**NCT02544035**

**Protocol Title**
Determining Age Appropriateness of Children's Products and Toys:
An Interagency Agreement with the Consumer Product Safety Commission

**Abbreviated Title**
Children's Products and Toys

**Protocol Number**
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Not applicable

**Human Research Protections Program Investigator and Staff Training:**
Before the protocol is submitted to PTMS, the research team will have completed all required Human Research Protections Program Training (i.e., CITI, CRT).

**Total requested accrual**
(0) Patients
(720) Healthy Volunteers

| | **Child participants (ages 6mos-12 years)** | **Accompanying parents (at least 18 years of age)** |
|---|---|---|
| **6-11 mos** | 60 | 60 |
| **12-18 mos (1-1.5 years)** | 60 | 60 |
| **19-35 mos (1.5-2 years)** | 60 | 60 |
| **36-71 mos (3-5 years)** | 60 | 60 |
| **72-107 mos (6-8 years)** | 60 | 60 |
| **108-144 mos (9-12 years)** | 60 | 60 |
| | **360** | **360** |

Total Number of participants (360 + 360) = **720**

**Project Uses Ionizing Radiation: X No** ☐ Yes (*attach RSC/RDRC documentation)*
☐☐Medically-indicated only
☐☐Research-related only
☐☐Both

**IND/IDE** **X No** ☐Yes *(attach FDA documentation)*
Drug/Device/#_____
Sponsor: _____

**Durable Power of Attorney** **X No** ☐ Yes

**Multi-institutional Project** **X No** ☐ Yes
Institution#1_____ FWA #_____
Date of IRB approval _____*(attach IRB documentation)*

Institution#2_____ FWA #_____
Date of IRB approval _____*(attach IRB documentation)*

**Data and Safety Monitoring Board X No** ☐ Yes

**Technology Transfer Agreement** **X No** ☐ Yes
Agreement type and number _____ Expiration Date_____

**Samples are being stored** **X No** ☐ Yes

**Flesch-Kincaid reading level of consent form:** N/A

## Précis

The proposed project is the outcome of an interagency agreement (IAG; #CPSC-I-14-0016) between the Consumer Product Safety Commission (CPSC) of the United States and the Child and Family Research Section (CFRS) within NICHD DIR. At the CPSC, the Division of Human Factors (ESHF) examines products and toys for U.S. children and determines the appropriate age of their potential users based on a set of Guidelines last revised in 2002. Due to the outdated nature of the 2002 Guidelines, the CFRS is charged with revising this rulebook after conducting an empirical research project to inform these amendments. The goal of the current study is to categorize traditional and contemporary children's products and toys into age appropriate groups and use this information to rewrite the Guidelines for efficient CPSC use.

Participants will be 360 parent-child dyads from 6 months to 12 years of age. We will recruit equal numbers of boys and girls from each of the following six developmentally determined and CPSC approved age groups: 6-11 mos, 12-18 mos, 19-35 mos, 36-71 mos (3-5 years), 72-107 mos (6-8 years), and 108-144 mos (9-12 years). Participants will be tested at the CFRS once parental consent and child assent have been obtained.

Each child will receive one of three counterbalanced children's products or toys that are targeted to their age group from 6 of the 9 following categories: (1) Building or Construction (e.g., blocks, interlocking building materials), (2) Exploratory (e.g., clay, sand toys), (3) Games & Puzzles, (4) Instructional Toys (e.g., books, science kits), (5) Sports, Recreation, & Outdoor, (6) Imaginative Play (e.g., puppets, dolls, dress up materials), (7) Small Wheeled Vehicles (e.g., car toys), (8) Arts and Crafts, and (9) Musical Toys (e.g., musical instruments). Children will also receive one of three (counterbalanced) children's products or toys from each of the categories aimed at the age group below their age as well as another from each of the categories aimed at the age group older than their age. Each child will first play alone and then play with a parent. Different sets of toys will be presented when children switch from playing alone to playing in a dyad.

Parents will provide information about their socioeconomic status and demographics. They will also complete the Vineland Adaptive Behavior Scales (i.e., an instrument assessing the child's socialization, motor, communication, and daily living skills) and an age-appropriate instrument that assesses the child's temperament. They will provide information about toys that are already in their home. Some parents may be invited to take part in a more in-depth qualitative focus group interview about children's toys. All play sessions will be video recorded and will be scored for relevant behaviors.

We will examine differences in play with toys from the three age groups that are chronologically adjacent (i.e., to determine differences in outcomes for a given age group with age-appropriate toys compared to toys of the same category from the next youngest and next oldest age groupings). Our outcome measures include the following: (1) Complexity of play, (2) Parts and features of toys used by the child, (3) Duration of time

spent with each toy, (4) Preference for the toys, and (5) Number of times and duration the child solicits the parent's involvement during play.

This observational study of children fits well with the CFRS program of research and the mission of the NICHD DIR. We will investigate children's interactions with toys that surround children in their natural environment, as well as study how parents moderate child play behavior. Observing and quantifying behaviors during play will allow us to have a richer understanding of social and cognitive growth during different stages of child development in the context of toy play with parents and will form an empirical basis for revising the 2002 CPSC Guidelines in light of changes in the last decade and a half in the toy industry.

The cost impact for this project is minimal. All necessary testing facilities are already available at the CFRS. Funding for additional staff needed to work with participants, subject reimbursement, and supplies to carry out the project is allocated through the IAG.

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**List of Abbreviations**

**ADD:** Attention Deficit Disorder
**ADHD:** Attention Deficit Hyperactivity Disorder
**ANCOVA:** Analysis of Covariance
**ASD:** Autism Spectrum Disorder
**CBQ:** Children's Behavior Questionnaire
**CFRS:** Child and Family Research Section
**CTSS:** Clinical Trials Survey System
**CPSC:** Consumer Product Safety Commission
**DIR:** Division of Intramural Research
**EATQ:** Early Adolescent Temperament Questionnaire
**ECBQ:** Early Childhood Behavior Questionnaire
**HOME:** Home Observation for Measurement of the Environment Inventory
**IAG:** Interagency Agreement
**IBQ:** Infant Behavior Questionnaire
**KEPS:** Knowledge of Effective Parenting Scale
**KIDI:** Knowledge of Infant Development Inventory

**PDD:** Pervasive Developmental Disorders
**PTQ:** Parent Toy Questionnaire
**RM-ANCOVA:** Repeated-Measures Analysis of Covariance
**TMCQ:** Temperament in Middle Childhood Questionnaire
**TQS:** Toy Quality Scale
**VABS:** Vineland Adaptive Behavior Scales

## 1. Introduction

### Overview

From building a tower of blocks, to playing "house" with a doll, to sharing a game of checkers with a friend, children's play has been described historically as a "leading source of development" (Vygotsky, 1967, p. 6) during childhood and is consistently implicated as a crucial component of children's healthy cognitive and social growth (Bergen, 2002; Ginsburg, 2007; Scarlett, 2005; Trawick-Smith & Dziurgot, 2011). For example, essential skills of abstraction and symbolism are acquired through play (Vygotsky, 1967), and play during preschool is linked to long-term mathematics achievement later in school (Wolfgang, Stannard, & Jones, 2001).

Much of the time that children devote to play is with toys and other child-directed products. Parents and other consumers spend substantial amounts on these items each year, with sales of toys and children's products totaling $18.1 billion in 2014 (Toy Industry Association, 2014). Moreover, this industry grows annually—revenues rose 4% between 2013 and 2014.

With such a plethora of children's products and toys available to U.S. consumers, how do American parents decide which toys are appropriate for their children? Play progresses in complexity with child age. As such, children's product and toy needs during play are largely a function of their age and developmental stage. A parent would not give a science kit to a 6-month-old, nor provide a rattle to a 10-year-old. However, many toy decisions are not as clear cut.

In addition, children's play with toys is influenced by their play partners. Children's play is more complex when playing with parents than when playing alone (Bornstein, Haynes, O'Reilly, & Painter, 1996; Bornstein, Haynes, Pascual, Painter, & Galperín, 1999, Cote & Bornstein, 2009; Damast, Tamis-LeMonda, & Bornstein, 1996).

Children's play with various types of toys and with a more advanced play partner across development is important from scholarly and theoretical perspectives as well as to policymakers and government stakeholders, such as the U.S. Consumer Product Safety Commission (CPSC). In 1973, the CPSC was established to regulate consumer products, including toys, which may pose risks to U.S. consumers. Before mechanical or chemical testing is performed on toys to identify health hazards, the Division of Human Factors (ESHF) first determines the appropriate age group of potential users. ESHF staff members currently consult a rulebook known as the *Age Determination Guidelines* (2002), which has become outdated in light of developments in the children's products and toy industry over the last 15 years. Due to the outdated nature of the 2002 Guidelines, the CFRS is charged with revising this rulebook after conducting an empirical research project to inform these amendments. The project we have proposed is

the outcome of an interagency agreement (IAG; #CPSC-I-14-0016) between the Consumer Product Safety Commission (CPSC) of the United States and the Child and Family Research Section (CFRS) within NICHD DIR.

The importance of understanding children's play with children's products and toys at different ages is clear, but very little recent research has systematically investigated play behavior interactions between child age and type of toy. Additionally, parent-child dyadic play with toys across different age groups is understudied. The aims of the current project are two-fold: (1) to add to the current body of knowledge on children's play with different categories of toys at different ages alone and with a parent and (2) to provide information to the Consumer Product Safety Commission about children's play with toys in the form of a revision of the 2002 *Age Determination Guidelines,* which the CFR at NICHD will edit after gathering information from the empirical study. Due to this partnership with the CPSC, the proposed NICHD study will have a significant impact on U.S. children, their families, and current practices of the CPSC.

**Children's Play with Different Types of Toys**

During play, much of children's time is spent with diverse products and toys, making these objects an integral part of children's daytime activities (Glassy & Romano, 2003). The bulk of children's toy play time involves constructing objects (Pellegrini & Gustafson, 2005) or manipulating these toys without any pretense involved (Gredlein & Bjorklund, 2005). Although children's products and toys are important elements of children's play, basic research that rigorously and systematically investigates qualities of toys and documents the effects of these qualities on children's play is surprisingly scant. Furthermore, existing research that touches on the topic is outdated and includes only a few age groups.

Kimmerle and colleagues (1995) demonstrated that children begin to manipulate toys with increasing complexity between the ages of 7-13 months if the toy is lightweight, easy to grasp, and has moveable parts that are accessible to infants' small fingers. For example, children showed the most advanced sensorimotor play using a barbell with a rotary knob at one end and a noisemaker at the other. Likewise, one extensive study examined the qualities of toys and the ways that infants played with toys between the ages of 3-12 months (Furby & Wilke, 1982). Overall, the authors discovered that 12-month-olds preferred objects with movable pieces and parts that could fit together more than the 3-month-olds. McCall (1974) explored infant play behavior among 7 ½ to 11-month-olds and discovered that infants were more likely to attend to toys that were "responsive". Responsiveness included *plasticity* (how easily the object could be changed in shape through manipulation) as well as *sound potential* (whether or not the object produced sounds when shaken).

Responsiveness and detail of toys continues to hold importance later during childhood. Preschool children spent more time with a toy that provided random (instead of predictable) responses dependent on the child's input (Schulz & Bonawitz, 2005). Furthermore, responsiveness afforded by interactive toys that 'talk' when a button is pressed can foster liking of the toy and rich engagement with it during play (Bergen &

Davis, 2011; Kahn, Friedman, Pérez-Granados, & Freier, 2006), as well as enhanced learning from the toy (Calvert, Richards, & Kent, 2014). Detail of toys is also important to preschoolers, as Robinson and Jackson (1987) found that 4-year-olds, regardless of their gender, played longer with toy cars that were more realistic in their detail (working doors, painted with racing stripes and bright colors) than with cars with less detail (no working doors, painted with a dull brown color).

**An Ecological Model of Play**

In addition to the types of toys with which children play, a multitude of other factors affects children's play. Bornstein (2006) proposed a model to outline the effects of these various elements on children's play (see Figure 1). The model illustrates that children's play does not happen in a vacuum. Rather, sociodemographics (e.g., socioeconomic status, cultural upbringing, schooling), characteristics of play partners (e.g., parent personality, parenting knowledge), and individual characteristics of the child (e.g., language, temperament, age) are interrelated and have profound effects on the ways in which children play.

Figure 1. *Ecological Model of Play, taken from Bornstein (2006)*

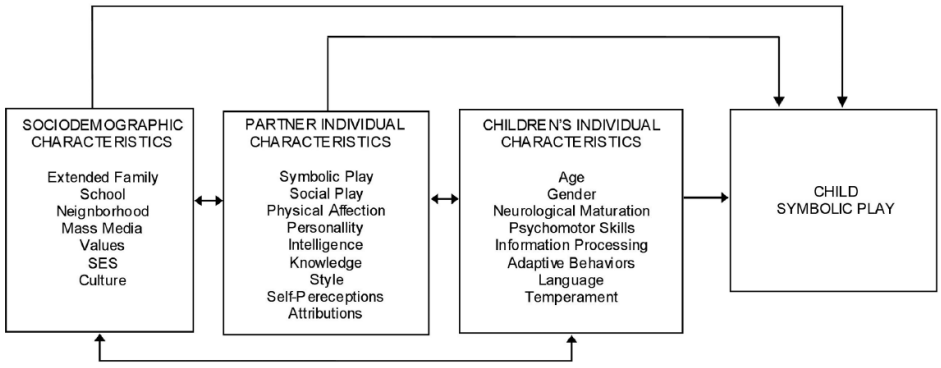


FIG. 5.1. An ecological model of child play: Expected predictive relations among child, mother, and sociodemographic characteristics on child symbolic play.

The two primary independent variables that will be manipulated in the experimental design of the proposed study are children's age and the absence or presence of a parent play partner. The proposed project will also control for relevant aspects of children's sociodemographic characteristics, partner individual characteristics, and the children's individual characteristics by gathering information about those domains through surveys described in the methods section of this proposal.

**Children's play differs with age.** Piaget (1962) long ago proposed three stages in the development of play—*sensorimotor play*, *symbolic play*, and *games with rules*, which still constitute a basic foundation for the progression of play throughout childhood. To build on Piaget's stages, chronological age acts as an organizational framework for

the following discussion of development of children's play. Our study of child play will extend from infancy (6 months) to middle childhood (12 years).

***Birth-2 years old.*** During infancy and early toddlerhood, play entails manipulating objects for the purpose of exploring them (e.g., mouthing, fingering, hitting, shaking objects), as children examine the texture, shape, and functionality of toys (Kimerlee et al., 1995). Piaget defined this class of play as *sensorimotor* play. Although sensorimotor play nurtures cognitive and motor growth, it only lasts for a small part of childhood.

When children engage in sensorimotor play, they perform *circular actions*, or the repetition of certain actions that are solitary and nonsocial (Piaget, 1962; Scarlett, 2005). These circular actions become more complex with increasing age through infancy. Between 4-8 months of age children discover that certain activities with objects are enjoyable and will repeat these actions (e.g., grabbing a rattle and shaking it). When children are between 8-12 months old, they begin to use two objects at once (such as clapping two cups together) to play. Finally, between 12-18 months, children engage in repetitive behaviors with objects and engage in trial and error, exploring new toys to see what types of new and interesting sounds and reactions they can create (Scarlett, 2005).

Fenson and colleagues (1976) followed children's toy play behaviors longitudinally between the ages of 7-20 months. Children in the earlier part of that age range (i.e., at 7 and 9 months old) tended to explore toys through touching, mouthing, shaking, and banging them. However, between the ages of 13 and 20 months, more symbolic forms of play emerged (e.g., pretending to drink out of a cup in a tea set or eat something from a plate; Fenson et al., 1976).

***Ages 2-6.*** Just as Fenson and colleagues (1976) discovered, as children approach the age of 2 years, they begin to engage in play that is more abstract in nature. During this imaginary play, termed *symbolic play* by Piaget, a toy can represent a real-world object, and gestures can represent real-life actions. During this play, the child is creating an "imaginative sphere" to express interpretations of the real world (Schousboe, 2013; p. 14).

Beginning around the age of 2 years, children may begin to engage in *object substitution*, e.g., using a toy milk bottle to feed a baby doll. When children first begin to engage in object substitution, they need an object that is similar and resembles the real object before they are able to pretend with it (Elder & Pederson, 1978). They also need to have seen another person perform that behavior, i.e., at this age, symbolic play is imitative (Scarlett, 2005). Starting at about age 3, children are able to substitute objects for dissimilar objects in their play (e.g., pretending to brush hair with a rubber ball). Finally, starting around age 3½ years, children do not need toys to support pretend play. They are able to act as though an invisible object is in the play scene, when in reality, the object is not present (e.g., believe that a princess is in the room; Elder & Pederson, 1978; Lillard, 2015). Around ages 4-5, storylines with loose narratives, fantastical characters, and scenes emerge (Scarlett, 2005). Symbolic play becomes more complex throughout the preschool years and peaks in prevalence around 4 years of age, starting to decline around the age of 6-7 (Eckler & Weininger, 1989; Trawick-Smith, 1998; Lillard, 2015).

***Ages 7-12 years.*** Between 7-12 years of age, children begin to set their own a-priori rules, deciding what is fair and just during play (Scarlett, 2005). During this age range, children are not as reliant on pretense and symbolism in their play. Instead, they engage in games that have rules and regulations such as basketball or board games (Piaget, 1962). One illustrative qualitative study examined how boys played soccer together. Winther-Lindqvist (2013) found that playing games with rules was an integral part of how boys socialized and formed a community with one another. Furthermore, understanding rules, such as who would be the judge, gatekeeper, etc. during the game was an essential part of how they played with one another.

It should be noted that during this age range, children's games still often contain elements of pretense. For example, games with rules, such as Dungeons and Dragons, require players to create fantastical characters who exist in imaginary worlds. Furthermore, symbolic play has been shown to continue until children are 11 years old (Smith & Lillard, 2012), and may occur in private settings away from observers to avoid the embarrassment of appearing too immature (Scarlett, 2005). There are some benefits to continuing to engage in symbolic imaginary play in the elementary and middle school years. For example, children may become better at controlling their emotions and improve their empathic understanding (Niec & Russ, 2002; Singer, 1994).

**Children's play with adults**. Although children play alone, they often have play partners, such as parents, caregivers, siblings, and friends. The effects of these companions on children's play behavior are large (Bornstein, 2006). During the early stages of life, parents and other adult caregivers are children's primary playmates. Vygotsky (1967) recognized the importance of adults in children's play, due to the adult's ability to guide within the child's *zone of proximal development* during play. A task within the child's zone of proximal development is one that the child has not yet mastered, but that becomes possible for him or her to achieve with the aid of a skilled other. Vygotsky contended that, with the help of parents, children could advance in development through the use of *scaffolding*, or the careful guidance of adults during task execution (Wood, Bruner, & Ross, 1976). Indeed, sensitive fathers and mothers who engage in scaffolding during playtime have beneficial effects on children's subsequent cognitive development (Tamis-LeMonda, Shannon, Cabrera, & Lamb, 2004).

Consistent with this idea, when playing with parents, children play at more sophisticated levels because parents often prompt them to engage in more complex behaviors (O'Reilly & Bornstein, 1993). For example, when using a standard set of toys, children are more likely to engage in more sophisticated pretense play when collaborating with their mother than when playing alone (Bornstein et al., 1996; Bornstein et al., 1999, Cote & Bornstein, 2009; Damast et al., 1996). In addition, non-parental adult play partners can scaffold increases in the child's level of play sophistication (Bornstein, Haynes, Legler, O'Reilly, & Painter 1997; Kwak, Bornstein, & Putnick, 2008; Trawick-Smith & Dziurgot, 2011).

## The Current Study

The interplay among child age, toy type, and presence/absence of an adult play partner is complex, and adequate understanding of this interplay is lacking. Most currently available research focuses on children of infant and preschool age, and less attention has been paid to children in the elementary and middle school years. Furthermore, experimental designs that systematically compare play with different toy types alone vs. with a parent across all stages of development do not exist. Therefore, there are two main goals in the current study. First, we aim to categorize traditional and contemporary children's products and toys into age appropriate groups by observing children's play alone and with a play partner to enrich our theoretical understanding of play and how toys and parents mediate child play. Second, the information derived from our empirical study will be used in an applied setting to revise the CPSC's 2002 *Age Determination Guidelines* for children's products and toys as part of this interagency agreement with the CPSC.

## 2. Study Objectives

### a. Primary objectives

The primary objective of the current observational study is to categorize traditional and contemporary children's products and toys into age appropriate groups based on their intended use. To do this, we will examine differences in child play among toys from the three chronologically adjacent age groups to determine the differences in play for a given age group with an age-appropriate toy in comparison with toys from the same toy category intended for the next youngest and the next oldest age groups.

### b. Secondary objectives

There are three secondary objectives of this research project:

(1) To determine how play group type (i.e., play alone, play with parent) affects children's play with toys.

(2) To determine how the qualities of toys differ depending on the manufacturer's suggested age.

(3) To determine how parents gauge age appropriateness when making decisions about the types of products and toys to give to their children.

## 3. Subjects

### a. Description of study populations

The participants in our study are healthy volunteers. Parents and their children between the ages of 6 months to 12 years of age will be invited to participate. All children will need consent from their parent or legal guardian, and children over the age of 4 will need to provide assent. Our accrual ceiling is 360 parent-child dyads (720 participants total). If participants withdraw, they will be replaced.

### b. Inclusion criteria

All children between the ages of 6 months to 12 years of age who are *typically developing* and born of a full term pregnancy if under 24 months of age, healthy, and English speaking are eligible for inclusion in the study. *Typically developing* children would not have any diagnosed congenital conditions, developmental delay or disability, dyslexia, PDD, ADD, ADHD, or ASD. In addition, we will only enroll subjects if they are from a racial and ethnic group that is still needed to ensure the diversity and representative nature of our sample as set forth in the Planned Enrollment Form. These are the initial screening criteria that will be used.

**c. Exclusion criteria**

If the participants do not meet the inclusion criteria, they will not be included in the study. Children who are deaf or blind will also need to be excluded from the study. The Eligibility Checklist will be used by investigators at the time of screening for admission to the protocol and will list the inclusion criteria to determine the dyad's eligibility.

While we want to make this study as inclusive as possible, our goal is to understand toy play for typical American children in the time allotted by the CPSC using only the resources allocated in our budget. Thus, the following bullet points explain why the following populations must be excluded from our study:

- *Children outside of the 6 month-12 year age range:* These years cover early life and are the ages of interest for children's play and are of central significance to the Consumer Product Safety Commission's goals.
- *Families not fluent in English:* Fluency in English is essential for parents to be able to fill out surveys. Families also need to be fluent in English so that they can comprehend verbal directions given by the experimenter during the testing session. If we included people who were not fluent in English, we would need many additional staff members who speak the multitude of languages of the diverse population of the Washington, D.C metro area to work with participants during the testing session and code the videos after the testing session is complete.
- *Children who are sick, not typically developing, born premature (if they are under 24 months of age), blind, or deaf:* We must recruit a healthy sample of typically developing children born in a full term pregnancy (if they are under 24 months of age) who are not blind or deaf for this project to remove any potential confounds that atypical conditions may have on children's play. *Typically developing* children would not have any diagnosed congenital conditions, developmental delay or disability, dyslexia, PDD, ADD, ADHD, or ASD. Including other populations such as deaf or blind children would require a different experimental set up, stimulus toys, and resources (i.e., someone who could convert our surveys to American Sign Language or Braille and could code the videos for the parent child behaviors during those sessions).

- *Children who are not adding to the ethnic and racial diversity of the sample:* The goal of our study is to recruit a sample of subjects who are racially and ethnically diverse. By making this diverse sample a priority, we hope that our results will be applicable to the diverse populations residing within the United States. To keep with this goal of a diverse and representative sample of children, we may have to exclude some families if we have already reached the quota of families from that particular racial or ethnic group.

## 4. Study Design and Methods

### a. Study overview

Participants will be children aged 6 months to 12 years and their parents. Participants will receive children's products or toys to play with during an hour play session. Based on the manufacturer's suggested age, some products will be geared towards children who are younger, some will be geared toward children their own age, and others will be aimed at older children. Each child will first play alone and then play with a parent. Different sets of toys will be presented when children switch from playing alone to playing in a dyad. The play sessions will be videorecorded. Video records will subsequently be scored for children's play with the toys.

Participation in this project will take roughly 1-2 hours for the play session of the visit and approximately 1 additional hour for the parent to complete accompanying relevant questionnaires, which can be done at home. Participation in the study requires one visit to the CFRS lab.

This research is social and behavioral in nature, and the visits are considered outpatient. Participants will be tested at the CFRS laboratory in Bethesda, MD.

Subjects who participate in this study are not required to participate in other protocols.

### b. Recruitment

Subjects will be recruited through the following methods:

(1) Birth records: We will purchase lists of local addresses and phone numbers of families with children. This recruitment procedure has been used in CFRS studies previously approved by the NICHD IRB (Study # 88-CH-0032; Study # 02-CH-0278). If we have only the family's mailing address, a short letter or postcard describing the study will be mailed to each family, with an invitation to call or email the lab to learn more. If the family's telephone number is available, we also may directly call families, provide a short description of the study, and ask if they would like to participate in the project.

(2) The local community: We will contact authorized personnel in the community and ask for permission to post or circulate information. We may contact:

- Newspapers, magazines, local community publications
    - A short blurb of information with the CFRS contact information would be printed.
- Neighborhood listservs, blogs, and online parenting communities on social networking sites such as Facebook
    - A short blurb of information with the CFRS contact information would be posted.
- Schools, child care centers, and after-school programs
    - Directors may post flyers or place informational flyers or brochures in children's backpacks or mailboxes to take home to their parents.
- Coffee shops, libraries, recreation centers, and other places known to attract parents and their children.
    - Flyers with detachable CFRS contact information tabs would be posted.

(3) Prior participants in CFRS studies: Families who have previously participated in other approved CFRS studies (e.g., 04-CH-0250, 03-CH-0069) and have provided their phone numbers will be re-contacted with information about this new study and will be recruited for participation.

(4) NIH websites and recruitment hubs: Those reading about the study on the Clinical Center website, the Clinical Center Facebook or Twitter, the OPR Listserv, the Clinical Center Newsletter, ClinicalTrials.gov, ResearchMatch, and the CFRS website and who contact the CFRS or the Clinical Center with interest in the study will be considered for participation.

We anticipate that we will be able to recruit at a rate of 5 children per week.

**Screening**
We plan to have a telephone conversation with parents who express interest in the study. During the call, the study will be explained in detail, and parents will be encouraged to ask questions. For those who wish to participate, we will conduct a short interview to check their eligibility criteria (see the Intake Criteria checklist). Parents who are eligible and interested in the study will receive the Informed Consent Form and surveys in the mail in paper format, which they will fill out and return to CFRS staff. Surveys and consent forms may also be completed electronically on the Clinical Trials Survey System (CTSS).

### c. Study procedures

**Procedure**
Participants will be 720 parents and their children from 6 months to 12 years of age. We will recruit children divided into the following six age groups:

- 6-11 mos

- 12-18 mos (1-1.5 years)
- 19-35 mos (1.5-2 years)
- 36-71 mos (3-5 years)
- 72-107 mos (6-8 years)
- 108-144 mos (9-12 years)

Each child will first :

- Play alone

*then*

- Play with parent

Each child in each age group will receive children's products and toys from 6 of the 9 following categories:

(1) Construction toys (e.g., blocks, interlocking building materials)
(2) Exploratory toys (e.g., clay, sand toys)
(3) Games & Puzzles
(4) Instructional toys (e.g., books, science kits)
(5) Sports, Recreational, & Outdoor Equipment
(6) Imaginative play toys (e.g., puppets, dolls, dress up materials)
(7) Small Wheeled Vehicles (e.g., car toys)
(8) Arts & Crafts toys
(9) Musical toys (e.g., musical instruments)

- Prior to testing, all toys used in this project will be inspected for safety hazards by staff trained in conducting safety evaluations of toys for the Consumer Product Safety Commission. Toys will be inspected for small parts, mechanical hazards (cord length, magnet strength, etc.), lead, and phthalates. All small parts will be removed from toys for children under age 3, and toys will be replaced with similar ones if any mechanical hazards, lead, or phthalates are identified.
- There is a large body of research regarding children's gravitation towards and play with sex-stereotyped toys (O'Brien & Huston, 1985; Caldera et al., 1989). Although child gender is an important factor to consider when studying the qualities of toys, the current study will use gender neutral toys as stimuli in an attempt to eliminate any potential gender confound.

The experimenters will select three representative target toys from each toy category. Target ages are determined by the manufacturer's suggested age.

- Children will be presented with one of three (counterbalanced) toys targeted for their age group from 6 of the 9 toy categories.
- When presented, each target toy will be paired with two additional toys from the same toy category: one targeted to the age group just below and one from the age group just above the target toy.

- Children will receive novel sets of toys when switching from playing alone to play with parent.

To decrease the burden on parents and their children, reduce unplanned missingness, and increase data quality, we are using a 3-form planned missingness design. Because of this design, parents and their children will only have to play with toys from 6 of the 9 categories.

Parents and their children will be offered to take a break from playing approximately every 15 minutes during the toy play session in the event that they are tired of playing with the toys. In addition, to ease frustration that can occur when transitioning from one toy type to the next, we will give children and their parents a couple of minutes notice before the transition occurs.

All play sessions will be video recorded.

**Measures and Surveys:**
The following questionnaires will be sent to the parent to complete before the scheduled visit with the child. Parents can bring these documents with them to the scheduled visit or return them by mail. Although the surveys are currently in paper format, for ease of completion, we may convert them to electronic format that parents can fill out online through CTSS. These questionnaires include the following:

- Consent form and permission to use videorecorded data.
- Basic demographics about the child/family/home life, measuring: Number/ages of children at home, birth order, parental age, parental education, parental marital status, race/ethnicity, etc. (see Bornstein et al., 1996).
- Hollingshead Four-Factor Index of Social Status (Hollingshead, 1975): Measures SES of the family.
- Vineland Adaptive Behavior Scales (VABS; Sparrow, Balla, & Cicchetti, 1984): Measures the child's developmental level in a more sensitive way than by the rough proxy of age
- Temperament through the use of validated scales for different age groups: Infant Behavior Questionnaire (IBQ), Early Childhood Behavior Questionnaire (ECBQ), Children's Behavior Questionnaire (CBQ), Temperament in Middle Childhood Questionnaire (TMCQ), Early Adolescent Temperament Questionnaire (EATQ) (see Bornstein et al., 2015; Rothbart, 2007).
- Social Desirability Scale, Short Form (Reynolds, 1982): A questionnaire used during self-reporting to detect and control for possible social desirability bias.
- Knowledge of Infant Development Inventory (KIDI) for children < 2; or the Knowledge of Effective Parenting Scale (KEPS) for children ≥ 2: The KIDI has been previously approved by the IRB in CFRS protocol (Study# 88-CH-0032; Study # 02-CH-0278). The KIDI and the KEPS are designed to assess knowledge of parental practices, developmental processes, and infant norms, areas that form a knowledge base that may influence and regulate parental behavior vis-a-vis an

individual child (MacPhee, 1981; Morawska, Sanders, & Winter, 2007). The KIDI is appropriate for use with parents with children up to 2 years old and the instrument is comprised of 75 items covering four areas: Norms and Milestones, Principles (developmental processes), Parenting (strategies), and Health and Safety (guidelines). The KEPS is appropriate for use with parents with children as young as 2 years old and is comprised of 28 items covering four areas: Promoting Development, Principles of Effective Parenting, Using Assertive Discipline, and Causes of Behavior Problems.

- Knowledge of Play (see Tamis-LeMonda et al., 1994): A questionnaire used to assess parent's knowledge of children's play, specifically, what types of play behaviors are more complex than others.
- Parent Toy Questionnaire (PTQ): Uses some new and some similar questions from a previous (2002) CPSC-sponsored study of toy play. Parents would be asked: "Where do you get information about toys? Where do you buy your toys? What information do you gather about toys before purchasing them? What is some information you wish that you had before purchasing toys?
    - **Optional parent focus group:** If time and resources permit, we may invite a small number of parents to participate in a focus group conversation about toys.
        - The PTQ will ask parents to check a box if they are interested in this focus group opportunity. We will only contact parents who have checked this box.
        - Topics discussed in the focus group will elaborate on the topics highlighted on the PTQ. The focus group will give parents an opportunity to elaborate verbally on their thoughts about age appropriateness of children's toys and how they make their toy purchasing decisions. This mixed methods research can supplement the quantitative data that parents provide in the PTQ.
        - The focus group may take place at the CFRS or we may use a phone conference call for ease of scheduling.

The following questionnaires will be completed at the end of the testing session.

- Perceptions of child's comfort during testing situation, as reported by (1) the parent and (2) the experimenter (Bornstein et al., 1999).
- Questions adapted from the Home Observation for Measurement of the Environment Inventory (HOME; see Linver, Brooks-Gunn, Cabrera, 2004) to gather information about what toys are already at the child's home and in the child's play environment.
- Additional questions about the toys and their features, including the toys that the child played with during the testing session and additional toys of interest to the CFRS and the CPSC.

Child questions

- For children over the age of 4, we will ask children questions to assess what they thought of each toy by asking: "How much did you like [toy]? Why?" Children will respond to scaled items by pointing to a visual representation of a Likert-type scale in the form of smiley faces (adapted from Harter, 1982; Richards & Calvert, 2015).
- We will also ask the child whether or not she/he has played with the toys before.

Video behavior coding

Video records of the toy play session will be scored for certain qualitative and quantitative behaviors, including, *but not limited to*:

- The Toy Quality Scale (TQS): Qualities of the toy itself (i.e., are there moving parts, does the toy make noise, how soft is the toy? Is it a branded toy with a licensed character on it?). This coding system is being developed in CFRS.
- Parts and features of toys used by the child.
- Duration of time child spends with each toy.
- When playing with parent, how often, in what way, and for how long does the child solicit the parent's involvement? How often, in what way, and for how long does the parent solicit the child's involvement?
- Level of Play Complexity (taken from Bornstein et al., 1996; Cote & Bornstein, 2009, Suizzo & Bornstein, 2006):
  (0) *default* (no play);
  (1) *unitary functional activity* (e.g., throw the ball);
  (2) *inappropriate combinatorial activity* (e.g., put the ball into a teacup): Was the toy used as intended or features of toy fully exploited?
  (3) *appropriate combinatorial activity* (e.g., put the cup on the saucer);
  (4) *transitional play* (e.g., put the telephone to the ear without speaking);
  (5) *self-directed pretense* (e.g., drink from a cup);
  (6) *other-directed pretense* (e.g., pretend to feed the doll);
  (7) *sequential pretense* (e.g., dial and speak into the telephone); and
  (8) *substitution pretense* (e.g., pretend the block is a telephone receiver and speak into it).

Note that all of these procedures described above are solely for research purposes, not for medical or clinical evaluation or treatment. Radiation is not used in this study.

There are no follow-up visits associated with this study. The study has no relations to any other existing protocol.

### d. End of participation

Because this is a social and behavioral research project, transfer of care to assure continuity, the provision of additional medical care, and sharing information with health care providers is not applicable. When the project is complete, parents may request a summary of the findings from the study. However, all findings from the study will be anonymized.

Experimenters will not provide individual-level survey information to participants. This will aid in guarding against any possible negative feelings that could arise from families knowing their results (e.g., feeling inadequate as a parent because he or she did not score highly on the Knowledge of Effective Parenting Scale) or inappropriate use of the data by the family (e.g., using the score on the Vineland Adaptive Behavior Scale as part of a school entrance exam). If parents request a video of their session, we will not distribute a copy to them until the study is over. Parents must provide a written request for the video. We will not distribute the videos to parents until the completion of the study to guard against their sharing it with friends, neighbors, on social media, etc. Other people who view the video through these outlets could potentially become participants in the study without our knowledge. If these people ever do become participants, already having watched a video like this could confound their results and behaviors, weakening the scientific integrity of the study.

## 5. Management of Data and Samples

### a. Storage

Data will be stored according to NICHD and NIH policy. We will not collect any specimens or samples. All data will be stored permanently in an archival database by the National Institutes of Health. They will be retained for analysis in perpetuity. The Principal Investigator will maintain subjects' records after completion of the study.

In addition, data may be stored in a password-protected database via CTDB. For statistical analyses, data will be de-identified according to the Privacy Act, and when possible, by all 18 HIPAA identifiers. If a limited dataset is needed (for example to include dates), a user agreement will be executed. Only investigators or designees authorized to use CTDB will have access to the data.

The anonymity and rights of the study's participants and their families will be fully protected. The full proper names of participants will not appear on the video record or questionnaires, although it is possible that a child's first name might be used during the video recorded play session. All data will be tallied and analyzed without reference to individual names.

Child participants will be assigned ID numbers at the outset of the study, and the key linking the ID numbers with the participants' identity, as well as digital video records of the children filmed during the testing session, will be kept in a locked filing cabinet in a locked room when no researchers are present at the CFRS laboratory. ID numbers are linked with personal identifying information, and only the clinical site investigators or designees have access to it. The linkage is critical to interpretation of the data, as data will be compared across subject groups. No one other than members of the research team will have access to this linkage data without the explicit consent of the volunteer adult.

This protocol will be kept open as long as there is a possibility of future research use of the data. When there is no longer a need, data will be archived by the investigator in compliance with the requirements for retention of research records, or after IRB approval, destroyed or transferred to another repository.

Any loss or unanticipated destruction of data that would affect the scientific integrity of the study will be reported to the IRB as an unanticipated problem.

**b. Data (*if applicable*: including genomic data) and sample sharing plan**

At this time, we do not have any approved collaborators, but anticipate this in the future. Other investigators (both intramural and extramural to the NIH) may wish to study these data. Before sharing the data approved outside collaborators, we will submit an amendment with specific information about the other investigators/institutions and what data/samples will be shared. IRB approval will be sought prior to any sharing of data.

The broad public sharing of data generated by this project is not possible until participant consents to share data publicly are obtained. Data generated by this study will be made available through vetted collaborations and IRB approvals in the interim. This study will be registered on our NICHD Intramural website (https://science.nichd.nih.gov/confluence/display/cfr/Home) along with the above justification.

Any use of this data by a secondary party after submission to a designated repository must be shared by that party according to the permissions granted by the original consent form of the study participants unless additional permissions are obtained. Secondary parties must adhere to the NIH Human Data Sharing guidelines for broad data sharing and to the limitations for use set forth by the Institutional Certification associated with this project. Access to identified data for secondary research will only be granted after IRB review or OHSRP clearance, as applicable.

Any publications and presentations authored or co-authored using data generated by this project will clearly indicate where the data will be available and how to access it. The repository(s) and funding source will also be acknowledged in any publications and presentations.

## 6. Additional Considerations

**a. *Research with investigational drugs or devices***

This provision is not applicable to our research. We will not be using investigational drugs or devices.

**b. *Gene therapy***

This provision is not applicable to our research. We will not be using gene therapy.

## 7. Risks and Discomforts

Participation in this study involves minimal risk. The probability and magnitude of harm or discomfort anticipated with the research are not greater in and of themselves than those ordinarily encountered in daily life. We will minimize risk by choosing stimulus toys that are approved as safe by the CPSC. It is possible that while completing the questionnaires, participants may find that some questions touch on areas of personal sensitivity and may experience discomfort when answering the questionnaires. Parents and children may decline to answer any question.

All procedures are non-invasive. Previous work conducted in the CFRS reassures us that, while some parents may initially feel slightly self-conscious while being observed (perhaps more so when being filmed), in a short period of time they relax and enjoy being involved in a study that focuses on their child and his or her development. Parents will be assured that if their child becomes distressed by any procedure, the session will be interrupted and she will be allowed to soothe the child and resume any caregiving responsibilities.

## 8. Subject Safety Monitoring

We will monitor the play room and end the play session if a child engages in a potentially dangerous action. Because this is social and behavioral research, we will not use toxicity tables, etc. for subject safety monitoring. Participating in this study is voluntary, and participants may withdraw at any time without penalty. At the time of the play session, we will ask each child if s/he would like to play with toys. If a child says that they do not want to play, or decides in the middle of the study that they want to play no longer, the child will be allowed to withdraw without penalty. Parents may also elect to stop their own or their child's participation in the study at any time.

## 9. Outcome Measures

### a. Primary outcome measures

The primary study outcomes are the video-coded measures of age-appropriateness and play complexity. We will examine differences in the mean scores of play among toys from the three age groups that are chronologically adjacent (i.e., the differences in outcomes for a given age group with the age-appropriate toy in comparison with toys from the same toy category just below and just above that age group).

### b. Secondary outcome measures

Our other secondary outcome measures include the following:

- Parts and features of toys used by the child
- Duration of time child spends with each toy
- Child preference for the toys based on child-report (smiley face Likert scale)
- Number of times and duration of time the child solicits the parent's or friend's involvement during play

## 10. Statistical Analysis

### a. Analysis of data/ study outcomes

For our primary outcome measure, our independent variables will be the age group for which the toy is aimed (younger vs. age-appropriate vs. older; within-subject) and the age group of the child (6 groups; between-subject), and our dependent variables will be the video-coded measures of play. The statistical methodology that we will use to analyze this question is a repeated-measures ANCOVA with up to five covariates. Our five covariates include the following: (1) toy characteristics, (2) child temperament, (3) family socioeoconomic status, (4) child preferences for the toy, and (5) parenting knowledge.

For our secondary outcome of interest (how children play alone vs. with parent), we will conduct another repeated-measures ANCOVA with condition (alone vs. with parent) and designated toy age (younger vs. age-appropriate vs. older) as within-subject factors and child age (6 groups) as a between-subject factor. Again, our dependent variables will be the video-coded measures of play. We will also use the same five covariates mentioned above: (1) toy characteristics, (2) child temperament, (3) family socioeconomic status, (4) child preferences for the toys, and (5) parenting knowledge.

Both of the repeated-measures ANCOVA designs will also be employed when we examine the dependent variables of secondary interest noted in section 9b, such as parts and features of toys used by the child, duration of time child spends with each toy, child preference for the toys based on child-report (smiley face Likert scale), and the number of times and duration of time the child solicits the parent's involvement during play. The independent variables mentioned above would remain the same.

We do not have any planned interim analysis. Our criteria for significance is alpha = .05. Due to the protocol's design, unplanned missingness will be low. Missing data procedures, such as Full Information Maximum Likelihood and Multiple Imputation, will be used.

### b. Power analysis

For our primary research question, a power analysis revealed that 360 parent child dyads split across 6 age groups and 3 within-subject designated toy ages (younger vs. age-appropriate vs. older) is sufficient to detect a medium effect ($f = .25$) for between-subjects and within-subjects effects and their interactions in a RM-ANCOVA with 5 covariates (power = .80 and alpha = .05).

For our secondary research question, a power analysis revealed that 360 parent child dyads split across 6 between-subject age groups, 2 within-subject conditions (alone vs. with parent), and 3 within-subject designated toy ages (younger vs. age-appropriate vs. older) is sufficient to detect a medium effect ($f = .25$) for within- and between-subject effects and their interactions in a RM-ANCOVA with 5 covariates (power = .80 and alpha = .05).

For both our primary and secondary research questions, our five covariates include the following: (1) toy characteristics, (2) child temperament, (3) family socioeoconomic status, (4) child preferences for the toys, and (5) parenting knowledge. Subject dropouts will be replaced with other comparable subjects who complete the protocol.

## 11. Human Subjects Protection

### a. Subject selection

Participants of any race, ethnicity, sex, nationality, religion, and handedness may participate. Approximately equal numbers of male and female children will be recruited, and to the extent possible, the sample will be racially and ethnically diverse.

However, we must exclude the following populations:

- *Children outside of the 6 month-12 year age range:* These years cover early life and are the ages of interest for children's play and are of central significance to the Consumer Product Safety Commission's goals.
- *Families not fluent in English:* Fluency in English is essential for parents to be able to fill out surveys. Families also need to be fluent in English so that they can comprehend verbal directions given by the experimenter during the testing session. If we included people who were not fluent in English, we would need many additional staff members who speak the multitude of languages of the diverse population of the Washington, D.C metro area to work with participants during the testing session and code the videos after the testing session is complete.
- *Children who are sick, not typically developing, born premature (if they are under 24 months of age), blind, or deaf:* We must recruit a healthy sample of typically developing children born in a full term pregnancy (if they are under 24 months of age) who are not blind or deaf for this project to remove any potential confounds that atypical conditions may have on children's play. *Typically developing* children would not have any diagnosed congenital conditions, developmental delay or disability, dyslexia, PDD, ADD, ADHD, or ASD. Including other populations such as deaf or blind children would require a different experimental set up, stimulus toys, and resources (i.e., someone who could convert our surveys to American Sign Language or Braille and could code the videos for the parent child behaviors during those sessions).
- *Children who are not adding to the ethnic and racial diversity of the sample:* The goal of our study is to recruit a sample of subjects who are racially and ethnically diverse. By making this diverse sample a priority, we hope that our results will be applicable to the diverse populations residing within the United States. To keep with this goal of a diverse and representative sample of children, we may have to

exclude some families if we have already reached the quota of families from that particular racial or ethnic group.

**b. Justification for inclusion of children**

The following project must include children because child behavior is at the heart of the research question for this project. Without including a young subject population, we would not be able to provide the required information to the Consumer Product Safety Commission.

**c. Justification for inclusion of other vulnerable subjects** AND/OR
**Justification for exclusion of other vulnerable subjects**

Not applicable.

**d. Justification for sensitive procedures**

Not applicable—there are no sensitive procedures in this project.

**e. Safeguards for vulnerable populations and sensitive procedures**

Children are welcome to withdraw from the study at any time, and their confidentiality will be protected throughout the testing process.

**f. Qualifications of investigators**

Principal Investigator: **Diane L. Putnick, Ph.D., NICHD**
has extensive research experience designing experiments, working with minors, collecting data, analyzing data, and writing research reports.

Associate Investigators:
**Melissa N. Richards, Ph.D., NICHD**
**Diane L. Putnick, Ph.D., NICHD**
**Todd D. Little, Ph.D., Texas Tech University**
**Kyle M. Lang, Ph.D., Tilburg University**
**Laura Bradley, B.A., University of Pennsylvania**
**Marc H. Bornstein, Ph.D., NICHD**
All Associate Investigators have extensive research experience designing experiments, working with minors, collecting data, analyzing data, and writing research reports. Dr. Little, Dr. Lang, and Dr. Bornstein's protocol related duties will not include obtaining consent from patients. They will only engage in analysis of de-identified data.

Research Assistants and Data Collection Aides:
**Post-baccalaureate IRTA Research Assistants**
All IRTA Research Assistants have Bachelor's degrees in psychology or other social science related fields and have prior experience working in

a research laboratory. IRTAs will be trained thoroughly in the methods of the protocol.

Only the principal investigator and the associate investigators are eligible to obtain informed consent.

The Principal Investigator has verified that all individuals working on this protocol required to take HRPP training under OHSRP SOP 25 (Training requirements for the NIH Human Research Protections Program) will have completed all required training before starting work on the protocol.

**12. Anticipated Benefit**

This study does not offer direct benefit to participants but will yield generalizable knowledge about how to categorize traditional and contemporary children's products and toys into age appropriate groups. The age determinations based on this research that are made by the CPSC have a large and generalizable impact on U.S. children, their families, and the current practices of toy manufacturers and the CPSC. First, the changes made to the CPSC Guidelines based on the results of this study will have a large impact on how the CPSC determines the age appropriateness of children's products and toys. In addition, manufacturers of children's products and toys adhere to the CPSC Guidelines when determining what target age to label on packages of their products. Finally, U.S. Consumers of these goods are steered in their purchasing decisions of these products based on the age labels on the toys.

**13. Classification of Risk** *(for the study as a whole)*

For the child participants, this project is classified under 45CFR46.404; it does not involve greater than minimal risk to children. The probability and magnitude of harm or discomfort anticipated with the research are not greater in and of themselves than those ordinarily encountered in daily life.

For our adult (parent) participants, this study does not involve greater than minimal risk. It is possible that some participants may find that some of the questions touch on areas of personal sensitivity and experience discomfort. Participants can decline to answer any question. No invasive procedures or interventions are involved.

**d. Overall risk and benefit consideration**

The less than minimal risk involved in this project is reasonable in relation to anticipated benefit. The benefit of this study lies in the extension of knowledge of how to effectively categorize children's toys in the U.S. for parents into age appropriate categories, leading to a safer consumer market for children and their families.

**14. Consent Documents and Process**

**a. Designation of those obtaining consent**

Study investigators designated as able to obtain consent in Section #11f above will obtain informed consent. All study investigators obtaining informed consent will have completed the NIMH HSPU 'Elements of Successful Informed Consent' training. Verbal or written assent will be obtained from minor subjects over age 4.

**b. Consent procedures**

Permission for participation of minors will be obtained from parents/legal guardians. Parents will have the opportunity to carefully review the written consent form and ask questions regarding the study prior to signing. After the consent form has been filled out and parental permission is obtained, the parent and child may begin participation in the study.

Permission from only one parent is being requested. The permission of one parent is sufficient for compliance with 45 CFR 46.404, as the proposed research poses risk no greater than that ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (i.e., minimal risk).

At the time of the play session, CFRS staff will also obtain assent from the children to ensure that they want to participate in the study as well. Parents will be present during the assent process and will sign the bottom of the assent form to certify that they witnessed their child's assent.

Children between the ages of 4-5 will provide verbal assent. Researchers will sign the form to certify that they received assent from the participant. Language for verbal assent will be as follows:

> "We are doing this project because we want to know more about how kids play with toys. If you join in, you will play with some toys. My friend here is going to use a camera to make a video of you while you play with the toys. Nobody will see the video except people who work with us, and we will keep the video private by putting it in a locked room. Then, I will ask you some questions. You might like playing with these toys, but you might not like it. If you do not want to play with them, you do not have to. We will get to learn about what kids like and how they think if you will help us. You will also get to play with some toys. If you do not want to play anymore, you do not have to. Just tell me if you do not want to play anymore! If you decide you want to stop, you can leave—I will not be upset. Anything that you say to me will be safe. Do you have any questions? Would you like to do this?"

Children over the age of 6 will be read the same statement and will be asked to sign a written assent form to indicate their willingness to participate.

**c. Consent documents**

The consent form contains all required elements of information needed to understand the goals and procedures of the study and will use the language set forth in the NICHD

consent form template  The information will be taken from this protocol, but worded in such a way that it is easy to understand at approximately an 8th grade reading level.

As such, it will contain information about the following elements:
Introduction, Purpose of The Study, Background, Study Population, Inclusion Criteria, Exclusion Criteria, Procedures, Risks, and Discomforts, Use of Stored Data, Anticipated Benefits, Right of Withdrawal, How Findings will be Shared with Participants, Alternatives to Participation, Confidentiality, Compensation, Policy Regarding Research-Related Injuries, Conflict of Interest, and Problems or Questions.

## 15. Data and Safety Monitoring

### a. Data and safety monitor

Data and safety will be monitored by the Principal and Associate Investigators. Ultimately, the Principal Investigator is responsible for all aspects of the study.

This protocol does not meet the criteria as outlined in the NIH HRPP SOP 17 for data to be submitted to a data safety monitoring committee, therefore, this project does not have a DSMB.

### b. Data and safety monitoring plan

Participant safety will be monitored while playing with the toys; because this is not a clinical trial, we will not engage in planned interim analyses.

Lead Associate Investigator Melissa Richards is responsible for coordinating data collection and will review the data for accuracy and completeness within 48 hours of each subject visit, including review of subject consent documents. An evaluation of subject recruitment, accrual, and retention as specified in the protocol will be ongoing. Review of literature and results of related studies will be assessed throughout the study for any impact on patient safety or ethical questions.

### c. Criteria for stopping the study or suspending enrollment or procedures

In the event that the study is stopped or enrollment or procedures are suspended, a review will be completed by the principal and associate investigators to determine if research can resume.

## 16. Quality Assurance

### a. Quality assurance monitor

This research is social/behavioral in nature and minimal in risk and does not involve interventions or drugs.  Therefore, the people who will perform monitoring are the Principal and Associate Investigators, as well as the NICHD Quality Assurance Program.

### b. Quality assurance plan

Oversight of monitoring will be performed by the NICHD Quality Assurance (QA) Program. The NICHD Quality Assurance Program will perform random audits annually on at least 10% of actively accruing NICHD protocols (policy: https://science.nichd.nih.gov/confluence/display/ocd/Protocol+Navigation).

**17. Reporting of Unanticipated Problems, Adverse Events and Protocol Deviations**
The Principal Investigator is responsible for detecting, documenting, and reporting unanticipated problems, adverse events (AEs), including serious adverse events (SAEs), and deviations in accordance with NIH policy, IRB requirements, and federal regulations. Relatedness to the research of all serious adverse events will be determined by the PI in consultation with the Clinical Director (CD).

All Unanticipated Problems (UP), Protocol Deviations (PD), deaths, and Adverse Events (AE) will be reported to the IRB or the Clinical Director (CD) using PTMS, in accordance with SOP 16. When PTMS is not available, the NIH Problem Report Form will be used. (https://federation.nih.gov/ohsr/nih/ohrdocs/NIH_Problem_Report_Form_Fillable_DDIR_v1_6-11-13_508.pdf).

Serious unanticipated problems and serious protocol deviations will be reported to the IRB and CD as soon as possible but not more than 7 days after the PI first learns of the event. Non-serious UP's will be reported to the IRB and CD, and non-serious PD's to the IRB not more than 14 days after the PI first learns of the event. Written reports will be submitted in PTMS. Deaths will be reported to the CD within 7 days after the PI first learns of the event.

An aggregated summary of all UP's, PD's, UADE's, and AE's will be reported to the IRB at the time of Continuing Review (CR).

All IRB documentation can be found in PTMS. The Principal Investigator is responsible for maintaining IRB documentation, including records of all reviews of the study and submissions to the IRB.

**18. Alternatives to Participation** OR **Alternative Therapies**
Participants do not receive any treatment in this study or forego any treatment in order to participate in this study. The alternative, therefore, is not to participate.

**19. Privacy**
All research activities will be conducted in as private a setting as possible. All research activities will be conducted by researchers who have been trained on the protocol of the project.

All information collected in connection with this study is confidential. If CTSS is used, each participant will be provided with a unique password to access the website in order to

complete the questionnaires. Online responses are identified with a randomly generated coded number, rather than with the name of the participant. Data will be stored permanently on the National Institute of Child Health and Human Development computerized database. No one other than members of the research team will have access to the data without the explicit consent of the participant adult.

We will do everything we can to keep outsiders from learning about families' participation in this study. To further help us protect their privacy, we will obtain a Certificate of Confidentiality from the United States Department of Health and Human Services (DHHS). With this Certificate, we cannot be forced (for example by court order or subpoena) to disclose information that may identify subjects in any federal, state, local, civil, criminal, legislative, administrative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify participants, except to prevent serious harm to themselves or others.

**20. Confidentiality**

**a. For research data and investigator medical records**

Child participants will be assigned ID numbers at the outset of the study. The key linking the ID numbers with the participants' identity and videos taken of the children will be kept in a locked filing cabinet in a room that is locked when unoccupied.

Electronic data will be kept in password-protected computers and servers. Only study investigators will have access to the samples and data. Data collected on paper will be de-identified through the use of the ID number assigned to the participant at the outset of the study. Data collected on paper will be entered into electronic spreadsheets. All participant identifying data except for subject numbers will be removed from these spreadsheets.

In addition, parents will have the option of indicating on the consent form whether or not they will allow the use of short video clips of themselves and their child at professional presentations and conferences. Parents may contact us to change their preferences for the public use of these videos at any time, both during or after the study.

Subject confidentiality will be maintained to the greatest extent possible. Research results will be labeled using a unique code. Publications will not include subject names nor will they contain personal identifying information.

**b. For stored samples**

Not applicable, we are not collecting any samples, only data.

**c. Special precautions**

Not applicable

## 21. Conflict of Interest

### a. Distribution of NIH guidelines

NIH guidelines on conflict of interest have been distributed to all investigators.

### b. Conflict of interest

There are no conflicts of interest to report.

### c. Role of a commercial company or sponsor

Not applicable; this study does not have a commercial company collaborator or sponsor.

## 22. Technology Transfer

Not applicable; there are no associated tech transfer agreements for this study.

## 23. Research and Travel Compensation

Volunteers will be compensated for time and research-related inconveniences. Each parent-child dyad enrolled will be paid a total of $30 for participation in the study.

If parents participate in the focus group, they will receive an additional $10 of payment for participating.

Participants may elect to have the payment dispersed either through a check mailed to their home or directly deposited into their bank account. In both circumstances, researchers will register the payment in the NIH Clinical Center Research Volunteer System (https://rvs.cc.nih.gov). If participants elect to the have the payment directly deposited into their bank account, an additional form with the participants' bank routing number will have to be completed through RVS. Payment will be coordinated through Ms. Mandy Jawara, *Program Coordinator*, NIH Clinical Center Office of Patient Recruitment—Healthy Volunteer Program. If parents would prefer to not fill out the form, they may call Mandy Jawara directly and provide her with this information over the phone. Payment will be sent after the visit to the CFRS.

Compensation will be prorated for parts completed if participants do not complete the entire study.

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