Institutional Review Board Office
Northwestern University

Biomedical IRB
750 North Lake Shore Drive
Suite 700
Chicago, Illinois 60611
312-503-9338

Social and Behavioral Sciences IRB
600 Foster Street
Chambers Hall, Second Floor
Evanston, Illinois 60208
847-467-1723

NORTHWESTERN
UNIVERSITY

Form for Determining Whether a Project Involves Human Subjects Research

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The Northwestern University IRB is required to review and approve all research involving human subjects. This application is intended to help you determine if your project requires IRB approval. If you require written documentation from the IRB Office, complete the entire form, and email the signed form and any relevant supporting documents (i.e., grant, protocol, consent forms) to irb@northwestern.edu. You should receive an IRB response within 10 business days.

Current Status of the Project

Has the project already been conducted (i.e., data has already been collected and analyzed)?
☐ Yes ☒ No

SECTION I: Activities Determined by the NU IRB Office Not to Represent Human Subjects Research

A. ☐ **Case Report:** The project consists of a case report or series which describes an interesting treatment, presentation or outcome. A critical component is that nothing was done to the patient(s) with prior "research" intent.

NOTE: For case reports, HIPAA requires that the disclosure of an individual's protected health information must be authorized by that individual. If a case report contains any of the 18 protected health information identifiers as defined by the HIPAA regulations, a signed authorization (using the authorization form from the entity that holds the record) to disclose this information must be obtained from the individual(s) whose information is being disclosed.

B. ☐ **Course-Related Activities:** The project is limited to course-related activities designed specifically for educational or teaching purposes where data are collected from and about students as part of a routine class exercise or assignment and is not intended for use outside of the classroom.
NOTE: IRB approval **is** required if a student is involved in an activity designed to teach research methodologies and the instructor or student wishes to conduct further investigation and analyses in order to contribute to scholarly knowledge.

C. ☐ **Decedents:** The project involves research that is limited to death records, autopsy materials, or cadaver specimens. If the project involves the use and/or collection of Protected Health Information (PHI), HIPAA regulations apply to decedent research. As the Privacy Board, the IRB Office requires that you confirm the following conditions as set forth in the Privacy Rule at 45 CFR 164.512(i)(ii)(iii), have been met.

i. ☐ the use will be solely for research on the information of a decedent; and
ii. ☐ the Principal Investigator has documentation of the death of the individual about whom information is being sought, and
iii. ☐ the information sought is for the purposes of the research

Note, however, that this exception may not be available for decedent Information that contains Psychotherapy Notes or Information relating to HIV, mental health, genetic testing, or drug or alcohol abuse

D. ☐ **Journalism/Documentary Activities:** The activities are limited to investigations and interviews that focus on specific events, views, etc., and that lead to publication in any medium (including electronic), documentary production, or are part of training that is explicitly linked to journalism. There is no intent to test a hypothesis.

NOTE: IRB approval may be required when journalists conduct activities normally considered scientific research intended to produce generalizable knowledge (e.g., systematic research, surveys, and/or interviews that are intended to test theories or develop models).

E. ☐ **Oral History:** The project is limited to oral history activities, such as open ended interviews, that only document a specific historical event or the experiences of individuals without the intent to draw conclusions or generalize findings.
NOTE: IRB approval is required when the oral history activities are intended to produce generalizable conclusions (e.g., that serve as data collection intended to test economic, sociological, or anthropological models/theories).

F. ☐ **Program evaluation /Quality Improvement/Quality Assurance Activities:** The project is limited to program evaluation, quality improvement or quality assurance activities designed specifically to assess or improve performance within the department, hospital or classroom setting. The intention of the project is not to generate conclusions that can be applied universally, outside of the immediate environment where the project occurred.
Note: Investigators who plan to conduct a QI/QA project, should ensure that they have received approval from any applicable committees within their department or the site in which the activity will occur.

G. ☐ **Public Use Datasets:** The project is limited to analyzing de-identified data contained within a publicly available dataset. Below are examples of data sources that qualify as not-human subjects research (unless the researcher has received the restricted use data):

☐ Data files downloaded from the ICPSR (Interuniversity Consortium for Political and Social Research): http://www.icpsr.umich.edu/icpsrweb/ICPSR/ or the Roper Center for Public Opinion Research http://www.ropercenter.uconn.edu.

- ☐ American National Election Studies, (ANES) 1948-2010 http://www.electionstudies.org/
- ☐ Bureau of Economic Analysis: http://www.bea.gov/
- ☐ Bureau of Labor Statistics (BLS): http://www.bls.gov/
- ☐ Center for Disease Control (CDC): http://www.cdc.gov/
- ☐ Consumer expenditure Survey: http://www.bls.gov/cex/
- ☐ Current Population Survey: http://www.bls.gov/cps/
- ☐ FBI Uniform Crime Reporting Program: http://www.fbi.gov/about-us/cjis/ucr/ucr or National Archive of Criminal justice data: http://www.icpsr.umich.edu/icpsrweb/NACJD/index.jsp
- ☐ General Social Survey: http://www3.norc.org/GSS+Website/
- ☐ National Center for Education Statistics (NCES): http://nces.ed.gov/
- ☐ National Longitudinal Surveys (NLS): http://www.bls.gov/nls/
- ☐ Survey of Income and Program Participation: http://www.census.gov/sipp/
- ☐ Government sites that bring data files together: Data.gov (http://www.data.gov/); FedStats (http://www.fedstats.gov/); and USA.gov (http://www.usa.gov/Topics/Reference_Shelf/Data.shtml)

NOTE: IRB review is required if the publicly available data set contains identifiers, or if the merging of multiple data sets might result in identification of the subjects. In both cases, Exempt Category #4 may apply.

H. ☐ **Coded* Private Information and/or Human Biological Specimens:** The project is limited to the use of existing and/or prospectively collected coded private information and/or human biological specimens (hereafter referred to as "specimens"). IRB Approval is not required if all of the following conditions apply to the project:

i. ☐ (1) The private information or specimens were/are not collected specifically for the currently proposed research project through an interaction or intervention with living individuals; **and**

☐ (2) The investigator(s)** cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain because, for example:

- ☐ (a) the investigators and the holder of the key enter into an agreement prohibiting the release of the key to the investigators under any circumstances, until the individuals are deceased (note that the HHS regulations do not require the IRB to review and approve this agreement);
- ☐ (b) there are IRB-approved written policies and operating procedures for a repository or data management center that prohibit the release of the key to the investigators under any circumstances, until the individuals are deceased; **or**

☐ (c) there are other legal requirements prohibiting the release of the key to the investigators, until the individuals are deceased, **and**

ii. ☐ Specimens are <u>not</u> being used to test the effectiveness of a medical device or as a control in an investigation of an investigational device and the results of the activity are to be submitted to the FDA or held for inspection by the FDA, **and**

iii. ☐ The records/images/charts that are being collected for this study are <u>not</u> from individuals who are or will become recipients of an FDA regulated product (approved or experimental) or act as a control as directed by a research protocol and not by medical practice, and the results are to be submitted to the FDA or held for inspection by the FDA.

From the Office for Human Research Protections (OHRP) guidance document dated October 16, 2008:
**Coded* means that: (1) identifying information (such as name or social security number) that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol, or combination thereof (i.e., the code); and (2) a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.

***Investigator* includes anyone involved in conducting the research. The act of solely providing coded private information or specimens (for example, by a tissue repository) does not constitute involvement in the conduct of the research. If the individuals who provide coded information or specimens collaborate on other activities related to the conduct of this research with the investigators who receive such information or specimens, then the IRB would consider such additional activities to constitute involvement in the conduct of the research. Examples of such additional activities include, but are not limited to: (1) the study, interpretation, or analysis of the data resulting from the coded information or specimens; and (2) authorship of presentations or manuscripts related to the research.

l. ☐ **De-Identified Private Information or Human Biological Specimens:** The project is limited to the use of existing and/or prospectively collected de-identified private information and/or human biological specimens (hereafter referred to as "specimens"). IRB Approval is not required if you can confirm the following:

i. ☐ The private information or specimens were/are not collected specifically for the currently proposed research project through an interaction or intervention with living individuals; **and**

ii. ☐ The investigator can confirm that the use of the private information or specimens is not in violation of the terms of use under which the information or specimens were/will be collected; **and**

iii. ☐ The investigator will only receive information or specimens that are fully de-identified. De-identified means that the materials to be studied are devoid of any of the 18 Protected Health Information elements set forth in the Privacy Rule, as well as any codes that would enable linkage of the information or specimens to individual identifiers. Note: To be considered de-identified, nobody, including individuals who are not involved in the conduct of the project, should be able to link the information or specimens back to

identifiers. **and**

iv. ☐ Specimens are <u>not</u> being used to test the effectiveness of a medical device or as a control in an investigation of an investigational device and the results of the activity are to be submitted to the FDA or held for inspection by the FDA, **and**

v. ☐ The records/images/charts that are being collected for this study are <u>not</u> from individuals who are or will become recipients of an FDA regulated product (approved or experimental) or act as a control as directed by a research protocol and not by medical practice, and the results are to be submitted to the FDA or held for inspection by the FDA.

Instructions: If your activity did not fall into the categories described in Section I, continue to Section II and III to assess if you are engaged in human subjects research per the regulations set forth by the Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA).

SECTION II. Activities subject to HHS human subject research regulations (45 CFR 46)

1. **Is the activity RESEARCH: a systematic investigation designed to contribute to generalizable knowledge?**

   TIP: If the investigation characterized by order, planning, and methodology and the intention of the investigation is to generate conclusions that can be applied universally, outside of the immediate environment where the investigation occurred (i.e., the classroom, hospital, department), then the activity meets the definition of research.

   ☒ Yes, Go to #2 ☐ No, Go to FDA section III

2. **Does the research involve obtaining information about LIVING individuals?**

   ☐ Yes, Go to #3 ☒ No, Go to FDA section III

3. **Does the research involve collecting data through <u>intervention</u> (i.e., physical procedures or manipulation of the environment) or <u>interaction</u> (i.e., communication or interpersonal contact between investigator and person) with the individuals?**

   ☐ Yes, IRB review required. ☐ No, Go to #4

   Go to FDA section III to assess if FDA regulations apply to your study.

4. **Does the research involve collecting identifiable information (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information)?**
☐ Yes, Go to #5 ☐ No, Go to FDA section III

5. **Is the information private? (About behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, or provided for specific purposes by an individual and which the individual can reasonably expect will not be made public)**
☐ Yes, IRB review required ☐ No, Go to FDA section III
Go to FDA section III to assess if FDA regulations apply to your study.

SECTION III. Activities subject to FDA human subject regulations: If your answer is "yes" to any of the 3 questions below, IRB approval is required and the FDA regulations apply to your study.

1. Is this is an experiment that involves a test article * and one or more human subjects, and the results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit? A subject is an individual (either health or a patient) who is a recipient of the test article or a control.

*Test article *Test article* means any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the Food, Drug, and Cosmetic Act.

☐ Yes , IRB review required ☒ No

2. Is this is a clinical investigation or research involving one or more human subjects to determine the safety or effectiveness of a device? A subject is an individual (healthy or has a medical condition or disease) on whom or on whose specimen an investigational device is used, or who participates as a control.

☐ Yes, IRB review required ☒ No

3. Is this an experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects? This excludes the use of a marketed drug in the course of medical practice. A human subject is an individual (healthy or patient with a disease) that participates either as a recipient of the investigational new drug or as a control.

☐ Yes, IRB review required ☒ No	
Instructions: **If IRB Review is required, you will need to submit NEW STUDY application eIRB.**	

SECTION IV: Complete this section if you have determined that your activities do not constitute human subjects research and you require written confirmation of this determination from the IRB Office. E-mail the signed form and any relevant supporting documents (i.e., grant, protocol, consent forms) to irb@northwestern.edu.		
Investigator Information		
Name (Last, First) **Gershon, Richard**	PhD	University Status/Title **Associate Professor**
Department **Medical Social Sciences**		College **Feinberg School of Medicine**
Phone Number **312-503-3453**		E-mail Address **gershon@northwestern.edu**
Project Information		
Project Title The National Children's Study - Assessment of Executive Function		
Name of Funding Source (i.e., Department, NIH, Foundation) NIH		
Grant Number (if applicable)		
Project Description (describe the aims of the study and any activities involving interaction, intervention with human subjects, and/or their information or specimens) To assess Executive Function (EF) skills in the National Children's Study (NCS) in a manner that is sensitive for young children from diverse economic backgrounds. The proposed study is designed to adapt existing EF measures, such that the measures 1) demonstrate similar robustness when used with culturally diverse individuals and (2 are sensitive to capturing useful variance in the youngest participants. It will seek to refine and validate measures of Executive Function for possible use in the NCS Main Study. Participants will include children 2.5-5.5 years of age and their parents, who will be recruited though either the University of Minnesota or Delve. Northwestern University (NU) will be involved with both data management and data analyses. NU will manage FISMA (Federal Information Security Management Act of 2002) compliance in terms of programming computers used for data collection and maintaining all security, servers, and processes for uploading data daily from the computers used in data collection including; assembling all data from multiple sites into a single data base, data storage after it is collected, transferring all (de-identified) data to Minnesota for analysis, and submitting interim and final reports and data to the NCS in the form required by NCS (e.g., encrypted files of measures and reports). In maintaining the secure server, Northwestern will only have access to de-identified data. NU will NOT be able to view any participant's personal identifiable information.		

Signature of Investigator: Richard C Gershon

Date: 04/24/2014

SECTION V: IRB Determination (to be completed by IRB Office)*

The activities as described in the ☒ submitted protocol and/or ☒ materials and description of activities provided by the investigator,

☒ **Do not constitute research with human subjects in accordance with 45 CFR 46 and 21 CFR 50 & 56. IRB approval is not required.**

☐ **For activities involving decedents and their Protected Health Information (PHI), the conditions as set forth in the Privacy Rule at 45 CFR 164.512(i)(l)(iii), have been met.**

- the use or disclosure sought is solely for research on the protected health information of decedents;
- documentation can be provided, at the request of the covered entity, of the death of such individuals; and
- the protected health information for which use or disclosure is sought is necessary for the research purposes.

Authorized IRB Personnel Printed Name: Debra G. Tice

Authorized IRB Personnel Signature: Debra G. Tice

Title: IRB Special Projects Manager

Date: 4/28/2014

*If any activities completed were or possibly were not in compliance with federal regulations regarding prior IRB review, please forward the form to the IRB Compliance Manager for review. For example, the investigator reports activities which are already completed but initially required IRB approval.

Assessment of Executive Function for the National Children's Study

Background:

The National Children's Study (NCS) Vanguard 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 correspond to counties across the U.S. The purpose of the NCS Vanguard Study is to assess the feasibility, acceptability, cost, and utility of the recruitment strategies, study procedures and outcome assessments that will be used in the Main NCS. The National Children's Study Greater Chicago Study Center was previously approved by the Northwestern University IRB on January 8, 2009 [IRB # STU00008199]. In late 2011, the NCS was reorganized into four Regional Operations Centers (ROCs), including Central, East, South and West. As such, all Study Centers including the Greater Chicago Study Center were closed, and the NCS-GCSC NU IRB was closed. In September 2012, Northwestern University was awarded a contract for the South Regional Operations Center (SROC) of the National Children's Study.

Multiple formative research projects have been funded as methodological studies within the NCS Vanguard Study, which will inform the implementation and analysis of the Main NCS. This project represents a continuation of a formative research project that was designed to develop robust and brief measures of Executive Function (EF) for the NCS suitable for preschool-aged children and their parents. Earlier phases of this project yielded promising new measures of EF, including two computerized tasks – Flanker-Downward extension (Flanker-Dext) and Dimensional Change Card Sort-Downward extension (DCCS-Dext; based on Carlson's EF Scale for Early Childhood) – and a revised version of the Children's Behavior Questionnaire Very Short Form, which includes a new supplemental scale to serve as a parent report EF measure (CBQ-VSF+EF). The computer tasks were designed for touchscreen administration as downward extensions of the comparable NIH Toolbox tasks (suitable for a more diverse range of children, including those having difficulty with the regular Toolbox versions of Flanker and DCCS).

Purpose of the Study:

It is widely recognized that EF skills are important for many aspects of human development, including physical, mental health, and education success of children and adults. Thus, it is critical to assess EF skills in the NCS in a manner that is sensitive for young children from diverse economic backgrounds. The proposed study, *Assessment of Executive Function for the NCS,* is designed to adapt existing EF measures, such that the measures 1) demonstrate similar robustness when used with culturally diverse individuals and (2 are sensitive to capturing useful variance in the youngest participants. It will seek to refine and validate measures of Executive Function for 2.5 to 5.5 year olds and their mothers for possible use in the NCS Main Study. In addition, this study will finalize training materials required to train administrators who do not have a professional background in child development or testing to administer these measures.

Specific Aims

1. Final refinements of the downward extensions of the NIH Toolbox Flanker and DCCS tasks developed during the initial stage of this formative project, including a Spanish version of Flanker-Dext and DCCS-Dext.

2. Final refinements of an Executive Function Supplemental Scale for parent report version of the Children's Behavior Questionnaire Very Short Form, in English and Spanish.

3. Validation of the new measures with respect to time burden, usability, reliability, and construct validity in diverse families with preschool-aged children ages 2.5 to 5.5 years of age.

4. Preparation of training materials (manuals and video training) suitable for local or online training of administrators to administer the Flanker-Dext, DCCS-Dext, CBQ-VSF+EF.

Research and Study Design

Northwestern University (NU), the University of Minnesota (UM), and Delve will collaborate to execute The *Assessment of Executive Function for the NCS:*

Northwestern University (SROC) Activities

Northwestern University personnel, through its leadership of the South Regional Operations Center (SROC), will oversee this project, working closely with personnel at the University of Minnesota. The Scientific Director for health measurement will communicate regularly and directly with the Minnesota team of investigators and the accrual vendor, Delve, to ensure that all project deliverables are on schedule and are consistent with the stated measurement goals.

The SROC has the responsibility for overall administration of the project as noted above, including communications with the National Children's Study (NCS) at NICHD as well as the University of Minnesota team and Delve, OMB submission, managing FISMA (Federal Information Security Management Act of 2002) compliance, purchasing all computers and test materials, Spanish translations of all measures requiring this, programming and distributing the testing computers, assembling all data from multiple sites into a single data base, data storage after it is collected, transferring all (de-identified) data to Minnesota for analysis, and submitting interim and final reports and data to the NCS in the form required by NCS (e.g., encrypted files of measures and reports). The SROC will also assist in monitoring fidelity of administration in the Delve sites outside of Minneapolis (e.g., through direct observation on site by the Scientific Director or other trained experts on the method).

NU will manage FISMA compliance in terms of programming computers used for data collection and maintaining all security, servers, and processes for uploading data daily from the computers used in data collection. The data collected on iPads will be wiped as soon as the upload occurs. In addition, the NU-SROC has obtained an Authority to Operate (ATO) from the NICHD to guarantee FISMA compliance (*See Attachment SROC Authority to Operate*). An infrastructure for confidential data management is in place, which includes sophisticated use of firewall technologies, dedicated database servers, and related technological capabilities. High standards of data security practices for all projects and clients are observed.

University of Minnesota and Delve

Recruitment and Data Collection Procedures

Participants will include children 2.5-5.5 years of age and their parents, who will be recruited though either the University of Minnesota or Delve. These will be non-NCS participants. The University of

Minnesota will recruit 60 children (60 parents/guardians) from diverse backgrounds, including a high proportion of disadvantaged families, with a random subset of approximately 30 retested for reliability. Delve will recruit 300 children (300 parents/guardians). Delve will randomly select participants from its database of potential participants. A random subsample of approximately 114 children will be retested after 1 to 2 weeks to test reliability.

Given the possibility of children deciding to stop mid-assessment or being unable to continue for any reason (e.g., tired or becoming ill) 396 children (396 parent/guardians) sampling recruitment will be the goal.

Eligibility criteria will include having a child between 2.5 and 5.5 years of age and being a native speaker of either English or Spanish, without a major disability that would preclude fully participating (such as a pervasive developmental disability, blindness, or deafness).

Session 1 (validity):

Child Session (50 to 60 minutes)

- Peg-tapping (3 min)
- Touchscreen tutorial (3 min)
- Toolbox Picture Vocabulary (5 min)
- Flanker- Downward Extension (Dext) (7 min)
- Dimensional Change Card Sort- Dext (7 min)
- Toolbox Picture Sequence Memory (5 min)
- WPPSI-IV Block Design (8 min)
- Woodcock-Johnson-III Letter-Word Identification (7 min)
- Woodcock Johnson-III Applied Problems (8 min)

Parent Session

- Demographic questionnaire (7 min)
- Children's Behavior Questionnaire with EF extension (10 min)
- Ages and Stages - Social Emotional (10 min)
- Q-ABC (Quick Assessment of Behavior in Children) (3 min)
- Strengths and Difficulties Questionnaire (5 min)

Session 2 (reliability):

Child Session (30 min)

- Peg-tapping
- Touchscreen tutorial
- Toolbox Picture Vocabulary
- Flanker- Dext
- Dimensional Change Card Sort- Dext
- Toolbox Picture Sequence Memory

Parent Session

- Children's Behavior Questionnaire with EF extension

- Q-ABC (Quick Assessment of Behavior in Children)

The University of Minnesota will supervise training and data scoring and analysis as required to complete the study. Delve will collect a substantial portion of the data in three of their regular research communities (Minneapolis, Philadelphia, and Phoenix). Paper measures will be scanned (identified only by ID numbers) and placed in secure electronic storage, and then scored and entered in databases in a secure FISMA environment on a secure server by University of Minnesota staff. The FISMA compliant server space will be provided by Northwestern University. Data will be entered a second time by University of Minnesota staff to verify accuracy. Once these data are verified, the originals will be destroyed at each site.

Data management and Security

It is understood by Northwestern University and the subcontractor (University of Minnesota) that the costs for any specialized equipment or software or technical assistance needed for data collection, encryption, data transmission, or analysis that is pertinent to FISMA compliance will be provided by Northwestern University to the University of Minnesota. Northwestern University will provide the necessary information or technology policies, technical assistance, software, programming, and equipment within a reasonable time frame to ensure the timely implementation of a FISMA-compliant data stream essential for meeting the training, data collection, and data analysis requirements of the subcontract.

The database will be created and maintained on a FISMA-compliant server at Northwestern University. Data entry completed at University of Minnesota will be completed via secure web-based forms. All electronic data will be stored at Northwestern University. Paper data forms may be stored at University of Minnesota and/or Delve facilities.

Analyses:

Analyses will focus on administration burden and psychometric data reliability and validity. Reliability will be analyzed, including (as appropriate to the measure), internal consistency (alpha) and test-retest reliability. Multivariate analyses (e.g., correlations, regressions) will be conducted to analyze the convergent, discriminant, and construct validity, for example providing tables and figures related to correlations of new measures with age, each other, other measures of EF, traditional IQ measures, and criterion measures of school readiness (literacy and numeracy) that have established predictive validity, both overall and with age covaried. Analyses examining relation of child scores to family SES, income, and parent education level also will be conducted. Technical reports and papers suitable for publication will conclude the study.