SOCIAL & BEHAVIORAL SCIENCES APPLICATION FORM

Version 4.7
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IRB Use Only
IRB Study #

1. Project Identifiers

1.1 Project Title (Project title must match grant title. If different, also provide grant title):

Assessment of Executive Function for the National Children's Study

1.2 Person preparing this document

Name: Amanda Wenzel	Phone number: 920-362-2551
Email: wenz0107@umn.edu	Fax: 612-624-6373

- Please note that if you intend to perform work on this project, then you will also need to be listed as principal investigator, co-investigator, or staff.

1.3 Principal Investigator (PI)

Name (Last name, First name MI): **Masten, Ann S**	Highest Earned Degree: **PhD**
Mailing Address: **51 East River Rd** **Minneapolis, MN 55455-0345**	Phone Number: **612-624-0215**
	Pager or Cell Phone Number: **651-699-0204**
	Fax: **612-624-6373**
U of M Employee/Student ID: **0997544**	Email: **amasten@umn.edu**
U of M x.500 ID (ex. smith001): **amasten**	University Department (if applicable): **Institute of Child Development**
Occupational Position: ☒Faculty ☐Staff ☐Student ☐Fairview Researcher ☐Gillette Researcher ☐Other:	
Human Subjects Training ☐ CITI , ☒Investigator 101 (until 2008), ☐NIH training (EXCEPT for 5/8/06 to 2/29/08), ☒UM/RCR (between 1994-2003) ☐ Other - Indicate training received, when and from which institution:	HIPAA Training (Required if Data Contains PHI): ☒ HIPAA

As Principal Investigator of this study, I assure the IRB that the following statements are true:
The information provided in this form is correct. I have evaluated this protocol and determined that I have the resources necessary to protect participants, such as adequate funding, appropriately trained staff, and necessary facilities and equipment. I will seek and obtain prior written approval from the IRB for any substantive modifications in the proposal, including changes in procedures, co-investigators, funding agencies, etc. I will promptly report any unexpected or otherwise significant adverse events or unanticipated problems or incidents that may occur in the course of this study. I will report in writing any significant new findings which develop during the course of this study which may affect the risks and benefits to participation. I will not begin my research until I have received written notification of final IRB approval. I will comply with all IRB requests to report on the status of the study. I will maintain records of this research according to IRB guidelines. The grant that I have submitted to my funding agency which is submitted with this IRB submission accurately and completely reflects what is contained in this application. If these conditions are not met, I understand that approval of this research could be suspended or terminated.

amasten	**01/05/2011**	**Professor**
x.500 of PI	Date	Title of PI

Training Links:
FIRST (Fostering Integrity in Research, Scholarship and Training): http://cflegacy.research.umn.edu/first/humansubjects.htm
HIPAA: http://www.research.umn.edu/first/AdditionalCourses.htm
- "UM/RCR" includes all human subjects protection training offered in-person or online at the University of Minnesota from 1994-2003.
- The online NIH tutorial offered during the period May 8, 2006-February 29, 2008 is NOT acceptable to meet this requirement.
- If you completed a version of this training not included on the list provided, provide details as indicated

1.4 Co-Investigator(s)

Co-Investigators responsible for, or working on this project should be listed below. Include any individual who will have responsibility for the consent process, direct data collection from subjects, or follow-up.

Name (Last name, First name MI): **Zelazo, Philip D**	Highest Earned Degree: **PhD**
Mailing Address: **51 East River Rd.** **Minneapolis, MN 55455-0345**	Phone Number: **612-625-5797**
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Human Subjects Training ☒ CITI , ☐Investigator 101 (until 2008), ☐NIH training (EXCEPT for 5/8/06 to 2/29/08), ☐UM/RCR (between 1994-2003) ☐ Other - Indicate training received, when and from which institution:	HIPAA Training (Required if Data Contains PHI): ☒ HIPAA

zelazo	**01/05/2011**	**Professor**
x.500 of Co-PI	Date	Title of Co-PI

Name (Last name, First name MI): **Carlson, Stephanie M**	Highest Earned Degree: **PhD**
Mailing Address: **51 East River Rd.** **Minneapolis, MN 55455-0345**	Phone Number: **612-625-6127**
	Pager or Cell Phone Number:
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Occupational Position: ☒Faculty ☐Staff ☐Student ☐Fairview Researcher ☐Gillette Researcher ☐Other:	
Human Subjects Training ☒ CITI , ☒Investigator 101 (until 2008), ☐NIH training (EXCEPT for 5/8/06 to 2/29/08), ☐UM/RCR (between 1994-2003) ☐ Other - Indicate training received, when and from which institution:	HIPAA Training (Required if Data Contains PHI): ☒ HIPAA

smc	**01/05/2011**	**Professor**
x.500 of Co-PI	Date	Title of Co-PI

Research Staff

Personnel you wish to be included in correspondence related to this study e.g. study coordinators

Name (Last name, First name MI): **Anderson, Jacob E**	Highest Earned Degree: **M.A.**
Mailing Address: **51 E. River Rd** **Minneapolis, MN 55455**	Phone Number: **612-624-4071**
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Occupational Position: ☐Faculty ☒Staff ☐Student ☐Fairview Researcher ☐Gillette Researcher ☐Other:	
Human Subjects Training ☒ CITI , ☐Investigator 101 (until 2008), ☐NIH training (EXCEPT for 5/8/06 to 2/29/08), ☐UM/RCR (between 1994-2003) ☐ Other - Indicate training received, when and from which institution:	HIPAA Training (Required if Data Contains PHI): ☒ HIPAA

Name (Last name, First name MI): **Ukestad, Laurie K**	Highest Earned Degree: **MS**
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Occupational Position: ☐Faculty ☒Staff ☐Student ☐Fairview Researcher ☐Gillette Researcher ☐Other:	
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Need more space for Co-Investigators and Staff? *Download an extra personnel sheet and include it with your application.*

1.5 Student Research

***If the PI of this research is a student**, include **Appendix J** filled out by the advisor with this application form and include the advisor's x500 below.*

Advisor Name (Last name, First name MI):	Highest Earned Degree:
Mailing Address:	Phone Number:
	Pager or Cell Phone Number:
	Fax:
U of M Employee/Student ID:	Email:
U of M x.500 ID (ex. smith001):	University Department (if applicable):
Occupational Position: ☐Faculty ☐Staff ☐Student ☐Fairview Researcher ☐Gillette Researcher ☐Other:	
Human Subjects Training ☐ CITI , ☐Investigator 101 (until 2008), ☐NIH training (EXCEPT for 5/8/06 to 2/29/08), ☐UM/RCR (between 1994-2003) ☐ Other - Indicate training received, when and from which institution:	HIPAA Training (Required if Data Contains PHI): ☐ HIPAA
x.500 of Advisor	Date

2. Funding

2.1 Is this research funded by an internal or external agency?

☒ **Yes.**

Type of Funding Source: ☒ Federal Funds ☐ Foundation ☐ Business and Industry

Name of Funding Source: National Institute of Health (NIH), National Institute of Child Health and Human Development (NICHD), National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

Include Appendix A

☐ **No.** Explain how costs of research will be covered:

3. Institutional Oversight

3.1 Is this research proposal being reviewed by any other institution or peer review committee?

☒ **Yes.** Attach copy of materials submitted for peer review.
☐ **No.**

If yes, Please select which other committee approvals are required for this research and provide documentation of their approval:

☐ Cancer Protocol Review Committee (CPRC)
☐ Cancer Protocol Review Committee/Non-Therapeutic Interventional Trials Review (CPRC/NTI)
☐ Conflict Management Review Committee (CMRC)
☐ University Research Opportunity Program (UROP)
☐ Nursing Research Council
☐ Grant-In-Aid of Research, Artistry, and Scholarship Program (GIA)
☐ Other IRB, please specify: ___
☒ Other, please specify: National Children's Study (NCS), Office of Management and Budget (OMB); submission pending

Peer review Web sites:

- Cancer Protocol Review Committee (CPRC)
- Cancer Protocol Review Committee/Non-Therapeutic Interventional Trials Review (CPRC/NTI)
- University Research Opportunity Program (UROP)
- Grant-In-Aid of Research, Artistry, and Scholarship Program (GIA)

3.2 Does this research involve cancer prevention, treatment, survivorship, or supporting care?

☒ No.

☐ Yes.
If this research is cancer-related, including prevention, treatment, survivorship or supportive care, then documentation of approval from the Cancer Protocol Review Committee (CPRC) or CPRC/NTI (Non-Therapeutic Interventional) MUST be provided before final IRB approval can be granted. If this cancer-related research has been peer-reviewed by NIH, CPRC approval is still required.

4. Conflict of Interest

Federal Guidelines emphasize the importance of assuring there are no conflicts of interest in research projects that could affect the welfare of human subjects. Disclosure of financial interests is required from all individuals involved in the design, conduct or reporting of the research. If this study involves or presents a potential conflict of interest, additional information will need to be provided to the IRB. Examples of potential conflicts of interest may include, but are not limited to:

- A researcher or family member participating in research on a technology, process or product owned by a business in which the faculty member holds a financial interest
- A researcher participating in research on a technology, process or product developed by that researcher
- A researcher or family member assuming an executive position in a business engaged in commercial or research activities related to the researchers University responsibilities
- A researcher or family member serving on the Board of Directors of a business from which that member receives University-supervised Sponsored Research Support
- A researcher receiving consulting income from a business that funds his or her research

"Immediate Family" means, at a minimum, spouse and each dependent child.
"Financial Interest Related to the Research" means financial interest in the sponsor, product or service being tested.

University of Minnesota Researchers, please refer to:
http://www1.umn.edu/regents/policies/administrative/Individual_COI.pdf
Fairview Health System Researchers, please refer to:
http://www.fairview.org/prof/research
http://www.gillettechildrens.org/

4.1 Do any of the Investigators or personnel listed on this research have a business interest or a financial interest of $10,000 or more associated with this study when aggregated for their immediate family?

☒ No.
☐ Yes.

If yes, identify the individual(s) and complete section 4.3:

4.2 Do any of the investigators or personnel (when aggregated for their immediate family) listed on this research have:

Ownership interests less than $10,000 when the value of interest could be affected by the outcome of the research.
☒ No. ☐ Yes.

Do ownership interests exceed 5% interest in any one single entity when aggregated for the immediate family?
☒ No. ☐ Yes.

Compensation less than $10,000 when the value of the compensation could be affected by the outcome of the research.
☒ No. ☐ Yes.

If yes, identify the individual(s) and complete section 4.3:

4.3 Has this potential conflict of interest been disclosed and managed?

☐ No.
If you are a University of Minnesota researcher, please disclose your potential conflict of interest online for review by your Department Head and Dean via the Report of External Professional Activities (REPA) at https://egms.umn.edu/REPA/
If you are a Fairview Health System researcher, please complete the Fairview Health Services Conflict of Interest Disclosure forms (http://www.fairview.org/prof/research/proceed_forms.asp) and submit the completed forms to the Fairview Office of Research.
If you are a Gillette Children's Specialty Healthcare researcher, please contact the Director of Research Administration, at 651-229-1745.
☐ Yes. Date of Management Plan:

The IRB will verify that a management plan is in place with the Conflict Review and Management Committee (CRC). If the CMC does not have an approved management plan for this research, the CMC will contact the individual(s) listed in question 4.1 for additional information.

Final IRB approval cannot be granted until all potential conflict matters are settled. The IRB requires a recommendation from the CRC regarding disclosure to subjects and management of the conflict. The full IRB committee determines what disclosure language should be in the consent form.

5. Compensation

5.1 Will you give subjects gifts, payments, compensation, reimbursement, services without charge or extra credit?

☒ Yes.
☐ No.

If yes, please explain:

In the pilot phase of the study children will receive a small toy or book (valued at about $5) and their parent will receive a thank you for participation ($20 gift card to Target). Teachers will receive a $10 gift card after each packet (one per child) they complete. Each participant will also receive a small National Children's Study souvenir with the study logo (e.g., t-shirts for children, pen, keychain).

In the second phase of the study (validity study), children will receive a small toy (valued at $5) and their parent will receive a thank you for participation ($20 gift card) after each session they complete. Teachers will receive a $10 gift card. A random subset of 30 families will be invited to participate in two follow-up sessions, two weeks after the initial session and again two months after the first session, for a total of 3 sessions). For these families, the parent will receive a $20 gift card for each session and an additional $20 gift card bonus for completing all the sessions. Teachers will also be provided with $10 gift cards for each follow-up assessment for completing the teacher packet of questionnaires. Each participant in the validity study will also receive a small National Children's Study souvenir with the study logo (e.g., t-shirts for children, pen, keychain).

6. Summary of Activities

Use lay language, do not refer to grant or abstract.

6.1 Describe the objective(s) of the proposed research including purpose, research question, hypothesis and relevant background information etc.

Background:
The National Children's Study (NCS) Pilot Recruitment Study is a longitudinal study that will follow a representative sample of children from before birth to age 21, born to women recruited from 105 locations that generally correspond to counties across the U.S. Locally, the Pilot Recruitment Study will recruit and enroll eligible individuals from Ramsey County, one of the locations identified by the NIH. The purpose of the Pilot Recruitment Study is to assess the feasibility, acceptability and cost of the recruitment strategies, study procedures and outcome assessments that will be used in the Main NCS.
Multiple formative research projects have also been funded as methodological studies within the Pilot Recruitment Study which will inform the implementation and analysis of the Main NCS. The proposed study, called Assessment of Executive Function for the National Children's Study, is one of the methodological studies that will augment the overall efforts of the NCS-Pilot Recruitment Study. The Principal Investigator of this formative research project, Dr. Ann Masten, is collaborating closely with the research team currently conducting the Pilot Recruitment Study.

The National Children's Study Pilot Recruitment Study was approved by the University's IRB on September 20, 2010 (HCS# 1007M86413).

Currrent proposed study:

The objective of this formative project study for the NCS is to develop measures of Executive Function (EF) for 3-5 year olds and their mothers for possible use in the NCS Main Study. It is widely recognized that EF skills are important for many aspects of human health and development, including physical and

mental health and educational success of children and adults (Blair & Razza, 2007; Buckner, 2008; Carlson & Zelazo, in press; Obradović, 2010). Currently available measures were not developed for the assessment of diverse cohorts of children, especially in regard to psychosocial disadvantage and ethnic or cultural diversity. It is important that the measures adopted by the NCS be efficient and also broadly suitable for the full range of families that will be included in the NCS. This project is designed to adapt existing EF measures that have good evidence of validity and reliability for middle class or more advantaged samples, such that the measures demonstrate similar robustness when used with less advantaged or with culturally diverse individuals.

Three key measures will be adapted for preschool-aged children (ages 3 to 5): two computer-administered tests from the NIH Toolbox assessment battery that were developed to measure EF for individuals spanning ages 3 to 85 (Flanker and the Dimensional Change Card Sort; DCCS); and the Children's Behavior Questionnaire (CBQ) developed by Mary Rothbart and colleagues. The two NIH Toolbox measures of EF were recently developed by a team that included Professor Zelazo (creator of the DCCS and lead adaptor of the Flanker and DCCS tasks for the Toolbox) and Jacob Anderson (who did the programming), both involved in this formative project. The Toolbox project was also guided by the research of Professor Carlson, internationally known for her expertise on the assessment of EF in preschool children. Mary Rothbart, creator of the CBQ is consulting on this project to help adapt the CBQ.

The CBQ, Flanker, and DCCS tasks have all been used in recent research projects here directed by Professors Masten, Carlson and Zelazo. Their research has corroborated the value of these measures for predicting important developmental outcomes (such as school success), while at the same time indicating that they need to be revised to be more suitable for culturally diverse, minority and low SES families. For example, the floor of the two Toolbox tasks appears to be too high for young disadvantaged children and the CBQ has some items that less educated parents find confusing. The CBQ also has some content more salient for middle class families than for parents from more diverse backgrounds. Given the growing evidence of the significance of EF skills for understanding human development, education, and health, and the goal of the NCS to have efficient measures that will work across diverse families that represent the population of the United States, it is important to adapt these measures and confirm their reliability and construct validity for a more diverse range of families. This project is particularly focused on adapting the measures so they are effective for use with low-income families as well as more advantaged families.

6.2 Which methods will this study include? (check all that apply)

- ☐ Descriptive
  - ☐ Ethnographic
  - ☐ Experimental/Control Design
  - ☐ Field work (***If checked, please include Appendix L)***
  - ☒ Formative
  - ☒ Longitudinal
  - ☐ Oral history
  - ☐ Phenomenological
  - ☒ Qualitative
  - ☒ Quantitative
  - ☐ Other, specify : ___

6.3 Describe the research study design.

This is a short-term formative project to adapt and then assess the usability and psychometric properities of measures that will be modified to be more accessible to participant families with a wide variety of socioeconomic bacgrounds. Families with a preschool-aged child, ages 3 to 5, will be recruited to participate in two different phases of this study through the programs at three sites: the Institute of Child Development at the University of Minnesota (families recruited from the Shirley G. Moore Laboratory School or research participant pool at the Institute of Child Development); families attending programs operated by The Family Partnership (formerly called Reuben Lindh Family Services), who operate

several preschools, and families with children in the early childhood programs at People Serving People, which is a shelter for homeless families. The Family Partnership and People Serving People serve low-income families from culturally diverse populations.

Professor Masten has conducted research with families from People Serving People for over 20 years. Professors Masten, Zelazo, and Carlson have been collecting data for other studies of EF in this shelter collaboratively in recent years and the shelter provides dedicated space for their research. The Family Partnership (Reuben Lindh) has newly remodeled space for their preschool programs at their main site with ample room to accommodate this project. Letters of support from these two community sites (People Serving People and Reuben Lindh) are included with this application. Usual recruitment procedures as described in section 8 will be followed to invite participation of families from the Lab School and the participant pool at the University. All three of the faculty leading this project are housed in the same department and building as the Lab School and the participant pool. Professors Carlson and Zelazo regularly collect data in studies related to EF and its development with these two populations of potential participants.

The project has two phases after the EF measures are adapted. In Phase 1 (pilot study), the newly adapted measures will be tested with 15 families (preschool child and mother or primary caregiver) at each of the three sites plus an additional 5 families for training. In Phase 2, 150 families (preschool child and caregiver) at each site will be recruited for a validity study. The study designs of these two phases are described below.

Phase 1 is designed to assess the user friendliness, burden (time and appeal), and fidelity of administration of the adapted measures with parents and children. Fifteen families with a preschool child will be recruited and tested at each of the 3 sites (on campus, The Family Partnership, and People Serving People), plus an additional five families for training (from any site). After consent procedures, parent and child will complete the assessment in separate rooms (nearby). If parents prefer, they may choose to come at a separate time from their child for the assessment to accommodate parent and preschool schedules. The parent will be asked to complete a demographic form, the CBQ, the EF Toolbox measures, the Ages and Stages Questionnaire and also to complete a short form evaluating the experience of completing these measures. Children will complete the newly modified Toolbox measures of EF and a set of additional measures of EF, cognitive and school readiness skills that will be evaluated for time burden and appeal to the children, within a one hour time limit. Teachers of the children in preschools will be invited to complete the new CBQ, portions of the Health Behavior Questionnare that assess learning and classroom behavior, and a very short rating of daily behavior in the child, the Q-ABC (all decribed below). Sessions will be videorecorded for reviewing fidelity of administration. .

After Phase 1, the methods may be further improved based on feedback from parents and research staff administering these tests, and the final set of measures for the validity study below will be chosen from those evaluated in Phase 1.

Phase 2 is designed to test the reliability and validity of the EF battery. One hundred fifty families with a preschool child ages 3-5 will be recruited from the three sites described above. After consenting procedures, the parent and child will be tested separately, either at the same time or a different times that best fit the parent's schedule and the child's preschool schedule. The parent protocol will include a demographic form, the CBQ, the Toolbox EF measures, the Ages and Stages Questionnaire, and the Q-ABC. The child tasks will include the Toolbox EF measures and a battery of cognitive and school readiness measures for the purpose of construct validation. These IQ measures, and school readiness measures of literacy and numeracy described below (TOPEL, Applied Problems, PPVT), and additional EF tasks as time permits. The child session will take one hour to complete. Preschool classroom teachers of the child will be asked to complete the CBQ and the Health Behavior Questionnaire for teachers, and a brief daily report of behavior, the Q-ABC, which will take a total of about 25 minutes.

A random subset of 10 children in each site (stratified to balance age and gender) will be invited to participate in repeated administration of the new measures to ascertain their test-retest reliability, stability and promise for assessing growth. On two more occasions at intervals two weeks and two months after the original session, the parent will be invited to complete the EF tasks, and the CBQ, Ages and Stages SE, and Q-ABC about their child (45 minutes). Children will be administered the Flanker and DCCS

tasks, along with the MPSI-R (2 week session) and/or additional EF validation tasks (same as Phase 1 tasks). Teachers will be asked to complete the CBQ, the HBQ, and the Q-ABC.

Parents will be given a $20 Target gift card to thank them for their participation, following completion of each session. Children will receive a small toy or book for participating in each session. A parent who completes all three sessions will receive an additional $20 gift card. Preschool teachers will be compensated $10 for their time for completing each set of child ratings.

Literacy can be an issue for some parents in the community sites. In order to be inclusive, the consent form and questionnaires will be read aloud to the parent as she or he follows along. This approach makes it possible for parents who have difficulties with reading accurately to participate without indicating that this is a problem.

6.4 Describe the tasks subjects will be asked to perform. Attach surveys, instruments, interview questions, focus group questions etc. Describe the frequency and duration of procedures, psychological tests, educational tests, and experiments; including screening, intervention, follow-up etc. (If you intend to pilot a process before recruiting for the main study please explain.)

Parent tasks:

Basic demographic information will be gathered pertaining to family structure, the age, education, and ethnicity of the parent and child, current occupation of parent(s) living in the home, and residential mobility. (10 minutes)

The Children's Behavior Questionnaire (CBQ). Parent perspectives on child personality will be assessed by a modified version of the very short form of the Children's Behavior Questionnaire (CBQ; Rothbart et al., 2001). The modifications (e.g., adding or simplifying items) will be made in consultation with Mary Rothbart, the creator of the CBQ, based upon previous findings in studies conducted by the investigators working with culturally diverse and disadvantaged populations. (10-15 minutes).

The Ages and Stages Questionnaire: Social-Emotional (ASQ-SE; Squires, Bricker, & Twombly 2002) is a widely used developmental screening tool that assesses seven areas of behavior (self-regulation, compliance, communication, adaptive functioning, autonomy, affect, and interaction with people) for children 3 months to 5 ½ years old. The version for children 3 to 5 years old contains 36 items. (10-15 minutes).

NIH Toolbox EF Measures (for child or parent). The standard NIH Toolbox versions of the DCCS and Flanker tasks (which take about 5 minutes each) will be administered to parent and child, if feasible. If a participant does not pass either the practice or the basic level on either the DCCS or Flanker (which we expect to be common for disadvantaged children), we will administer the new, less challenging preschool module (also taking about 5 minutes each) that we are creating for each. The DCCS task measures flexible rule use and requires the subject to adhere to stated rules governing the matching of target stimuli to different categories (Zelazo, 2006). The Flanker tasks measure selective attention and resistence to interference from distracting stimuli (Reuda et al., 2004). In the DCCS, the person plays a sorting game with shape or color rules. The subject must attend to the rule and sort correctly by the cued rule (shape or color). Accuracy and response time are measured by the computer program. In the Flanker task, the person is instructed to pay attention to which direction the middle image (a fish or an arrow) is pointing while distracted by flanker fish (children all start with fish) or flanker arrows (more advanced levels). The flankers can be pointing the same way (congruent) or the opposite way (incongruent). Children, for example, are instructed to feed the fish by touching the direction the middle fish is pointing.

These tasks will each be made simpler by adding levels that are easier. For example, in the Flanker task, the distractors can be separated by distance or the target fish can be made a different color to make the task easier. Adaptation of both these tasks will be based on the graduated scaling approach for the DCCS, pioneered by Carlson here in her studies of how to simplify these types of EF measures for

younger or less capable children.

Validation tasks for children

It is important to measure general intellectual function as a control variable and also to have independent comparison assessments for EF and school readiness in order to validate the new measures.

General intellectual functioning (an important control and comparison variable for evaluating the specific significance of EF) will be assessed by the Block Design (5 to 10 minutes) subtest of the Wechsler Preschool and Primary Scale of Intelligence – 3rd Edition (WPPSI-III, Wechsler, 2002) and the Peabody Picture Vocabulary Test – Fourth Edition (PPVT-4; Dunn & Dunn, 2007; 10-15 minutes). These have worked well in our assessments of cognitive skills in very disadvantaged children.

School readiness will be assessed by a set of subtests from two widely used and standardized measures of preschool literacy and numeracy, and the most prevalent local screening instrument. Applied Problems (5-10 min) is a subtest of the Woodcock-Johnson III NU Tests of Achievement (Woodcock, McGrew, & Mather, 2001), which has predicted EF in previous research (e.g., Blair & Razza, 2007; Bull & Scerif, 2001) and is itself a good predictor of learning in school. Three subtests of the Tests of Preschool Early Literacy (TOPEL; Lonigan, Wagner, Torgesen, & Rashoote, 2007) will be used to assess emergent literacy skills (Print Knowledge, Definitional Vocabulary, Phonological Awareness). These tasks have national norms for children (ages 3-6); excellent reliability and convergent validity with other measures of early literacy (Wilson & Lonigan, 2010), and work well for children with delayed emergent literacy skills. Phonological awareness scores were related to EF performance in prior research (e.g., Alloway et al., 2005; Swanson, 2006). We will test the time burden for each subtest and the set of three for the disadvantaged children in this project, and examine how EF skills relate to performance (15-20 minutes). The Minneapolis Preschool Screening Instrument – Revised (MPSI-R) is the standard screener for 3- to 5-year-olds, developed, revised, and validated by the Research, Evaluation and Assessment office in the Minneapolis Public Schools. It measures important indicators of school readiness, including cognitive (e.g., colors, information, matching, counting), language and literacy skills, motor and perceptual skills, and social-emotional function. Scores show strong predictive validity for early school achievement and behavior (15-20 minutes). The MPSI-R will be administred only for the subgroup of 30 children retested after 2 weeks.

Other EF measures will include the following tasks that are drawn from the design of our basic study, “Early School Success in Homeless and Highly Mobile Children” (approved under IRB# 0604S84367). The tasks were chosen with careful consideration of validity, low burden and appeal for participants and have worked well with children in the age range to be studied, including children in shelters.

Peg Tapping (Diamond & Taylor, 1996). This widely used task requires children to tap twice with a wooden dowel when the administrator taps once and to tap once when the administrator taps twice. After practice, there are 16 counterblanced test trials (3 minutes).

Computerized Pointing Stroop Task (Berger, Jones, Rothbart, & Posner, 2000). Children are trained first to point to a picture matching an animal sound (e.g., congruent trials, point to a cat after hearing “meow”) and then to point to a picture not matching the animal sound (e.g., point to a dog after hearing “meow”). After practice, children are presented with 16 congruent and 16 incongruent trials, counterbalanced (10 minutes).

Spin the Pots is a memory task. Depending on age and difficulty, 8 to 10 different pots or containers with lids are arranged on a lazy susan tray. The child and experimenter place one sticker in each pot, leaving two pots empty. Then the tray is covered with a cloth and spun. The child is asked to choose a pot to open in order to find the stickers. This is repeated until all stickers are found with a maximum of 16 to 20 trials depending on the number of pots. (5 to 10 minutes)

Teacher questionnaires

CBQ (described above under parent measures) will also be completed by teachers (10 minutes)

The MacArthur Health and Behavior Questionnaire (HBQ; Armstrong, Goldstein, & The MacArthur Working Group on Outcome Assessment, 2003) is a brief measure of developmental history, health, and behavior (there are parent and teacher versions) that has worked well in our recent research with diverse low-income parents, including homeless parents living in a shelter. Sections of this measure that have shown the best predictive validity in our research will be administered, including assessments of social competence, behavior, peer relationshipes and emotional function in the child. (10 minutes)

Q-ABC rating scales of daily child behavior (described above under parent measures) will also be completed by teachers.

6.4a List here any procedures that would be performed for these subjects if there were no research involved (i.e. procedures performed for diagnostic or treatment purposes)

None.

6.5 How many months do you anticipate this research study will last from the time final approval is granted?

This study has been planned and initially funded to last approximately 10 months from the time final IRB approval is granted.

7. Participant Population

7.1 Expected number of participants: 400

110 **of Male** 290 **of Female**

7.2 Expected Age Range

Check all that apply:

☒ **0-7** (Include parental consent form)
☐ **8-17** (Include child's assent form and parental consent form)
☒ **18-64**
☐ **65 and older**

Exact ages to be included:_____

7.3 Inclusion/Exclusion of Children in this Research

If this study proposes to ***include*** children, this inclusion must meet one of the following criterion for risk/benefit assessment according to the federal regulations (45CFR56, subpart D).
Check the one appropriate box:

☒ (404) Minimal Risk
☐ (405) Greater than minimal risk, but holds prospect of direct benefit to subjects
☐ (406) Greater than minimal risk, no prospect of direct benefit to subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.

Explain how this criterion is met for this study:

This research poses minimal risk in terms of the methods used. For children, the study involves non-invasive and child-friendly tasks, appropriate for use with the participant population (3- to 5 year-old children) under investigation, similar to preschool activities and games. The tasks are designed to be engaging to children this age.

For the parents as well, methods also are designed to be non-invasive and low-risk, and are not expected to pose any distress.

If this study would ***exclude*** children, NIH guidelines advise that the exclusion be justified, so that potential for benefit is not unduly denied. Indicate whether there is potential for direct benefit to subjects in this study and if so, provide justification for excluding children. Note that if inclusion of children is justified, but children are not seen in the PI's practice, the sponsor must address plans to include children in the future or at other institutions.

☐ No direct benefit to participation (exclusion of children permissible)
☐ Potential for direct benefit exists.

Provide justification for exclusion of children:

7.4 Other Protected Populations to be Targeted or Included in this Research. Check all that apply:

Protected by Federal Regulations

☐ Pregnant Woman/Fetuses/IVF
Refer to guidance at http://www.research.umn.edu/irb/guidance/women.html and 45CFR46 subpart B
☐ Prisoners
Include Appendix C and Refer to and 45 CFR 46 subpart C on the populations protected by Federal Regulations

Protected by Federal Guidelines

Include Appendix I
☐ Mentally/Emotionally/Developmentally Disabled/Impaired Decision Making Capacity
☒ Minority Group(s) and Non-English Speakers
☒ Gender Imbalance—all or more of one gender

7.5 Inclusion and Exclusion of Subjects in this Research Study

Describe criteria for inclusion and exclusion of subjects in this study

Inclusion Criteria:

Three- to five-year old children and their primary caregivers who attend programs at The Family Partnership (Reuben Lindh), People Serving People, or the U of M Lab School in the Institute of Child Development or who have volunteered for the Participant Pool of the Institute of Child Development.

Exclusion Criteria:

Children and parents who do not speak English. Children with a parent-reported disability that would preclude full participation (such as a pervasive developmental disability, blindness, or deafness).

7.6 Location of subjects during research activity or location of records to be accessed for research:

Check all that apply:

☐ University of Minnesota Medical Center, Fairview
☐ Fairview Southdale
☐ Fairview Ridges

☐ Other Fairview Facility, specify: _____
☐ Gillette Children's Hospital
☐ Other Hospitals, specify: _____
☐ Community Clinic, specify: _____

☐ Elementary/Secondary Schools (*include Appendix M*), specify: _____
☐ Community Center, specify: _____
☒ University Campus (non-clinical), specify: Shirley G. Moore Laboratory Preschool at the University of Minnesota, Carlson and Zelazo Child Development Labs
☐ University Campus (clinical), specify: _____

☐ Prisons/Halfway houses *(include Appendix C*), specify: _____
☐ Nursing Home(s), specify: _____
☐ Subject's Home, specify: _____
☐ International Location: _____ *(include Appendix K)*
☒ Other special institutions, specify: People Serving People Shelter, The Family Partnership (Reuben Lindh Family Services)

7.7 Describe the rationale for using each location checked above. Include IRB approvals or letters of cooperation from other agencies or sites, if applicable.

Assessments will be conducted in the Institute of Child Development at the University of Minnesota, People Serving People (PSP), and The Family Partnership (Reuben Lindh). These sites were chosen to represent very diverse participants and to include families living in emergency shelter and low-income families. For the two community sites, letters of support are included with this application. Professor Masten has conducted research on site at People Serving People for many years, recently in collaboration with Professors Carlson and Zelazo. Reuben Lindh Family Services (now known as The Family Partnership due to a merger) was approached on the recommendation of Maureen Seiwert, who directs early childhood services in the Minneapolis School District, because they serve diverse, low-income families. Administrators and teachers are enthusiastic about collaborating on this project (see letters of support that accompany this application). The S.G. Moore Laboratory Preschool and the Participant Pool at the Institute of Child Development represent more advantaged range of families in terms of education and socioeconomic background. Families will be tested on site in the Institute of Child Development in the lab space in the Lab School or at the labs of Professors Carlson and Zelazo nearby in the same building. Professor Carlson and Zelazo have assessed many children from the Participant Pool and the Lab School using very similar methods to those in the proposed research.

8. Recruitment

8.1 Describe the recruitment process to be used for each group of subjects:
Attach a copy of any and all recruitment materials to be used e.g. advertisements, bulletin board notices, e-mails, letters, phone scripts, or URLs.

For the Institute of Child Development (ICD) site, two approaches will be used. Participants from the S.G. Moore Lab School will be recruited using the lab school's procedures for recruitment (HSC #9610511829). Participants will also be recruited from the ICD participant pool of families who have expressed interest in participating in research. Parents with eligible-age children will be contacted via

telephone from a list of families drawn from the database of families maintained by ICD who have expressed interest and provided information for contact by telephone. Potential participant families will be contacted by a trained research assistant using a calling script as described in section 13.1.

At People Serving People and the Family Partnership (Reuben Lindh), staff who are collaborating with us on this project will inform parents of families with children from 3 to 5 about this study. These include the following methods. Fliers and letters of invitation will be given to parents at the Family Partnership by staff or delivered to the rooms or mailboxes of eligible families at People Serving People. Small posters will be posted in common spaces at the community sites (e.g., bulletin board). Announcements may be made at community meetings.

These various fliers and announcements will indicate how to contact the study staff to find out more information or set up an appointment. In our experience, families also tell each other about research opportunities and thus we would expect some parents to approach study staff directly at the community sites. These methods have worked very well in past research in the same or similar community sites. Example text for a note of invitation is indicated in section 13.1 below. A flier example is included with this application as an Appendix.

8.2 Explain who will approach potential subjects to take part in the research study and what will be done to protect individuals' privacy in this process:

Initial contact of subjects identified through records search must be made by the official holder of the record, i.e. primary physician, therapist, public school official.

For the community sites, staff members who routinely meet with families will inform eligible families very generally about the study or distribute fliers through routine channels at that site (mailboxes, meetings, posters, mailings). If a family is interested in learning more and wants to be contacted, the community site staff person will provide the family with contact information for the study staff. Families also will be able to contact study staff directly from information on fliers or letters to set up an appointment to learn more about the study. These methods have worked well in the same or similar community sites. Community site staff will not be told whether a family comes to find out more about the study or chooses to participate or not.

Research staff will be well trained and supervised. All study staff, graduate students, and undergraduate students will be required to have completed CITI (or equivalent) and HIPAA training. All staff who will have direct contact with children will also be required to have background checks which will be performed by HireRite through the University's Academic Health Center. All identifying information collected during recruitment will transported and stored in secure environments. See 10.4.

8.3 Are subjects chosen from records?

☐ **Yes.** Who gave approval for use of the records: ___
☒ **No.**

If yes, are records "private" medical or student records?

☐ **Yes.** Provide the protocol, consent forms, letters, etc. for securing consent of the subjects of the records. Written documentation for the cooperation/permission from the holder or custodian of the records should be attached.
☐ **No.**

8.4 University of Minnesota policy prohibits researchers from accepting gifts for research activities. Is the study sponsor offering any incentive connected with subject enrollment or completion of the research study (i.e. finders fees, recruitment bonus, etc.) that will be paid directly to the research staff?

☐ Yes.
☒ No.

If yes above, please affirm that you have declined acceptance of gifts in the box below.
Code of Conduct - ***http://www1.umn.edu/regents/policies/academic/Code_of_Conduct.pdf***

9. Risks and Benefits

9.1 Does the research involve any of these possible risks or harms to subjects?

Check all that apply:

☐ Use of a deceptive technique. (*Include Appendix N*)
☐ Use of private records (educational or medical records)
☐ Manipulation of psychological or social variables such as sensory deprivation, social isolation, psychological stresses
☒ Any probing for personal or sensitive information in surveys or interviews
☐ Presentation of materials which subjects might consider sensitive, offensive, threatening or degrading
☐ Possible invasion of privacy of subject or family
☐ Social or economic risk
☒ Other risks, specify: frustration with tasks

9.2 Describe the nature and degree of the risk or harm checked above. The described risks/harms must be disclosed in the consent form.

1. Potential social risk could occur if confidentiality is violated.

2. Potential psychological risks could occur if individuals feel a sense of coercion to participate in the study.

3. Parents and children could experience potential frustration if they have difficulty with the problem-solving tasks.

4. Answering questions about child behavior could potentially remind parents of concerns they have about a child.

9.3 Explain what steps will be taken to minimize risks or harms and to protect subjects' welfare. If the research will include protected populations (see question 7.4) please identify each group and answer this question for each group.

1.Strict data security and confidentialy measures are in place as outlined in section 10. The consent process for parents will describe how the data will be kept strictly confidential except in specific cases where researchers are required to report information to the authorities. These situations occur when there is reason to believe that a child is in danger or has been abused or neglected, or when a parent poses a danger to self or others. Limits of confidentiality will be explained and discussed.

2. The likelihood of psychological risk due to coercion is small since participants have multiple opportunities to discontine participation in the study. Fully trained research staff will describe the study in full and ample time will be given during recruitment sessions or telephone calls to answer and discuss questions. Individuals will be assured that participation is voluntary and that they may discontinue participation at any time without penalty. Parents will be given a signed copy of the consent for their records.

3.The activities for children will be described to them and they will be told that their parent gave permission for them to play the games if they want to and that it is okay to stop at any time of they do not wish to do the activities any more. Test administrators are trained to stop the procedures if a child displays any sign that the testing should cease (e.g. fatigue, illness, distress). The tasks are intended to be enjoyed by children of this age and have been widely used with this age group successfully.

4. Parents are told that they do not have answer any question and they can discontinue participation at any time. The faculty directing this research (Professors Masten, Carlson and Zelazo) have extensive experience collecting data on site in the community with disadvantaged families and families from preschools in the community, at the University and from the Participant Pool. The research assistants are diverse in race and ethnicity and are fully trained to issues of sensitivity to minority and low-income families. The questions and measures used in the study have been frequently used by the researchers, as well as by the Minneapolis and St. Paul School Districts, to screen children. Demographic questions and very similar versions of the CBQ have been previously used with parents from diverse backgrounds without problems. All computer tasks are non-invasive and designed to be engaging and user-friendly.

The community sites for this research both have extensive referral services available to families. Many resources are accessible on site, such as social workers, school district liaisons, family advocates, health clinic, and other services are available by consultation. If special referral were to be requested by families or indicated by the testing (e.g., hearing issue), Professor Masten (who is a licensed psychologist) would gather information and speak to the family as needed.

9.4 Describe the anticipated benefits of this research for individual subjects in each subject group. If none, state "None."

(**Hint**: For instance, if the intervention proves effective, subjects in active arms will benefit but controls will not.)

None. There are no direct benefits for individuals participating in this study

9.5 Describe the anticipated benefits of this research for society, and explain how the benefits outweigh the risks.

Risks are minimal for parents, children, and teachers participating in this study.

Children participating in the National Children's Study will be from a variety of cultural, social and economic backgrounds, and it is important that the methods and measures used to collect information be suitable and appealing for diverse families, including low-income and mobile families. We anticipate there will be substantial benefit from this study that will inform the Main NCS. One of the legislative mandates for the Main NCS is that the research be responsive to issues of health disparities. We believe that the evaluation of EF methods will enhance the NCS, ensuring that representative data is collected that can be used to understand the many factors that impact child health and development.

10. Confidentiality of Data

See Protecting Private Data Guideline from the Office of Information Technology (OIT) for information about protecting the privacy of research data.

10.1 Will you record any direct identifiers, names, social security numbers, addresses, telephone numbers, etc?

☒ Yes.
☐ No.

If yes, explain why it is necessary to record findings using these identifiers. Describe the coding system you will use to protect against disclosure of these identifiers.

We will collect personal identifying information (PII) to facilitate communication with participants and their families regarding appointments, reminder calls, rescheduling of appointments, or gathering data on children from teachers, and to track participation.

Video records (digitial) will be collected and securely stored. Video will be watched for the purposes of checking fidelity of administration and for checking the scoring (e.g., executive functions tasks like Peg Tapping). Parents will also be asked permission on the consent form to show video material to illustrate the tasks for educational and other specific purposes.

10.2 Will you retain a link between study code numbers and direct identifiers after the data collection is complete?

☒ Yes.
☐ No.

If yes, explain why this is necessary and state how long you will keep this link.

Yes for families where the parent indicates potential interest in further participation (see consent form). The study could be extended to allow follow-up for interested families. The link would be necessary to connect past data with follow-up data in this eventuality.

10.3 Will you provide the link or identifier to anyone outside the research team?

☐ Yes.
☒ No.

If yes, explain why and to whom:

10.4 Where, how long, and in what format (such as paper, digital or electronic media, video, audio, or photographic) will data be kept? In addition, describe what security provisions will be taken to protect this data (password protection, encryption, etc.).

Data collection will be carried out in the field using digital video cameras and laptop computers configured by the UMN NCS Study Center IT group. Configuration secures all information with operating system controls which include two-factor authenticaton and by full disk encryption. Field data will be transferrred over encrypted channels (SSL) to UMN OIT compliant secure servers managed by the EnHS IT group at its location [Suite 350, McNamara Alumni Center, UMN]. Once data has been successfully uploaded to the secure server, it will be deleted from the mobile devices (camera, laptop), within three days of data collection. Data from paper forms will

be electronically coded, and this data will be entered and stored on EnHS Health Studies Management System databases**.**

Data in paper format will be kept in locked cabinets within locked rooms in the offices of the investigators at the Institute of Child Development.

Some operational data e.g. the contact information log will be kept in computer and paper formats at ICD. Electronic data will be stored on a password-protected, hard drive-encrypted computer located at ICD. Paper records will be stored within a locked cabinet and locked room at the same location. All data in paper or electronic form will be identified with ID numbers and no contact information will be recorded in any of the test results or data files.

Unidentified or de-identified data will be kept in secure electronic or physical files for 7 years after publication of data. Video data will be kept in secure electronic files and will be destroyed/deleted once data collection and coding are completed. Video samples demonstrating task administration (in cases of parents who gave permission for specific uses) will be kept until no longer needed for training or education purposes.

10.5 Will you place a copy of the consent form or other research study information in the subjects' record such as medical, personal or educational record? (This information should be explained on the consent form.)

☐ Yes.
☒ No.

If yes, explain why this is necessary:

10.6 Federal Certificates of Confidentiality

If the data collected contains information about illegal behavior, visit the NIH Certificates of Confidentiality Kiosk (http://grants1.nih.gov/grants/policy/coc/) for information about obtaining a Federal Certificate of Confidentiality.

Will you obtain a Federal Certificate of Confidentiality for this research?

☐ **Yes.** Submit documentation of application (and a copy of the Certificate of Confidentiality award if granted) with this application form.
☒ **No.**

11. Use of Protected Health Information (PHI): HIPAA Requirements

11.1 As part of this study, do you:

a. **Collect protected health information (PHI)* from subjects in the course of providing treatment/experimental care; or**
b. **Have access to PHI* in the subjects' records?**

Please read the definition of PHI below before answering.

*PHI is defined under HIPAA as health information transmitted or maintained in any form or medium that:

1. identifies or could be used to identify an individual;
2. is created or received by a healthcare provider, health plan, employer or healthcare clearinghouse; and
3. relates to the past, present or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present or future payment for the provision of healthcare to an individual.

The following records ARE EXEMPTED from the definition of PHI even though they may contain health-related information: student records maintained by an educational institution and employment records maintained by an employer related to employment status. If your study uses these kinds of records, it is not subject to HIPAA. However, existing IRB rules on informed consent and confidentiality still apply.

Health-related information is considered PHI if (any of the following are true):

1. the researcher obtains it directly from a provider, health plan, health clearinghouse or employer(other than records relating solely to employment status);
2. the records were created by any of the entities in "1" and the researcher obtains the records from an intermediate source which is NOT a school record or an employer record related solely to employment status; OR
3. the researcher obtains it directly from the study subject in the course of providing treatment to the subject.

Health-related information is not considered PHI if the researcher obtains it from:

1. student records maintained by a school;
2. employee records maintained by an employer related to employment status; OR
3. the research subject directly, if the research does NOT involve treatment.

☐ **Yes. If yes to a or b above, complete Appendix H to show how you will satisfy HIPAA requirements for authorization to use PHI in research.**

☒ **No. If no, continue to section 12.**

12. Expedited Review Eligibility

Federal criteria for risk assessment make some studies eligible for Expedited Review (see 45 CFR46.110 and 21 CFR 56.110). Expedited review categories can be found at http://www.irb.umn.edu/expedited.html Studies eligible for Expedited Review must meet the federal definition of minimal risk, which is as follows: “"the probability and magnitude of harm or discomfort anticipated in the research 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". Expedited Review eligibility decisions are made by the IRB following receipt of the application.

12.1 What is the level of risk to subjects in this research study?

☒ **Not greater than minimal risk.** Justify minimal risk in accord with the federal definition and indicate which expedited review category (1-9) applies to this research:

7

☐ **Greater than minimal risk (full committee review)**

13. Informed Consent Process

13.1 Recognizing that consent itself is a *process* of communication, build on your responses to questions 8.1 and 8.2 and describe what will be said to the subjects to introduce the research. Do not say "see consent form". Write the explanation in lay language. If you are using telephone surveys, telephone scripts are required.

Our introduction for both parts, Pilot and Validity, will be:

"I want to let you know about a study taking place here to develop measures for the National Children's Study. This study is being conducted by child development researchers from the University of Minnesota. The goal of the project is to improve the measures of personality and thinking skills that could be used in the National Children's Study. The National Children's Study is the largest study ever planned to study a national sample of children in the United States from before birth to adulthood. It is scheduled to begin in the near future. To get ready for this large national study, our study is looking at the best ways to measure the attention and cognitive thinking skills of children and their parents, and child personality. Some of these measures are questionnaires that parents complete about their children and others are computer tasks for children or parents. We are trying to design very short and appealing measures with the help of families in Minnesota."

Explanation of Pilot study (Phase 1) –

"In this study, you will be asked to answer questions about family background (such as education and moving) and brief questionnaires about what your child is like. One has questions about your child's personality (asking for example whether your child is outgoing or shy, adventurous or cautious). A second short questionnaire asks questions about your child's social and emotional development (such as whether your child uses words for feelings or does what you ask). The third asks questions about common daily child behavior (such as "played well with other children" or "threw temper tantrums"). With your permission, your child's preschool teacher will be asked to fill out two of the same questionnaires from a teacher's point of view, the ones about personality and daily behavior. In addition, the teacher will be asked to fill out a questionnaire about how your child is behaving in the classroom, with items about getting along with other children, paying attention, disruptive behavior, learning, and relationship with the teacher.

You will also be asked to do the adult versions of the two computer tasks that your child will be asked to complete. These computer tasks are short game, sorting pictures by color or shape or indicating which way a particular fish or arrow on the screen is pointing. Your child will be asked to play an easier version of these same computer games. In one game he/she will sort pictures (such as a boat a rabbit) by color or shape. In the other game, they will feed the fish by figuring out which way a fish is pointing in the middle of other fish. Each of these games takes about 5 minutes. In addition to these games your child will be asked to complete several other tasks that measure problem solving or school readiness, as time permits. These include tasks such as making designs out of blocks, a memory game to find stickers in little pots, a tapping game, and a game identifying animals that make or do not make a sound (like "meow" for a cat or dog), and other popular tasks that check how ready a child is to learn to read and understand numbers.

We will also ask your opinion of the questions and computer tasks and how they could be improved. Whether you decide to participate in this study is up to you. The study is completely voluntary and your decision to join or not to join will not affect any relationships with anyone here or at the University of Minnesota. To protect your privacy, names will be removed and will not appear on any information gathered during the study. No data about you or your family will be shared with the preschool or this agency."

The parent and child sessions take about an hour. If you choose to participate, we will give you a $20 Target gift card and a souvenir of the National Children's Study to thank you for your time. To thank your child, we will give him/her a small toy, book or stickers, and a souvenir of the National Children's Study."

Explanation of Validity Study (Phase 2)

In this study, you will be asked to answer questions about family background (such as education and moving) and three short questionnaires about what your child is like. One has items about personality (such as outgoing or shy, adventurous or cautious). A second short questionnaire asks questions about your child's social and emotional development (such as whether your child uses words for feelings or does what you ask). The third asks about about common daily child behavior (such as "played well with other children" or "threw temper tantrums"). With your permission, your child's preschool teacher will be asked to fill out two of the same questionnaires from a teacher's point of view, the ones about personality and daily behavior. In addition, the teacher will be asked to fill out a questionnaire about how your child is behaving in the classroom, with items about getting along with other children, paying attention, disruptive behavior, learning, and relationship with the teacher.

You will also be asked to complete a third brief questionnaire called Ages and Stages You will also be asked to do the adult versions of the two computer tasks that your child will also be asked to complete. These computer tasks are short games, sorting pictures by color or shape or indicating which way a particular fish or arrow on the screen is pointing.

Your child will play an easier version of the same computer games. In one game he/she will sort pictures (such as a boat or a rabbit) by color or shape. In the other game they will feed the fish by figuring out which way a fish is pointing in the middle of other fish. Each of these games takes about 5 minutes. In addition to these games your child will be asked to complete several other tasks that measure problem solving or school readiness. These include tasks such as making designs out of blocks, a memory game to find stickers in little pots, a tapping game, and a game identifying animals that make or do not make a sound (like "meow" for a cat or dog), and other popular tests that check how ready a child is to learn to read and understand numbers.

The parent tasks and questionnaires will take about an hour. To thank you for your time, we will give you a $20 Target gift card and a souvenir of the National Children's Study. The session for your child takes about an hour too. To thank him/her, we will give him/her a small toy, book or stickers and a souvenir of the National Children's Study.

Whether you decide to participate in this study is up to you. The study is completely voluntary and your decision to join or not to join will not affect any relationships with anyone here or at the University of Minnesota. You can decide not to participate at any time. To protect your privacy, names are removed and do not appear on any information gathering during this study. Information that we obtain is identified by a number. No data about you or your family will be shared with the preschool or this agency."

If parents spontaneously approach the study staff in the shelter or contact us:

"Hello, my name is …. and I am a researcher from the University of Minnesota. We are inviting families with 3 to 5 year old children to join a study to develop measures of child behavior for the National Children's Study. The goal of the study is to learn the best ways to measure personality and thinking skills, using short questionnaires and game-like computer tasks. If a family joins the study… [see above for each phase of the study]…"

If a parent leaves a note or asks to be contacted by telephone.
"Hello, my name is … and I am a researcher from the University of Minnesota helping with a study to develop measures of personality and thinking for the National Children's Study. I understand that you requested that we contact you so you could learn more about this study. Is this a good time to talk about it? "[If time is good, research staff proceed, along the lines of relevant scripts above. If time is not good, then another time will be scheduled.]

Note in mailbox of the site:
Dear ____
We are writing to invite families of children 3 to 5 years of age to learn more about a study to develop measures for the National Children's Study. This study is being conducted by professors at the University of Minnesota to develop or improve the measures of problem solving and child personality

for families with 3 to 5 year old children. Parents who participate will answer questionnaires about child behavior and do gamelike computer activities. Children will do a variety of computer games and tasks or puzzles that measure school readiness. Family sessions take about an hour. To thank them for their help, parents who participate will be given a $20 Target gift card and children will receive toys, stickers, or books. Families will also receive small souvenirs of the National Children's Study. This study is completely voluntary and will not affect any relationships or services of this agency or the University of Minnesota.

You can learn more about this study by calling us at the numbers listed below or stopping by…[office].

13.2 In relation to the actual data gathering, when will consent be discussed and documentation obtained? (e.g., mailing out materials, delivery of consent form, meetings) Be specific.

Information will be provided as described above when the parents come to find out about the study at the recruitment locations or over the phone. Parents will be encouraged to ask questions. If they wish to think about the materials or discuss the study with others before signing a consent form, they can return to another recruitment session. Likewise, follow-up phone calls will be scheduled at parents' convenience if they want more time to think about potential participation during an initial phone call. Consent will be throroughly discussed and documentation will be obtained in person when the parent comes to find out about the study or at the beginning of a scheduled assessment. The research assistants will explain the study and answer all questions, obtain the parent's signature if they agree to participate and provide a copy to the parent. Children will give verbal assent. If a parent has given written consent, but scheduled a later appointment, consent will be reviewed again when the assessment actually takes place.

13.3 Will there be any waiting period between informing the prospective participant and obtaining the consent? Please explain.

No.

13.4 Will the investigator(s) be securing all of the informed consent?

☒ **Yes.**
☐ **No.**

If no, please name the specific individuals who will obtain informed consent and include their job title/credentials and a brief description of your plans to train these individuals to obtain informed consent and answer subjects' questions.

The consent will be obtained by the co-investigators listed who are trained in the consent process.

13.5 How will you determine who will give consent?

i.e. subject, parent, guardian, Legally Authorized Representative. If someone other than the subject will give consent, provide justification and a plan for obtaining surrogate consent.

The parent or legal guardian of the child will give consent. Children will give verbal assent rather than written assent because they range in age from 3-5 years old.

13.6 Describe the steps taken to minimize the possibility of coercion or undue influence.

It will be emphasized to both parents and all involved preschool or community staff, as well as the children, that their participation is entirely voluntary. Once a session begins, parent or child will be free to stop the study at any time. The parent gift card will be prorated for partial completion (in increments of $5 for starting any quarter hour of the session). Children will receive the same gift regardless of what is completed.

13.7 If subjects are minors, will they still be involved in this study when they reach the age of majority (18)?

☐ N/A – No Minor Subjects
☒ No.
☐ Yes. If yes, outline your plan to re-consent these subjects at the age of majority:

Subject Comprehension

It is the responsibility of the investigator to assess comprehension of the consent process and only enroll subjects who can demonstrate informed understanding of the research study (45 CFR 46.116)

The federal regulations require that consent be in language understandable to the subject. If subjects do not comprehend English, translated consent forms are required or the use of short forms with an oral explanation can be accepted. (see the Consent Process & Forms section of our Web site)

13.8 What questions will you ask to assess the subjects' understanding of the risks and benefits of participation? (Questions should be open-ended and go beyond requiring only a yes/no response.)

What is your understanding of the purpose of this study? What are the activities you expect to be doing today? What are some of the activities your child will be asked to do? What will happen if you choose to stop during the study?

Documentation of Consent

13.9 Prepare and attach a consent form for IRB review.

Please see the sample consent form and follow it carefully. Do not submit sponsor prepared forms without editing the form to include University of Minnesota IRB standard language and all essential elements of informed consent.

Under specific conditions, when justifiable, documentation of informed consent can be waived or altered. These limited conditions are described in 45 CFR 46.116 and 45 CFR 46.117. If you believe that this research qualifies according to the regulations, include Appendix W.

Resources for preparing informed consent forms:

- Informed Consent Online Tutorial – http://www.research.umn.edu/consent/
- Informed Consent section of the Human Subjects Guide - http://www.research.umn.edu/irb/guidance/guide4.html

You have reached the end of this form. Please make sure that you have responded to every question on this application (even if your response is "not applicable").