but do not need to be in very close contact with the child. Parents will either be instructed to keep their own technology (e.g., cellphones) present or the leave them outside of the room; they will also be told to let the child take the lead in the play session. The experimenter will leave the room. The video camera(s) will be set at a relevant angle to record the entire experiment session for the purpose of recording the child's behavior.
6. Experiment: After the parent and child are ready to begin, the Experimenter will leave the room for a minimum of 10 minutes. After the time runs down or if the parent stops the session, the Experimenter will re-enter the room and inform the family that the study has completed.
7. End of study: At the end of the study, the experimenter will then enter the room and tell the child that he/she did a "Great job!" and will return with the family to the waiting area.
8. End of visit: Once the family and experimenter return to the waiting area, the researcher will ask if the parent has any questions. She will

also give the child a small token of appreciation (i.e., a book, etc. and a personalized certificate).

7.2.2 Visit 2 or Day 2 or Post-test, etc. (If applicable)

Provide a description of what procedures will be performed on visit 2 or day 2 or post-test in order of how these will be done. If your study involves more than two sessions or visits replicate this section for each additional session or visit (e.g., 7.2.3, 7.2.4, etc.).

Not applicable.

7.3 Duration of Participation

Describe how long subjects will be involved in this research study. Include the number of sessions and the duration of each session - consider the total number of minutes, hours, days, months, years, etc.

In its entirety, the study will typically last less than 20 minutes. This is a one-time opportunity and no-follow-ups are involved. A visit to the laboratory typically takes about 45-60 minutes so that there is ample time for the consent process, for the child to get comfortable in the lab space, and for the presentation of a certificate and sticker at the completion of the study. This also allows sufficient time for any questions to be answered by a member of the study team.

8.0 Subject Numbers and Statistical Plan

8.1 Number of Subjects

- Indicate the maximum number of subjects to be accrued/enrolled. Distinguish between the number of subjects who are expected to be enrolled and screened, and the number of subjects needed to complete the research procedures if applicable (i.e., numbers of subjects excluding screen failures.)

100

8.2 Sample size determination

If applicable, provide a justification of the sample size outlined in section 8.1 to include reflections on, or calculations of, the power of the study.

This number (100) is based on previous experience with this study. Typically, a large number of children at varying ages (within this range) is needed to draw conclusions.

8.3 Statistical methods

Describe the statistical methods (or non-statistical methods of analysis) that will be employed.

Typical statistical tests such as ANOVA, t-tests, and descriptive statistics will be used. Additionally, the Parenting interactions with Children: Checklist of Observations Linked to Outcomes (PICCOLO) tool will be used.

9.0 Data and Safety Monitoring Plan

This section is required when research involves more than Minimal Risk to subjects as defined in “HRP-001 SOP- Definitions.”

Minimal Risk is defined as the probability and magnitude of harm or discomfort anticipated in the research that are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. For research involving prisoners, Minimal Risk is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

Please complete the sections below if the research involves more than minimal risk to subjects, otherwise indicate each section as not applicable.

9.1 Periodic evaluation of data

Describe the plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe.

Not applicable.

9.2 Data that are reviewed

- Describe the data that are reviewed, including safety data, untoward events, and efficacy data.

Not applicable.

9.3 Method of collection of safety information

Describe the method by which the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls and with subjects).

Not applicable.

9.4 Frequency of data collection

Describe the frequency of data collection, including when safety data collection starts.

Not applicable.

9.5 Individuals reviewing the data

Identify the individuals who will review the data. The plan might include establishing a data and safety monitoring committee and a plan for reporting data monitoring committee findings to the IRB and the sponsor.

Not applicable.

9.6 Frequency of review of cumulative data

Describe the frequency or periodicity of review of cumulative data.

Not applicable.

9.7 Statistical tests

Describe the statistical tests for analyzing the safety data to determine whether harms are occurring.

Not applicable.

9.8 Suspension of research

Describe any conditions that trigger an immediate suspension of research.

Not applicable.

10.0 Risks

List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related the subjects' participation in the research. Include as may be useful for the IRB's consideration, a description of the probability, magnitude, duration and reversibility of the risks. Consider all types of risk including physical, psychological, social, legal, and economic risks. Note: Loss of confidentiality is a potential risk when conducting human subject research.

- If applicable, indicate which procedures may have risks to the subjects that are currently unforeseeable.
- If applicable, indicate which procedures may have risks to an embryo or fetus should the subject be or become pregnant.
- If applicable, describe risks to others who are not subjects.

To minimize risks associated with the study itself, the P.I. is using a variation on a well-developed behavioral measure that is used in many infant laboratories across the globe. Only age-appropriate objects are used and a parent/guardian, as well as the researcher, is with the child throughout the entirety of the study. The P.I. has also been American Red Cross CPR and First Aid certified and a first-aid kit will be kept in the laboratory in case

of any health emergencies. To minimize risks associated with identity protection, data sheets and video footage will be stored using initials and subject numbers. Any identifiable information will be stored in locked cabinets in the laboratory.

The PI is up to date on Penn State Child Abuse Training as is all members of the research team. All team members are instructed that they have an ethical and legal obligation to report suspicions of child abuse IMMEDIATELY to the PI. They are told that they MUST immediately contact the PI with any suspicions of child abuse. This is a primary objective of research training and students are instructed both via the online training as well as going through hypothetical situation as a group to help them identify warning signs. They are told that they might have to call Child Line under the supervision of the PI or that the PI will call to report those suspicions.

11.0 Potential Benefits to Subjects and Others

11.1 Potential Benefits to Subjects

Describe the potential benefits that individual subjects may experience from taking part in the research. If there is no direct benefit to subjects, indicate as such. Compensation is not considered a benefit. Compensation should be addressed in section 13.0.

The only potential benefit to the child participants in the studies is a generally pleasurable and enjoyable experience. The laboratory has age-appropriate toys and a friendly researcher will guide the families through their entire visit. The benefit to the parent/guardian is an enjoyable visit to a developmental psychology laboratory and the opportunity to have a first-hand experience seeing how new knowledge about developmental psychology is generated.

11.2 Potential Benefits to Others

Include benefits to society or others.

The potential benefit to society is an improved understanding of the impact of technology on parent-child interactions and development. Although there are no direct applications of the results of this study currently planned, there may be future applications of the results of this work in the fields of psychology, education, etc.

12.0 Sharing Results with Subjects

- Describe whether results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with subjects or others (e.g., the subject's primary care physicians) and if so, describe how information will be shared.

- Approximately once a year, participants will be provided with a general summary of the findings of the lab, but no specific feedback or results will be given to any specific child/family.

13.0 Subject Payment and/or Travel Reimbursements

Describe the amount, type (cash, check, gift card, other) and timing of any subject payment or travel reimbursement. If there is **no** subject payment or travel reimbursement, indicate as not applicable.

Extra or Course Credit: Describe the amount of credit **and** the available alternatives. Alternatives should be equal in time and effort to the amount of course or extra credit offered. It is not acceptable to indicate that the amount of credit is to be determined or at the discretion of the instructor of the course.

Approved Subject Pool: Indicate which approved subject pool will be used; include in response below that course credit will be given and alternatives will be offered as per the approved subject pool procedures.

Families are given a children's book/sticker and certificate as a token of appreciation.

14.0 Economic Burden to Subjects

14.1 Costs

Describe any costs that subjects may be responsible for because of participation in the research.

- There are no direct costs to participate or be a part of the study. The only possible cost is that of transportation to the lab.

14.2 Compensation for research-related injury

If the research involves more than Minimal Risk to subjects, describe the available compensation in the event of research related injury.

If there is no sponsor agreement that addresses compensation for medical care for research subjects with a research-related injury, include the following text as written - DO NOT ALTER OR DELETE:

It is the policy of the institution to provide neither financial compensation nor free medical treatment for research-related injury. In the event of injury resulting from this research, medical treatment is available but will be provided at the usual charge. Costs for the treatment of research-related injuries will be charged to subjects or their insurance carriers.

For sponsored research studies with a research agreement with the sponsor that addresses compensation for medical care for research-related injuries, include the following text as written - DO NOT ALTER OR DELETE:

It is the policy of the institution to provide neither financial compensation nor free medical treatment for research-related injury. In the event of injury resulting from this research, medical treatment is available but will be provided at the usual charge. Such charges may be paid by the study sponsor as outlined in the research agreement and explained in the consent form.

It is the policy of the institution to provide neither financial compensation nor free medical treatment for research-related injury. In the event of injury resulting from this research, medical treatment is available but will be provided at the usual charge. Costs for the treatment of research-related injuries will be charged to subjects or their insurance carriers.

It is the policy of the institution to provide neither financial compensation nor free medical treatment for research-related injury. In the event of injury resulting from this research, medical treatment is available but will be provided at the usual charge. Such charges may be paid by the study sponsor as outlined in the research agreement and explained in the consent form.

15.0 Resources Available

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15.1 Facilities and locations

Identify and describe the facilities, sites and locations where recruitment and study procedures will be performed.

If research will be conducted outside the United States, describe site-specific regulations or customs affecting the research, and describe the process for obtaining local ethical review. Also, describe the principal investigator's experience conducting research at these locations and familiarity with local culture.

-

The research will be conducted in office/lab space within the social science wing located in the Commons building on the campus of Penn State Brandywine. Parents and children will be met at a reserved parking space located near the entrance to the building. There is an elevator for use of research participants. Parents and children will be escorted by Dr. Zosh or a research assistant to a waiting area on the second floor of the Commons

Building where paperwork will be completed. This paperwork will include basic biographical information, a vocabulary inventory, and the IRB materials that are shared with the participant families. After completing the paperwork, the family will be escorted to a testing room (Room 201) where the research will take place. This space is dedicated to research completed by Dr. Zosh. The parent and child will remain together the entire time, although the parent is instructed to be an observer and not participate in the research. Dr. Zosh or an IRB-approved research assistant will complete short behavioral tasks with the child participant. The task will be videotaped but no identifying information will be recorded on the tape. The session will either be recorded digitally or via traditional tape media that will later be transferred into digital format. These files will then be coded by experienced coders (Dr. Zosh and IRB-approved research assistants). There are at least 2 computers in the testing room and the computers will be password protected so that only students working in the lab have access to any files.

15.2 Feasibility of recruiting the required number of subjects

Indicate the number of potential subjects to which the study team has access. Indicate the percentage of those potential subjects needed for recruitment.

There are thousands of families in this general area. Because we recruit for general lab participation first, the chance that parents will be interested in participating in this session is higher.

15.3 PI Time devoted to conducting the research

Describe how the PI will ensure that a sufficient amount of time will be devoted to conducting and completing the research. Please consider outside responsibilities as well as other on-going research for which the PI is responsible.

The PI has previously run these types of studies while at Johns Hopkins University in Baltimore and thus has a good idea of the length of time it takes to run studies such as these. The PI will be using IRB-trained undergraduates throughout both the Fall and Spring semesters as well as throughout Summer.

15.4 Availability of medical or psychological resources

Describe the availability of medical or psychological resources that subjects might need as a result of their participation in the study, if applicable.

Not applicable.

15.5 Process for informing Study Team

Describe the training plans to ensure members of the research team are informed about the protocol and their duties, if applicable.

Dr. Zosh trains all of her undergraduates before they are allowed to work on a project. The first several weeks of an internships experience are devoted to training and many students work for more than 1 semester. Strict oversight is maintained. All students complete CITI training, the Child Abuse training module provided by Penn State, and are background checked and maintain proper clearances.

The study team will meet regularly for training prior to the commencement of research. Once recruitment begins, the team will meet for check ins and the PI will be available at any time for consultation. All members will complete the required CITI training prior to any work on the study.

16.0 Other Approvals

16.1 Other Approvals from External Entities

Describe any approvals that will be obtained prior to commencing the research (e.g., from engaged cooperating institutions IRBs who are also reviewing the research and other required review committees, community leaders, schools, research locations where research is to be conducted by the Penn State investigator, funding agencies, etc.).

Not applicable.

16.2 Internal PSU Committee Approvals

Check all that apply:

- ☐ Anatomic Pathology – **Penn State Health only** – Research involves the collection of tissues or use of pathologic specimens. Upload a copy of “HRP-902 - Human Tissue For Research Form” in CATS IRB.
- ☐ Animal Care and Use – **All campuses** – Human research involves animals and humans or the use of human tissues in animals
- ☐ Biosafety – **All campuses** – Research involves biohazardous materials (human biological specimens in a PSU research lab, biological toxins, carcinogens, infectious agents, recombinant viruses or DNA or gene therapy).
- ☐ Clinical Laboratories – **Penn State Health only** – Collection, processing and/or storage of extra tubes of body fluid specimens for research purposes by the Clinical Laboratories; and/or use of body fluids that had been collected for clinical purposes but are no longer needed for clinical use.

Upload a copy of “HRP-901 - Human Body Fluids for Research Form” in CATS IRB.

- ☐ Clinical Research Center (CRC) Advisory Committee – **All campuses** – Research involves the use of CRC services in any way.
- ☐ Conflict of Interest Review – **All campuses** – Research has one or more of study team members indicated as having a financial interest.
- ☐ Radiation Safety – **Penn State Health only** – Research involves research-related radiation procedures. All research involving radiation procedures (standard of care and/or research-related) must upload a copy of “HRP-903 - Radiation Review Form” in CATS IRB.
- ☐ IND/IDE Audit – **All campuses** – Research in which the PSU researcher holds the IND or IDE or intends to hold the IND or IDE.
- ☐ Scientific Review – **Penn State Health only** – All investigator-written research studies requiring review by the convened IRB must provide documentation of scientific review with the IRB submission. The scientific review requirement may be fulfilled by one of the following: (1) external peer-review process; (2) department/institute scientific review committee; or (3) scientific review by the Clinical Research Center Advisory committee. NOTE: Review by the Penn State Health Cancer Institute (PSCI) Protocol Review Committee or the PSCI Disease Team is required if the study involves cancer prevention studies or cancer patients, records and/or tissues. For more information about this requirement see the IRB website.

17.0 Multi-Site Study

- If this is a multi-site study (i.e., a study in which two or more institutions coordinate, with each institution completing all research activities outlined in a specific protocol) and the Penn State PI is the lead investigator, describe the processes to ensure communication among sites in the sections below.

17.1 Other sites

List the name and location of all other participating sites. Provide the name, qualifications and contact information for the principal investigator at each site and indicate which IRB will be reviewing the study at each site.

•

Not applicable.

17.2 Communication Plans

Describe the plan for regular communication between the overall study director and the other sites to ensure that all sites have the most current version of the

protocol, consent document, etc. Describe the process to ensure all modifications have been communicated to sites. Describe the process to ensure that all required approvals have been obtained at each site (including approval by the site's IRB of record). Describe the process for communication of problems with the research, interim results and closure of the study.

Not applicable.

17.3 Data Submission and Security Plan

Describe the process and schedule for data submission and provide the data security plan for data collected from other sites. Describe the process to ensure all engaged participating sites will safeguard data as required by local information security policies.

Not applicable.

17.4 Subject Enrollment

Describe the procedures for coordination of subject enrollment and randomization for the overall project.

Not applicable.

17.5 Reporting of Adverse Events and New Information

Describe how adverse events and other information will be reported from the clinical sites to the overall study director. Provide the timeframe for this reporting.

Not applicable.

17.6 Audit and Monitoring Plans

Describe the process to ensure all local site investigators conduct the study appropriately. Describe any on-site auditing and monitoring plans for the study.

Not applicable.

18.0 Adverse Event Reporting

18.1 Reporting Adverse Reactions and Unanticipated Problems to the Responsible IRB

By submitting this study for review, you agree to the following statement – DO NOT ALTER OR DELETE:

-

In accordance with applicable policies of The Pennsylvania State University Institutional Review Board (IRB), the investigator will report, to the IRB, any

observed or reported harm (adverse event) experienced by a subject or other individual, which in the opinion of the investigator is determined to be (1) unexpected; and (2) probably related to the research procedures. Harms (adverse events) will be submitted to the IRB in accordance with the IRB policies and procedures.

19.0 Study Monitoring, Auditing and Inspecting

-

19.1 Auditing and Inspecting

By submitting this study for review, you agree to the following statement – DO NOT ALTER OR DELETE:

The investigator will permit study-related monitoring, audits, and inspections by the Penn State quality assurance program office(s), IRB, the sponsor, and government regulatory bodies, of all study related documents (e.g., source documents, regulatory documents, data collection instruments, study data etc.). The investigator will ensure the capability for inspections of applicable study-related facilities (e.g., pharmacy, diagnostic laboratory, etc.).

20.0 Future Undetermined Research: Data and Specimen Banking

If this study is collecting **identifiable** data and/or specimens that will be banked for future **undetermined research**, please describe this process in the sections below. This information should not conflict with information provided in section 22 regarding whether or not data and/or specimens will be associated with identifiers (directly or indirectly). If **NOT applicable**, indicate as such below in all sections.

20.1 Data and/or specimens being stored

- Identify what data and/or specimens will be stored and the data associated with each specimen.

Not applicable.

20.2 Location of storage

Identify the location where the data and/or specimens will be stored.

Not applicable.

20.3 Duration of storage

Identify how long the data and/or specimens will be stored. If data and/or specimens will be stored indefinitely, indicate as such.

Not applicable.

20.4 Access to data and/or specimens

Identify who will have access to the data and/or specimens.

-

Not applicable.

20.5 Procedures to release data or specimens

Describe the procedures to release the data and/or specimens, including: the process to request a release, approvals required for release, who can obtain data and/or specimens, and the data to be provided with the specimens.

Not applicable.

20.6 Process for returning results

Describe the process for returning results about the use of the data and/or specimens.

Not applicable.

21.0 References

List relevant references in the literature which highlight methods, controversies, and study outcomes.

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Zosh, J.M., Verdine, B.N., Filipowicz, A., Golinkoff, R.M., Hirsh-Pasek, K., & Newcombe, N.S. (2015). Talking shape: Parental language with electronic versus traditional shape sorters. *International Mind, Brain, and Education Society*, 9(3), 136-144.

22.0 Confidentiality, Privacy and Data Management

IMPORTANT: The following section is required for all locations EXCEPT Penn State Health and the College of Medicine. Penn State Health and College of Medicine should skip this section and complete “HRP-598 Research Data Plan Review Form.” In order to avoid redundancy, for this section state “See the Research Data Plan Review Form” if you are conducting Penn State Health research. Delete all other sub-sections of section 22.

For research being conducted at Penn State Health or by Penn State Health researchers only: The research data security and integrity plan is submitted using “HRP-598 – Research Data Plan Review Form.”

Refer to Penn State College of Medicine IRB’s “Standard Operating Procedure Addendum: Security and Integrity of Human Research Data,” which is available on the IRB’s website. In order to avoid redundancy, for this section state “See the Research Data Plan Review Form” if you are conducting Penn State Health research. **Delete all sub-sections of section 22.**

For all other research: complete the following section. Please refer to [PSU Policy AD95](#) for information regarding information classification and security standards and requirements. It is recommended that you work with local IT staff when planning to store, process, or access data electronically to ensure that your plan can be carried out locally and meets applicable requirements. If you have questions about Penn State’s Policy AD95 or standards or need a consultation regarding data security, please contact security@psu.edu.

22.1 Which of the following identifiers will be recorded for the research project? Check all that apply. If none of the following identifiers will be recorded, do not check any of the boxes.

	Hard Copy Data	Electronic Stored Data
Names and/or initials (including on signed consent documents)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes,	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

a single category of age 90 or older		
Telephone numbers	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Fax numbers	<input type="checkbox"/>	<input type="checkbox"/>
Electronic mail addresses	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Social security numbers	<input type="checkbox"/>	<input type="checkbox"/>
Medical record numbers	<input type="checkbox"/>	<input type="checkbox"/>
Health plan beneficiary numbers	<input type="checkbox"/>	<input type="checkbox"/>
Account numbers	<input type="checkbox"/>	<input type="checkbox"/>
Certificate/license numbers	<input type="checkbox"/>	<input type="checkbox"/>
Vehicle identifiers and serial numbers, including license plate numbers	<input type="checkbox"/>	<input type="checkbox"/>
Device identifiers and serial numbers	<input type="checkbox"/>	<input type="checkbox"/>
Web Universal Resource Locators (URLs)	<input type="checkbox"/>	<input type="checkbox"/>
Internet Protocol (IP) address numbers	<input type="checkbox"/>	<input type="checkbox"/>
Biometric identifiers, including finger and voice prints	<input type="checkbox"/>	<input type="checkbox"/>
Full face photographic images and any comparable images	<input type="checkbox"/>	<input type="checkbox"/>
Any other unique identifying number, characteristic, or code (such as the pathology number)	<input type="checkbox"/>	<input type="checkbox"/>
Study code number with linking list	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Genomic sequence data	<input type="checkbox"/>	<input type="checkbox"/>
State ID numbers	<input type="checkbox"/>	<input type="checkbox"/>
Passport numbers	<input type="checkbox"/>	<input type="checkbox"/>
Driver's license numbers	<input type="checkbox"/>	<input type="checkbox"/>

22.2 If storing paper records of research data, answer the following questions:

22.2.1 Where will the paper records, including copies of signed consent forms, associated with this research study will be stored?

All data will only be stored using initials and subject numbers rather than names. The master list of codes and corresponding names will be stored in a locked cabinet in the locked laboratory and/or using Penn State servers (box) and the only accounts that will have access to online documents being individuals who have been approved through IRB. Signed consent forms will be stored in a locked cabinet within the lab space

22.2.2 How will the paper records be secured?

These paper records will be secured by the PI in a locked cabinet in the lab space.

22.2.3 How will access to the paper records be restricted to authorized project personnel?

Access to paper records will only be available to the PI or trained lab assistants involved with this study.

22.3 If storing electronic records of research data, indicate where the electronic data associated with this research study will be stored. Check all that apply.

- ☒ Penn State-provided database application. Check which of the following database applications are being used (check all that apply):
- ☐ Penn State REDCap
 - ☐ Other – Specify - provided and approved database application:
 - ☐ Penn State, College, or Department IT file server
 - ☒ Box.psu.edu (Apply for a Box NPA here: <https://box.psu.edu/non-person-account/>)
 - ☐ Web-based system provided by the sponsor or cooperative group - Specify URL and contact information:
 - ☐ Other – Specify the database application or server:

Provide details about the data security features or attach security documentation provided by sponsor or group:

If there is a list/key that links indirect identifiers (code numbers, participant IDs, etc.) to direct identifiers, that list must not be comingled (i.e., stored in the same location) as the identifiable data, including copies of signed informed consent forms. Additionally, access to that list/key must be restricted to authorized project personnel.

22.4 Is there a list/key that links code numbers to identifiers?

- ☒ Yes - explain how the list that links the code to identifiers is stored separately from coded data:

The master list of codes and corresponding names will be stored in a locked cabinet in the locked laboratory. The coded data will be stored separate from this master list and will only contain subject numbers, biological sex, and birthdates so that exact age can be calculated. This data will be stored on box and access to that box folder will be limited to members of the study team

- ☐ Not applicable, there is no list that links code numbers to identifiers. Skip to section 22.6.

22.5 Is there a list of people who have access to the list/key?

- ☒ Yes – explain how access to that list is restricted and why certain persons require access.

Only approved members of the research team will have access to this information. They need access so that they can check that birthdate and biological sex was entered into data sheets correctly. They also need to confirm that the same subject was not run in the study multiple times.

☐ No – explain why not:

22.6 Describe the mechanism in place to ensure only approved research personnel have access to the stored research data (electronic and paper).

- ☒ Password-protected files
☐ Role-based security
☐ Specify all other mechanisms used to ensure only permitted users have access to the stored research data.

The use of mobile devices or wireless activity trackers to collect identifiable research data must be approved by the Office of Information Security. Before completing this section, please contact security@psu.edu to confirm approval.

22.7 Will any research data (such as survey data) be collected on a mobile device, such as an electronic tablet, cell phone, or wireless activity tracker?

- ☒ No
☐ Yes - answer the following questions:

22.7.1 Specify the provider of the mobile device(s)

- ☐ Supplied by the sponsor
☐ Penn State owned device
☐ A personal device
☐ Other – Please specify source:

22.7.2 Specify the type(s) of mobile device(s) that will be used to capture data and all identifiers captured on the mobile device(s). Please list all devices, and if more than one, the identifiers to be collected on each.

22.7.3 Specify the type of data collected on the mobile devices(s).

22.7.4 Specify the application or website used to collect the data from the mobile device, if applicable.

22.7.5 Describe the measures taken to protect the confidentiality of the data collected on mobile device(s). Please address physical security of the device(s), electronic security, and secure transfer of data from device(s) to the previously indicated data/file storage location provided in section 22.3.

The use of online survey tools and email to collect or send research data containing identifiers that represent more than minimal risk to subjects must be approved by the Office of Information Security. Before completing this section, please contact security@psu.edu.

22.8 Will any research data be directly entered/sent by subjects over the internet or via email (e.g., data capture using on-line surveys/questionnaires, surveys via email, observation of chat rooms or blogs)?

☒ No

☐ Yes - answer the following questions:

22.8.1 Specify the identifiers collected over the internet or via email (Including IP addresses if IP addresses will be collected).

22.8.2 Specify the type of data collected over the internet or via email.

22.8.3 Describe the measures taken to protect the confidentiality of the data collected?

22.8.4 Describe how the research team will access the data once data collection is complete.

22.8.5 If the research involves online surveys, list the name(s) of the service provider(s) that will be used for the survey(s) (e.g., REDCap, Penn State licensed Qualtrics, Survey Monkey, Zoomerang)? (Note: The IRB strongly recommends the use of REDCap for online surveys that obtain sensitive identifiable human subjects data.)

☐ Penn State REDCap

☐ Penn State Qualtrics (de-identified data only)

- ☐ Other - Please specify:
 Application:
 URL (If applicable):

22.8.6 If the answer above is “Other” contact security@psu.edu for approval of an alternative data capture method

Depending on the nature of the subject matter involved, certain security requirements must be in place for the audio and/or video recording or photographing of subjects. If the subject matter presents more than minimal risk to the subjects, then, before completing the section below, please contact the Office of Information Security at security@psu.edu to confirm whether these requirements are required.

22.9 Will any type of recordings (e.g., audio or video) or photographs of the subjects be made during this study?

- ☐ No - skip to section 22.10
☒ Yes - answer the following questions:

**22.9.1 What will be used to capture the audio/video/images?
 Give a brief description of content.**

- ☒ Audio – Describe the intended content of the audio recording:
 Audio recordings will be used for coding once the play sessions have been completed, using the PICCOLO coding scheme.
- ☒ Video – Describe the intended content of the video recording:
 Video recordings will be used for coding once the play sessions have been completed, using the PICCOLO coding scheme.
- ☐ Photographs of the subjects – Describe the intended content of the photographs:
- ☐ 3-D Images – Describe the intended content of the of 3-D images:
- ☐ Other - Specify:

22.9.2 How will the recordings/photographs/images be stored (electronically or physically)?

The recordings will be stored in password protected files on the lab computers or on box.psu.edu. Only the PI or trained lab assistants will have access to these files.

22.9.3 Where will the recordings/photographs/images be stored?

The audio and video recordings will be stored on lab computers.

22.9.4 Who will have access to the recordings/photographs/images?

Only the PI or trained lab assistants will have access to the audio and video recordings.

22.9.5 Will any of the recordings be transcribed?

☐ Not applicable

☐ No

☒ Yes – indicate who will be doing the transcribing?

Only trained members of the research team will be transcribing the videos.

22.9.6 Will the recordings/photographs be used for purposes other than this research study?

☐ No

☒ Yes - specify purpose(s) (e.g., publication, presentations, educational training, future undetermined research):

The consent form includes an opportunity for parents to opt in or opt out of using non-identifiable video clips for educational purposes. If a parent consents to this use, clips may be used in classroom or educational settings.

22.10 Certificate of Confidentiality (COC) - Is the research biomedical, behavioral, clinical or other research that is funded by the National Institutes of Health (NIH)?

☐ Yes - check one of the following:

☐ The research involves human subjects as defined by the DHHS regulations (See Worksheet HRP-310).

☐ The research involves collecting or using biospecimens that are identifiable to an individual.

☐ If collecting or using biospecimens as part of the research, there is a small risk that some combination of the biospecimen, a request for the biospecimen, and other available data sources could be used to deduce the identity of an individual.

☐ The research involves the generation of individual level, human genomic data.

Note: If any of the 4 items above are checked, a COC is automatically issued by NIH and applies to the research. Information about the COC must be included in the consent form.

☒ No - answer the following question.

If the research is not funded by NIH, will the investigator apply for a COC for this research study?

- ☒ No
☐ Yes

Note: For research not funded by NIH, the IRB may require a COC if the research is collecting personally identifiable information and the information is sensitive and/or the research is collecting information that if disclosed could significantly harm or damage the subject.

22.11 What steps will be taken to protect subjects' privacy interests? (Check all that apply.)

- ☒ Identification and recruitment of potential subjects follows procedures consistent with privacy standards
☒ Consent discussion and research interventions will take place in a private setting
☒ Limiting the information being collected to only the minimum amount of data necessary to accomplish the research purposes
☒ Limiting the people with access to the identifiable research data to the minimum necessary as specified in the application and consent process
☐ Other – Specify:

22.12 What is the process for ensuring correctness of data entry?

- ☒ Double data entry to reduce risk of errors
☐ Electronic edit checks to ensure data being entered are not obviously incorrect
☒ Random internal quality and assurance checking of research data
☐ Direct entry by subjects
☐ Other - Specify:

22.13 Does this research involve the generation of large-scale human genomic data as defined in NIH Genomic Data Sharing Policy (<http://gds.nih.gov>)?

- ☒ No
☐ Yes – If Yes, describe the plan for de-identifying the dataset before sharing it with NIH-designated data repositories.

22.14 The European Union (EU) General Data Protection Regulation (GDPR)

22.14.1 To determine if the research is subject to the GDPR answer the following questions:

22.14.1.1 Will the Penn State principal investigator, or another entity under the Penn State principal investigator's direction, be collecting, recording, storing, using, any personal data* of any subjects physically located in the European Economic Area (EEA) at the time of data collection (even if the subject is NOT an EEA resident) or any EEA citizens? (This includes recruitment through social media sites, use of third-party internet sites, mobile devices or apps to collect data, and/or direct receipt of data from subjects.)**

☒ No

☐ Yes (This research may be subject to the GDPR)

22.14.1.2 Does this research involve the transfer of personal data collected under the GDPR from an EEA country? (This includes direct transfer of data from research collaborators.)

☒ No

☐ Yes (This research may be subject to the GDPR)

22.14.2 If the research may be subject to the GDPR as indicated in the answers to the questions above, answer the following:

22.14.2.1 Will any of the data fall into one of the following categories: health data, racial or ethnic origin, political opinions, religious or philosophical beliefs, trade union membership, genetic data, biometric data used for purpose of identifying an individual, sex life or sexual orientation?

☐ No

☐ Yes

22.14.2.2 Will any of the data be related to criminal convictions or offenses?

☐ No

☐ Yes

Comments on any of the above responses:

* “Personal data” means any information relating to an identified or identifiable natural person; an identifiable natural person is one who can be identified, directly or indirectly, by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.

** European Economic Area (EEA) – Includes the 28-member states of the European Union (Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia Spain, Sweden, UK) and Norway, Iceland, Lichtenstein.

22.15 Does this research involve transfer or disclosure of data and/or specimens to and/or from Penn State?

- ☒ No - skip the remainder of section 22.15.
☐ Yes - answer the following questions.

Check all that apply:

- ☐ **Data** are being transferred or disclosed **to** Penn State
 What is the name of the third party(ies) (the institution, sponsor, etc.) sending or providing the data?

Is the third party requiring us to sign a contract regarding the data?

- ☐ Yes - If Yes, this contract must go through the Office of Sponsored Programs <https://www.research.psu.edu/osp/overview-pages/data-use-agreements>

☐ No

- ☐ **Data** are being transferred or disclosed **from** Penn State
 What is the name(s) of the third party(ies) (the institution, sponsor, etc.) receiving or accessing the data?

Note: Data transfers or disclosures may require a Data Use Agreement (DUA).

- ☐ **Specimens** are being transferred **to** Penn State
 What is the name(s) of the third party(ies) (the institution, sponsor, etc.) sending the specimens?

- ☐ **Specimens** are being transferred **from** Penn State
 What is the name(s) of the third party(ies) (the institution, sponsor, etc.) receiving the specimens?

Note: All material transfers, either sending or receiving, require a Material Transfer Agreement (MTA). Please contact the Office of Technology Management for more information.

22.15.1 Describe how the data/specimens will be securely transferred or disclosed to/from the third party(ies).

22.15.2 How are the research data/specimens being transferred from and/or sent to the third party(ies)? Complete the appropriate section(s) and check all that apply within each completed section.

22.15.2.1 Data being transferred or disclosed to Penn State:

- ☐ Data are being received in aggregate/metrics (just counts, no individual data)
- ☐ De-identified individual data are being received and there is no linking list at either institution (no identifiers, or links to identifiers, such as code numbers)
- ☐ Coded research data without any identifiers are being received and the linking list remains with the entity sending the data; the recipient of the data will not have access to the linking list
- ☐ Coded research data with identifiers (such as dates and/or any of the identifiers listed in section 22.15.3 aside from Study Code) are being received and the linking list remains with the entity sending the data; the recipient of the data will not have access to the linking list
- ☐ Data with identifiers (such as dates and/or any of the identifiers listed in section 22.15.3) are being received and the linking list remains with the entity sending the data; the recipient of the data will have access to the linking list
- ☐ Data with identifiers along with the linking list are being received
- ☐ Other – Specify:

22.15.2.2 Data being transferred or disclosed from Penn State:

- ☐ Data are being sent in aggregate/metrics (just counts, no individual data)
- ☐ De-identified individual data are being sent and there is no linking list at either institution (no

identifiers, or links to identifiers, such as code numbers)

- ☐ Coded research data without any identifiers are being sent and the linking list remains with the entity sending the data; the recipient of the data will not have access to the linking list
- ☐ Coded research data with identifiers (such as dates and/or any of the identifiers listed in section 22.15.3 aside from Study Code) are being sent and the linking list remains with the entity sending the data; the recipient of the data will not have access to the linking list
- ☐ Data with identifiers (such as dates and/or any of the identifiers listed in section 22.15.3) are being sent and the linking list remains with the entity sending the data; the recipient of the data will have access to the linking list
- ☐ Data with identifiers along with the linking list are being sent
- ☐ Other – Specify:

22.15.2.3 Specimens being transferred or disclosed to Penn State:

- ☐ De-identified specimens are being received and there is no linking list at either institution (no identifiers, or links to identifiers, such as code numbers)
- ☐ Coded specimens without any identifiers are being received and the linking list remains with the entity sending the specimens; the recipient of the specimens will not have access to the linking list
- ☐ Coded specimens with identifiers (such as dates and/or any of the identifiers listed in section 22.15.3 aside from Study Code) are being received and the linking list remains with the entity sending the specimens; the recipient of the specimens will not have access to the linking list
- ☐ Coded specimens with identifiers (such as dates and/or any of the identifiers listed in section 22.15.3) are being received and the linking list remains with the entity sending the specimens;

the recipient of the specimens will have access to the linking list

- ☐ Coded specimens with identifiers along with the linking list are being received
- ☐ Other – Specify:

22.15.2.4 Specimens being transferred or disclosed from Penn State:

- ☐ De-identified specimens are being sent and there is no linking list at either institution (no identifiers, or links to identifiers, such as code numbers)
- ☐ Coded specimens without any identifiers are being sent and the linking list remains with the entity sending the specimens; the recipient of the specimens will not have access to the linking list
- ☐ Coded specimens with identifiers (such as dates and/or any of the identifiers listed in section 22.15.3 aside from Study Code) are being sent and the linking list remains with the entity sending the specimens; the recipient of the specimens will not have access to the linking list
- ☐ Coded specimens with identifiers (such as dates and/or any of the identifiers listed in section 22.15.3) are being sent and the linking list remains with the entity sending the specimens; the recipient of the specimens will have access to the linking list
- ☐ Coded specimens with identifiers along with the linking list are being sent
- ☐ Other – Specify:

22.15.3 If transferring data/specimens with identifiers to or from Penn State, which of the following identifiers will be included with the data/specimens? Check all that apply:

<input type="checkbox"/> Names	<input type="checkbox"/> Medical record numbers
<input type="checkbox"/> Initials	<input type="checkbox"/> Health plan beneficiary numbers
<input type="checkbox"/> Street address	<input type="checkbox"/> Account numbers
<input type="checkbox"/> City	<input type="checkbox"/> Certificate/license numbers
<input type="checkbox"/> Driver's License numbers	<input type="checkbox"/> Passport numbers

<input type="checkbox"/> State	<input type="checkbox"/> State ID numbers
<input type="checkbox"/> Zip Codes	<input type="checkbox"/> Vehicle identifiers and serial numbers, including license plate numbers
<input type="checkbox"/> County	<input type="checkbox"/> Device identifiers and serial numbers
<input type="checkbox"/> Geocodes	<input type="checkbox"/> Web Universal Resource Locators (URLs)
<input type="checkbox"/> Precincts	<input type="checkbox"/> Internet Protocol (IP) address numbers
<input type="checkbox"/> All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death	<input type="checkbox"/> Biometric identifiers, including finger and voice prints
<input type="checkbox"/> Ages > 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older	<input type="checkbox"/> Full face photographic images and any comparable images
<input type="checkbox"/> Telephone numbers	<input type="checkbox"/> Any other unique identifying number, characteristic, or code (such as the pathology number) Specify:
<input type="checkbox"/> Fax numbers	<input type="checkbox"/> Study code numbers
<input type="checkbox"/> Electronic mail addresses	<input type="checkbox"/> Master list linking study code numbers to subject(s)
<input type="checkbox"/> Social security numbers	<input type="checkbox"/> Genomic sequence data
	<input type="checkbox"/> Other – specify:

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ACADEMIC VITA

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Education

The Pennsylvania State University Spring 2020

Bachelor of the Arts Degree in Psychology

Minor in Human Development and Family Studies

Research Experience

Cooper Honors Scholar Spring 2018-Fall 2018

- Authorized for a Cooper Honors Independent Study under Dr. Evan Bradley
- Recruited speakers of various languages for language samples
- Presented preliminary results at PSUxLing Conference Fall 2018

Cooper Honors Scholar Spring 2019-Spring 2020

- Currently authorized to complete a thesis project titled “A Digital World: Do Screens Influence Parent-Child Interaction?” under Dr. Jennifer Zosh
- Recruiting subjects between 2 and 4 years of age
- Coding a play session with the PICCOLO coding tool
- Will complete thesis and graduate with honors in Spring 2020

Honors and Awards

- Honors Research Grant Summer 2019
- Dean’s List Fall 2017-Current
- Jane E. Cooper Honors Scholar Fall 2017-Current

Activities

- Poster presentation at Penn State Undergraduate Exhibition in Hispanic and General Linguistics October 2018