

UNIVERSITY OF MINNESOTA

Change In Protocol Request

Instructions:

Use this form when submitting change requests to approved IRB protocols. This form is for use when the changes are initiated by the PI. Do not use this form to respond when changes are requested by the IRB. Please do not use this form when responding to changes requested in a stipulation or deferral letter.

The UMN IRB reviewed and APPROVED this submission including all attachments listed on this form by expedited review.

By Jeffery Perkey on Nov 13, 2013

Submit this form to the Human Research Protection Program:

U.S. Mail Address: or
Human Research Protection Program
MMC 820
420 Delaware St. SE
Minneapolis, MN 55455-0392

Electronic Submission:
Submit to: irb@umn.edu
PI must submit request using
University of Minnesota e-mail
Account.

IRB Protocol Information

| | |
|-------------------------|---|
| IRB Study Number: | 1101S94592 |
| Principal Investigator: | Ann S. Masten |
| Primary Study Title: | Assessment of Executive Function for the National Children’s Study |
| Date of this Submission | 11/6/13 |
| Study Includes | <input type="checkbox"/> Drug(s) / Biologic(s) <input type="checkbox"/> Device(s) |

| Indicate the type of change(s) | Additional information/requirements |
|--|--|
| <input checked="" type="checkbox"/> Change(s) to Study Procedures/Protocol Amendment | <p>Is this protocol under Masonic Cancer Center’s Cancer Protocol Review Committee (CPRC) review?</p> <p><input checked="" type="checkbox"/> No <input type="checkbox"/> Yes, CPRC #</p> <p>Protocol amendments must be submitted to CPRC (CCPRC@umn.edu) prior to review by the IRB. CPRC will forward this submission to the IRB after CPRC approval. Submission to CPRC must meet the IRB signature requirement (signed by the PI or sent from the PI’s x.500 UMN email account).</p> <p>Protocol Version _____, Dated _____</p> |
| <input type="checkbox"/> Notice of Closure to Accrual | |
| <input checked="" type="checkbox"/> Recruitment changes/Advertisements | Attach a copy of the revised material (flyer, script, etc.) with the submission |
| <input type="checkbox"/> Revised Investigator Brochure | Version _____, Dated _____ |
| <input checked="" type="checkbox"/> Updated consent form | Include both an updated form with changes highlighted and a “clean” version |
| <input type="checkbox"/> Other | Briefly Describe: |

- Briefly summarize the change(s). For protocol amendments, do not say “See summary of changes provided with amendment.” Rather, summarize the nature of the significant revisions.**

This project has moved administrative “homes” due to the reorganization of the National Children’s Study. Northwestern University is the contractor and the University of Minnesota and Delve are both subcontractors (of Northwestern) for the study.

Northwestern University 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.

The University of Minnesota will supervise training and data scoring and analysis as required to complete the study.

Delve Marketing Research will collect a substantial portion of the data in three of their regular research communities (Minneapolis, Philadelphia, and Phoenix are the planned sites). As a result of adding Delve and multiple sites, the procedures will need to be changed as described further below. Delve will recruit participants using their usual procedures and their staff will conduct the consent process and data collection. However, the Minnesota team will train their staff on the consent procedures as well as test administration (at the Delve Minneapolis site). Delve personnel will be added to the personnel for this project at a later time (after OMB approval, funding, and hiring, but before any data collection for this project).

Consent forms will be retained by Delve in securely locked files in locked offices until the study is completed and then will be destroyed. Keys linking people or contact information to ID numbers will be maintained securely by each test site (in encrypted and password-protected computer files or locked regular files in locked offices, and separate from any data locations) until the study is completed and then the keys will be destroyed.

In the event of an audit or other necessary processes concerning consent forms by the University of Minnesota IRB, an authorized supervisor from Delve would bring any needed consent forms to Minneapolis.

Paper measures will be scored and entered on databases in a secure FISMA environment on a secure server. The FISMA compliant server space will be provided by Northwestern University in their role as contractor. After initial entry, original forms will be scanned (identified only by ID numbers) into secure files on the same servers in order to verify scoring and data entry from distant sites. Data will be entered a second time by University of Minnesota staff with access to the scanned data on the secure server. Once these data are verified, the originals will be destroyed at each site.

For Minneapolis data, paper forms from Delve will be transported by hand to the University of Minnesota offices for storage in secure and locked files until they are verified.

For data collected by the University team in Minneapolis, paper forms will be stored in secure and locked files and double-entered into the secure database. Once the data are verified, the originals will be destroyed.

More details about recruitment and data collection procedures follow below.

Session 1 (validity):

Child Session (50 to 60 minutes)

Peg-tapping (3 min)

Touchscreen tutorial (3 min)

Toolbox Picture Vocabulary (5 min)

Flanker- Dext (7 min)

Dimension 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

Demographic questionnaire (***Changes have been made – described below***) (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 (30 min)

Peg-tapping

Touchscreen tutorial

Toolbox Picture Vocabulary

Flanker- Dext

Dimension Change Card Sort- Dext

Toolbox Picture Sequence Memory

Parent

Children's Behavior Questionnaire with EF extension

Q-ABC (Quick Assessment of Behavior in Children)

Test Administrator

Behavior Rating Form

Description of newly proposed tasks:

NIH Toolbox Picture Vocabulary Test

This is a computerized measure of receptive vocabulary that is similar to and validated against the Peabody Picture Vocabulary Task, which was approved in the original IRB submission. We propose including this version of the task because it is a shorter and more adaptive measure of verbal skills. This measure is part of the standard battery of cognitive tests included in the NIH Toolbox.

NIH Toolbox Picture Sequence Memory Test

This task, also part of the standard NIH Toolbox battery of cognitive measures, is designed to measure episodic memory. It involves recalling increasingly longer series of pictures of objects and activities that are presented in a particular order on a computer screen. Participants are asked to recall the order of the pictures.

Strengths and Difficulties Questionnaire

This measure is a brief behavioral screening questionnaire. There are 25 items regarding children's emotional symptoms, conduct problems, hyperactivity/inattention, peer relationship problems, and prosocial behaviors. We propose including this measure to study concurrent validity for the Children's Behavior Questionnaire with EF extension. The questionnaire is available in English and Spanish. Both versions accompany this change of protocol.

Behavior Rating Scale

This is a 10-item report about how well the session with the child flowed, which we have often used in our other approved studies with child assessments. Five of the items come from a brief measure that is used in preschool screening by multiple school districts in the Twin Cities, including Minneapolis. Five additional items we have used in the past to assess the validity of a session are included.

Changes to Procedure

Participants

Delve will collect data for 240 children (and 240 parents/guardians) in English and 60 children in Spanish (and their 60 parents/guardians) at 3 locations, divided approximately equally across sites. A random subsample of children will be retested after 1 to 2 weeks to test reliability, including 90 in English and 24 in Spanish (30/8 at each site).

The University of Minnesota team will collect data as planned and approved for very disadvantaged children residing in shelters or attending community preschools for disadvantaged children. The goal is to assess 60 children (60 parents/guardians) with a random subset of approximately 30 retested for 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), we have included a 10% larger sample in our request for approval of participant numbers.

These numbers are as follows. We expect that the children will be about equally divided by sex. We expect the parents/guardians to be primarily female.

396 children (approximately 50% male and 50% female; ages 2.5 to 5.5) - sampling recruitment will aim for balanced age and sex within six 6-month age brackets: 2.5 (older than 2.5) -2.9 (younger than 3.0); 3.0-3.4; through...5.0-5.4 (younger than 5.5).

396 adult parents/guardians (approximately 80% female and 20% male)

Thus, the number of participants for this protocol should be changed to a total of 810, which includes the original 9 families (9 children and 9 parents) already completed plus the numbers listed above.

Recruitment and Testing Procedures

University of Minnesota sample

Recruitment will proceed as planned and approved, recruiting children from the People Serving People shelter and The Family Partnership preschool. Our team has years of experience working with these community partners.

Changes have been made in the consent form to reflect protocol measures.

The oral assent process for children has been simplified and shortened to accommodate younger children.

Greater flexibility will be allowed for sex/age balance within age brackets in the University sample as families in these community programs for disadvantaged families tend to be sensitive to exclusion from research opportunities.

Delve

Delve will randomly select participants from its database of potential participants. Delve uses an "opt-in" database from sources such as booths at community engagements, newspaper ads, Mommy-n-Me groups, social media, and word of mouth. These families have previously agreed to be contacted for future research studies, and the databases of its contractors, which, similarly, contain contact details of subjects interested in taking part in research.

Potential participants will be contacted by telephone and asked a series of questions to confirm their eligibility. Once the eligibility is confirmed, an appointment will be scheduled at the site office for testing. A Delve technician

will also confirm participant's mailing address and inform them that a packet – a consent form and directions to the testing site – will be mailed to that address shortly. When a child is selected, the telephone screening interview will be conducted with a parent or legal guardian.

The consent form(s) will only be mailed to potential participants as a source of additional information about the study. Participants will be formally consented by a trained Delve technician once they arrive at the testing site.

Once (a) consent forms have been signed (and children have orally assented), the parent and child will begin assessments simultaneously, either in the same room or in separate rooms near each other. Parents or legal guardians will be allowed to remain with their children in the testing room but not encouraged to do so. Having other people in the room can be distracting for a young child completing EF tasks; on the other hand, young children or their parents may prefer to be in the same room.

Videotaping

Sessions will no longer be videotaped to check fidelity of administration. Periodic live observation of test administrations will be done instead.

Payments

Parents who complete the parent session will be paid \$50 (debit or gift card) if they travel to the test site (\$25 plus a \$25 travel allowance) or \$25 if examiners travel to them or if the study pays for transportation. All Delve families will travel to central test sites. Families in the emergency shelter are usually tested on site in testing space dedicated for use by the University of Minnesota team. Parents from the Family Partnership are likely to be tested at their preschool community site, some traveling on their own, and some needing transportation, and thus may be compensated \$50 or \$25. Parents/guardians will be asked to sign a payment receipt when they are compensated. Delve routinely uses debit card for compensation. The University of Minnesota routinely uses Target or Walmart cards in similar studies, which have worked well with disadvantaged families.

Children recruited by Delve who participate will receive a \$25 debit card (given to the parent) by Delve (this is their standard compensation for children). Children recruited by the U of M will receive one or more gifts (toys, books, etc.) valued around \$25 (the standard approach of the faculty researchers in our department and for research in the same settings).

Changes to Measures

Please note that we will provide Spanish translations of all relevant measures and forms at a later time.

Demographic Form – the demographic form has been streamlined, made more structured, and shortened to simplify administration, reduce time burden, and simplify data entry. One question was added about whether a parent is in the military.

2. Does the protocol amendment affect study design and/or change the study endpoint(s)?

Yes

No

3. Describe the rationale for the change(s):

Data collection on this study has been on hold after completing assessments of 9 families as we awaited OMB clearance. While waiting, the initial contract period ended. In addition, the new EF measures were partially validated in a separate study (IRB #1206S15442). Now, a new contract to complete the goals of this formative project for the National Children's Study is pending. Thus, we have updated the goals of this study and the following changes of protocol reflect the goals of the new contract.

First, we propose discontinuing the pilot phase since the goals of that pilot were met in another study using the new measures. We have established feasibility of administration and preliminary construct validity. Therefore, we propose proceeding with the second phase of the study, which is focused on validation (construct validity and test-retest reliability). In the newly designed phase 2, described below, we would collect a larger sample in multiple states, both in English and Spanish, with a large portion of the testing conducted by Delve Marketing Research, the firm that collected the national norming study data for the original NIH Toolbox measures. The University of Minnesota team will still coordinate the study and collect data for the subsample of disadvantaged children as previously planned.

For this phase of the study, we propose still including both parent and child sessions, with neither lasting longer than an hour (parent session estimated to take 45 minutes; child session estimated to take 1 hour). Teacher reports will no longer be needed due to other studies that have or will provide validation data pertinent to teacher reports (IRB #: 1204S12361, 1105S99892, 1206S15442). A summary of the session protocol is listed below, including already-approved measures in the current and earlier versions of this IRB submission. The design reflects what we learned from the initial pilot cases of this study and our related work on executive function in other studies. This experience helped us determine which measures were best for the age group and diverse samples of children. New measures proposed for this study (in bold italics) are described below.

4. How will these changes affect the overall risk to subjects in this study?

There are no changes to risk.

5. Do the changes to the study prompt changes to the consent form(s)?

No.

Yes. If yes:

- Attach a copy of the revised consent form(s) with changes tracked or highlighted as well as a clean copy.

5.1 Will currently enrolled subjects will be notified of the changes?

No

Yes, explain below how they will be notified (i.e. subjects will be re-consented with the updated form once approved, subjects will be provided with an information sheet, subjects will be told of changes at next study visit, etc.).

6. List and attach all documents included with this request, including version dates:

Delve screening script, 11/6/13 version
Consent form for U of M families (without 2nd session, with changes highlighted), 11/6/13 version
Consent form for U of M families (without 2nd session, clean copy), 11/6/13 version
Consent form for U of M families (with 2nd session), 11/6/13 version
Consent form for Delve participants (without 2nd session), 11/6/13 version
Consent form for Delve participants (with 2nd session), 11/6/13 version
Child assent script for all participants, 11/6/13 version

Family Information Questionnaire (demographic form), 11/6/13 version
Strengths and Difficulties Questionnaire (SDQ; ages 3-4)
Strengths and Difficulties Questionnaire (SDQ; ages 4-10)
Behavior Rating Scale, 11/6/13 version

Principal Investigator's Signature

Date

Cancer Protocol Review Committee (CPRC) Use Only: