Supporting Statement A for

NIH Toolbox for Assessment of Neurological and Behavioral Function (NIA)

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Molly Wagster, Ph.D.
Contracting Officer Technical Representative
NIH Toolbox
National Institute on Aging

Gateway Building, 350
7201 Wisconsin Ave
Bethesda, MD 20892

Telephone: 301-496-9350
Fax: 301-496-1494
E-mail: wagsterm@nia.nih.gov

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A. JUSTIFICATION

A.1 Circumstances Making the Collection of Information Necessary

Although there are many studies that collect information on aspects of neurological function and behavioral health (e.g., cognition, sensation, motor functioning, emotion), there is little uniformity among the measures used to assess these constructs. When individual studies employ unique assessment batteries, comparisons between studies and combining data from multiple studies are quite challenging. Thus, investigators have expressed the need for brief, standard assessment tools to be used across diverse study designs and populations. For example, in 2005, a report (Hendrie et al., Alzheimer's & Dementia, vol. 2, 12-32, 2006) was submitted to the staff of the trans-NIH Cognitive and Emotional Health Project (CEHP) that suggested, among other ideas, the need for "standard questionnaires to measure cognitive and emotional health".

In response to these issues, the National Institutes of Health (NIH) Toolbox initiative seeks to assemble brief, comprehensive assessment tools to measure cognitive, emotional, sensory and motor function that will be useful to clinicians and researchers in a variety of settings, with a particular emphasis on measuring outcomes in large longitudinal or epidemiologic studies and prevention or intervention trials across the lifespan. Such comprehensive measures are rarely included in studies of this type, due in part to the lack of brief, well-validated instruments. Furthermore, the heterogeneity of measures used in studies to assess a particular domain is great and hinders the ability to compare data readily across studies. Thus, the Toolbox will provide a valuable and much needed resource across NIH and for the scientific community, by ensuring that assessment methods will be capable of comparison with existing and completed studies, will be valid for use in diverse populations (e.g., age, gender, racial/ethnic), and will maximize the

yield from large and expensive research projects. Advances in psychometric research methodology, including for example, computerized adaptive testing and where possible, virtual reality, combined with traditional performance-based tools, should lead to the efficient, flexible and responsive assessments. Specifically, the Toolbox will assess domains of Cognition (such as learning, memory, executive function, language/lexical retrieval, attention, speed of processing); Emotion (mood, adaptability, interpersonal relations, self- regulation); Motor Functioning (locomotion, non-vestibular balance, dexterity, strength); and Sensation (vision, hearing, vestibular balance, smell, taste, touch).

The NIH Toolbox assessments were selected through a multiphase process. During the first phase, input from subject and methodology experts, potential end users and other stakeholders was actively solicited through Requests for Information (RFI), individual interviews and several consensus meetings and used to determine the domains (areas) to target for assessment as well as criteria (e.g., sound psychometric properties, cost, length) each instrument should meet. Existing instruments were then reviewed and any that met criteria either as is or with some modification (e.g., additional development to extend the age range of the measure) were retained for potential NIH Toolbox inclusion. For domains where no existing instrument met criteria, new measures were developed. Both new and modified instruments were piloted to evaluate psychometric properties and ability to meet other criteria. Measures that did not meet criteria, or did not perform as well as a competing alternative, were dropped from the NIH Toolbox.

As the premier agency for conducting and supporting biomedical research in the United States, the NIH's mission is to pursue knowledge about the nature and behavior of humans and the application of that knowledge to extend healthy life and reduce burdens of illness and disability. Within the agency, a trans-NIH scientific collaborative effort termed the NIH Blueprint for

Neuroscience Research supports the development of new tools and other resources to assist neuroscience research and provide a framework for planning and implementing the NIH's neuroscience research efforts. The development of the NIH Toolbox addresses goals of both the NIH Blueprint and the larger NIH organization by providing a research tool to assess health, behavior and neurological function objectively across the lifespan that will accelerate and deepen the knowledge gained for attainment of health and prevention of disease. Section 410 of the Public Health Service Act (42 USC § 285) authorizes the collection of information for the NIH Toolbox for Assessment of Behavioral and Neurological Function.

In this document we provide supporting information for approval by the Office of Management and Budget (OMB) for data collection under the Paperwork Reduction Act.

The primary methods for data collection will be self- or technician administration via computer e.g.., computer-assisted self-interviewing - CASI).

A.2 Purpose and Use of the Information Collection

The proposed collection of data and the development of the Toolbox will assist NIH in reaching several of their goals. The NIH Blueprint for Neuroscience Research, a coalition of sixteen Institutes, Centers and Offices that support neuroscience research, aims to develop new tools, resources, and training opportunities to accelerate the pace of discovery in neuroscience research. Similarly, the NIA outlines an area of scientific priority related to the "development of tools to facilitate research on the basic biology of aging." As such, the Toolbox supports NIH's affirmation that longitudinal research spanning pediatric to geriatric populations and assessing normative functioning of multiple domains of neurological and behavioral health are required to understand developmental processes in illness etiology. Measures such as those developed as

part of the Toolbox are rarely included in large epidemiological studies where functioning is monitored over time, due in no small part to the lack of instruments that are well-validated and have a short administration time. While there are many assessments in these domains, they are expensive, normed on homogeneous non-diverse populations, and do not readily produce data that can be compared across studies.

Upon completion, the Toolbox will provide investigators, including both pediatric and aging specialists across our four primary domains, an innovative approach to measurement that will be responsive to research needs in a variety of settings, with a particular emphasis on measuring outcomes in large cohort studies such as epidemiological, large longitudinal, and prevention or intervention trials. The Toolbox would greatly facilitate cross-study comparisons involving a wide variety of nonclinical and clinical populations. Results can be readily combined or compared (e.g., in meta-analyses) to more quickly and confidently answer questions about functioning of various normal and abnormal groups, and its change over time due to aging, disease onset or progression, and interventions. Thus, the Toolbox would provide a truly "economic" and valuable resource for the entire neuroscience and behavioral research community with a minimal increment in subject burden and cost. Furthermore, because Toolbox measures are expected to be easy to obtain and use in research, they will likely promote more rapid and complete accumulation of knowledge regarding differences in functioning associated with various normal and abnormal conditions.

In order for the Toolbox battery to be considered viable and attractive for use in future research, the measures will have undergone different phases of development, including pretesting/pilot testing, validation and calibration, and the current phase of field testing. This phase (also called "norming") will involve the collection of data in large samples for establishing the psychometric

properties and comparative norms for the measures. Collecting nationally representative norms will be very important across age, race/ethnicity and geographic diversity, given that the NIH requires this level of diversity in preventive intervention trials, drug trials, and large scale epidemiological efforts. The targeted population will be non-institutionalized U.S. residents, aged 3-85 years, with the sample consisting of approximately 70% English-speaking and 30% Spanish-speaking residents. Measures will be administered related to cognitive, emotional, motor and sensory domains. An initial questionnaire will also be administered that contains questions related to sociodemographic characteristics, eligibility, medical history and health behaviors.

The normative data will be evaluated to produce mean scores and medians, the impact of missing data, and responsiveness to change. Results from the field testing phase will inform the development of the final Toolbox, including an evaluation of the instruments' psychometric properties; development of scoring program and summary scores; development of user's manual; and development of a training program.

The information from the proposed data collection will be used by the NIH (through a contract with NorthShore University HealthSystem Research Institute) to develop, structure, and refine the required measurement instrument for assessment of cognitive, sensory, motor and emotional function. The proposed data collection will support psychometric testing of the assessments and testing and refinement of the Spanish version of the assessments. The Toolbox will provide a much-needed, brief, standardized set of psychometrically-sound assessments with age, gender and ethnicity norms. The measurements as designed will be particularly important for tracking change over time in neurological and behavioral health variables in large longitudinal studies and in prevention or intervention trials. The resultant Toolbox will be used to facilitate and enhance the breadth of neurological and behavioral data collection for large cohort studies, thus

leveraging these very expensive studies to obtain a greater yield of information for NIH biomedical research efforts. The Toolbox will provide a form of 'common currency' across various study designs and populations and will allow comparison between studies and combination of data from multiple studies, again enhancing the NIH research enterprise by increasing the value of clinical datasets and advancing research discoveries more expeditiously.

A.3 Use of Information Technology and Burden Reduction

Most of the information that is collected directly from participants will be computer based. Individuals selected into the sample will complete screening interviews over the telephone and complete an initial socio-demographic questionnaire at home, prior to their visit to the testing site.. During the actual testing sessions, all of the NIH Toolbox measures will be administered via an integrated administration system created by the Toolbox Technology Team. All data collection will occur during one appointment for most participants. At the discretion of the test administrators, and with agreement from participants and their guardians, data collection may be divided into two appointments for small children. By eliminating the use of paper forms at testing centers, respondent burden is reduced, and data collection is more efficient (e.g., data on forms will not need to be re-entered). The NIA Privacy Impact Assessment officer has completed the Privacy Impact Assessment (PIA).

A.4 Efforts to Identify Duplication and Use of Similar Information

The Contracting Officer's Technical Representative (COTR; formerly known as "Project Officer"), assisted by an NIH Project Team of content experts and under the aegis of the NIH Blueprint for Neuroscience Research, conducted reviews of the literature and existing projects and determined that the requested assessment development does not duplicate other current

assessment tool(s). Although numerous instruments exist for the domains proposed for assessment by the Toolbox, these largely target assessment of disorder or illness related to these variables and not function or health. A brief, common set of measures for constructs in cognition, motor, sensory and emotional function and which are largely objective measures and not subjective (except in the domain of emotional function) do not exist for the large age span required (3 – 85 years). Through discussions with measurement experts, epidemiologists and clinical researchers, as well as Program staff at other NIH Institutes, the lack of and need for a comprehensive set of standard measures to capture neurological and behavioral function was identified.

The COTR and/or her NIH Project Team members attended meetings of the International Neuropsychological Society, the Society for Neuroscience, the Association for Research in Otolaryngology, the Population Association of America, among others, and discussed the current status of epidemiological research across the lifespan and in reference to consistency in neurological and behavioral assessment, including individuals who had developed instruments in these domains. The COTR and her team also drew guidance from members of the Critical Evaluation Study Committee for the trans-NIH Cognitive and Emotional Health Project and the Committee's publication (Hendrie et al., Alzheimer's & Dementia, vol. 2, 12-32, 2006), in which it was suggested that a standardized assessment tool for large-scale studies is needed in these domains. Additionally, two internet-based Requests for Information (RFI) were issued that tapped NIH funded researchers; response was received from almost 300 individuals between the two RFIs. More in-depth information was solicited from a subset of those interviewees (n = 44)

via phone interviews. A systematic literature review for each of the targeted domains was requested and conducted.

The actual data proposed to be collected do not currently exist. The data will be unique to the instrument that is currently being developed and will feed back into the psychometric evaluation of the assessments. Data from a community population are necessary to provide a basis and context for calibrating results with this new multi-domain assessment. Whenever possible and to avoid duplication, items from existing assessment tools (e.g., the NIH Patient Reported Outcomes Measurement Information System (PROMIS); NEI standardized 25- item Visual Function Questionnaire (NEI-VFQ-25), etc.) will be used. However, as appropriate and in order to construct an item bank that covers the full range of certain constructs, the group of items proposed for that bank will undergo Item Response Theory (IRT) analyses to determine how well they function and where they fit along the continuum.

A.5 Impact on Small Businesses or Other Small Entities

This information collection does not involve small businesses or other small entities.

A.6 Consequences of Collecting the Information Less Frequently

This is a single time research study. As a purpose of this data collection is to establish test-retest reliability and evaluate practice effects for all Toolbox measures, the measures will need to be re-administered to a subset of the norming sample. For test-retest reliability, 375 children (and their parents for proxy measures) and 375 adults will complete the entire battery of Toolbox measures one week after the initial administration. The full battery of Toolbox measures is located in Attachments 1-38; additional measures are located in Attachments 39-59. Assuming the true

intraclass correlation coefficient (ICC) for reliability is at least 0.7, this sample size of 375 in each group (children and adults) will provide precision of ± 0.05 for the 95% confidence interval around the ICC. To evaluate practice effects, all Toolbox measures will be administered to 375 children (and their parents for proxy measures) and 375 adults three months after the initial administration. This sample size of 375 in each group (children and adults) will allow us to estimate the practice effect of each Toolbox measure with precision of ±0.10 standard deviation units. There will be no overlap between samples used for test-retest reliability and evaluation of practice effects. Test-retest reliability and practice effects cannot be assessed if these follow-up assessments are not conducted after the initial administration.

A.7 Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

The proposed study is consistent with the information collection guidelines in 5 CFR 1320.5.

A.8 Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agency

The 60 day Federal Register Notice for this information collection was published in the Federal Register on January 11, 2011 (Vol. 76, No. 7, p.1621) and allowed 60 days for public comment. No comments were received.

The Toolbox Measures were developed with the consultation of several method and subject matter experts during the development period of these instruments. The names, telephone numbers or email addresses, and affiliations of the consultants are listed in Attachment 64.

A.9 Explanation of Any Payment of Gift to Respondents

Compensation is planned for each respondent participating in the study. Each Toolbox Project respondent will receive $90-$150 (actual value and the form of payment (cash, check or card) vary according to type of respondent and geographic location) for completing the in-person testing process, which on average is expected to last no more than three hours. This level of compensation is considered to be essential to obtaining as high a response rate as possible, while respecting participants' time and effort. Respondents participating in the follow-up testing at one week or three months after the initial testing will receive an additional $90-$150 for completing the additional session. This second round of testing will be comparable to the first and as a result it was determined respondents should be compensated accordingly.

Respondent compensation is based on the market research industry standards and what is being asked of respondents. Typically, a two hour focus group or interview is compensated at the rate of $90. If there are additional hours needed, the respondent is compensated at $40 an hour for each additional hour. NIH Toolbox norming is structured as an interview along with completing some tasks throughout. The average estimated time to complete the interview is 3hours per person, therefore we feel that depending on the location, $120-$150 is a fair compensation for adults and $90-$125 for the children as their interviews are not as long.

A.10 Assurance of Confidentiality Provided to Respondents

The Toolbox Project is fully committed to protecting the anonymity of all survey respondents. Toolbox Project data will be collected in conformance with the Privacy Act of 1974, and the Confidential Information Protection and Statistical Efficiency Act of 2002. This data collection is covered by the NIH Privacy Act Systems of Record 09-25-0200, Clinical, Basic and

Population-based Research Studies of the National Institutes of Health (NIH), HHS/NIH/OD (see Attachments 65).

The regulatory documents (see Attachments 61-63) have been approved by the Northwestern IRB (see Attachment 62). Standard data collection procedures incorporate numerous safeguards for the data. While collecting Toolbox Project data in the norming phase of the study, the following personal identifiers may be collected by Delve, the marketing research firm contracted to do the data collection: respondent name, respondent telephone number, respondent address, and respondent e-mail address. These data will be required to contact selected respondents requesting their participation in the study and to re-contact a subset of respondents participating in the follow-up testing at one-week and three-months after initial testing. All identifying data will be delivered to the principal investigator separately from the study data; all data and analyses will be reported in aggregate form only. The following procedures will be used to maintain the privacy of the data:

1) All identifying data will be kept in secured areas at the data collector's site and, later, at the principal investigator office;

2) Laptops used for data collection will be encrypted or pass-word protected; and

3) Data collection staff will be trained in protecting confidentiality of respondents and must receive certification of this training prior to collecting data or working with identifying respondent data.

Safeguards to protect the privacy of Toolbox respondents will be put into place. These include:

Obtaining informed consent. Respondents who choose to participate in the Toolbox Testing process will be subject to a consent process when they report to the testing site and in advance of the administration of the Toolbox measures. During this informed consent process, a Delve Field Technician will explain to the respondent the nature of the study, what to expect during testing, and detail their rights as a research participant. Respondents will be asked to sign the consent form (see Attachment 63) only after they have been informed of their rights as a study participant.

For participants less than 18 years of age, at least one parent or guardian will complete the informed consent process on behalf of the child and themselves to complete the proxy measures. Additionally, dependents between the ages of 7 and 17 will be led through an assent process to confirm their willingness to participate in the research. See Attachment 63 for copies of the pediatric assent and proxy consent forms.

This study has been reviewed by the Northwestern University IRB (see Attachment 62) and approvals have been received.

Maintaining privacy: Each Field Technician will receive training on the purpose of the study. All data collection staff will receive training in protecting the confidentiality and privacy of study respondents and complete the Collaborative Institutional Training Initiative (CITI).

Any hard copy screening questionnaires and other contact materials received at Delve's facilities will be housed in a secured on-site storage room. Hard copy materials are accessed from the secured room only by authorized staff and only when necessary for data collection activities. Delve's electronic systems are maintained on a local area network (LAN). All Delve systems

used to store electronic survey data are secure by design and protected by passwords only available to authorized study staff.

At each testing site, Delve will secure site office space that offers sufficient privacy for the private administration of the Toolbox Project measures. In addition, any hardcopy materials that are stored in the site offices (e.g., the self-administered portion of the Initial Questionnaire, see Attachments 39-40) will be kept secure in a locked cabinet. In all facets of scheduling and administration of the interviews, the contractor will be keenly aware of the imperative to protect the confidentiality and safety of the respondents.

Certificate of Confidentiality: Under section 301(d) of the Public Health Service Act (42 U.S.C. 241(d)) the Secretary of Health and Human Services may authorize persons engaged in biomedical, behavioral, clinical, or other research to protect the privacy of individuals who are the subjects of that research. This authority has been delegated to the NIH.

Northwestern University has been granted a Certificate of Confidentiality that will cover all data collection sites and the University itself (see Attachment 61). The Certificate will be issued by the NIH to protect the privacy of research subjects by protecting investigators and institutions from being compelled to release information that could be used to identify subjects with a research project. It will allow the investigator and others who have access to research records to refuse to disclose identifying information in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level.

Site monitoring: Site monitoring is the mechanism by which a data collection site is formally evaluated to determine the degree of accuracy and completeness of the data collected and to

assess compliance with Federal regulations and Good Clinical Practice (GCP) guidelines pertaining to recordkeeping and reporting requirements.

A site initiation visit will be performed by a Northwestern University site monitor before the site begins data collection. Prior to the site initiation visit, the monitor will verify that all necessary materials have been shipped and received by the site. During the visit, the monitor will meet with the site staff and review general study procedures and expectations for site performance. In addition, the roles and responsibilities of the personnel will be discussed. The monitor will explain Federal and GCP guidelines and clarify any general or specific protocol-related questions. The monitor will also tour the facilities and evaluate them accordingly. These areas include the data collection area and secured areas (e.g., computer, regulatory documentation, and case report form storage). Items to be considered include overall space and waiting areas; whether data collection areas provide sufficient privacy; and availability of locked file cabinets for record and computer storage.

A.11 Justification for Sensitive Questions

Some questions, such as those in the Emotional Health domain of Toolbox (located in Attachments 31-32), are sensitive but are included because they address areas of functioning that experts in the field have identified as being significantly important to an assessment of neurological and behavioral functioning. Therefore, these questions are necessary to include in order to fulfill NIH's requirement to develop a Toolbox that evaluates important aspects of functioning and which can be used in clinical trials and epidemiological studies. We will also ask about income (for the purpose of describing our sample), but attempt to make this inquiry less intrusive by asking respondents to choose an income "bracket" (e.g., "Between $20,001 and

$40,000") rather than to give a specific amount. Participants will be receiving some study materials via mail and contacted by phone for scheduling of appointments, which requires address and telephone information (see recruitment materials in Attachment 60). Delve will protect the confidentiality of this information and will not release this identifying information to third parties.

A.12 Estimates of Hour Burden Including Annualized Hourly Costs

Response burden estimates are shown in Tables A.12-1 and A.12-2 and are based on the measure development experience during which respondents completed similar types of tasks. The average time per response differs for different types of participants. For the typical adult and child participants, the time burden includes the initial questionnaire (0.5 hours) completed prior to completing the Toolbox measures, the Toolbox measures themselves (2 hours for adults, 1.5 hours for children), and an additional half hour for other measures. Testing sessions will be somewhat reduced for children ages 3-5 because not all measures are applicable to this group of young children. Furthermore, a parent/ guardian of each child participant, who may or may not be a study participant themselves, will complete approximately one half-hour of proxy questions regarding their child.

The norming sample will be used to establish test-retest reliability and evaluation of practice effects for all Toolbox measures. Therefore, the measures will need to be re-administered to a subset of the norming sample. For test-retest reliability, 375 children (and their parents for proxy measures) and 375 adults will complete the entire battery of Toolbox measures one week after the initial administration. For assessment of practice effects, all Toolbox measures will be administered to 375 children (and their parents for proxy measures) and 375 adults three months

after the initial administration. There will be no overlap between samples used for test-retest reliability and evaluation of practice effects. Therefore, a total of 750 adults and 750 children (with their parent-proxies) will complete two assessments. Table A.12 – 3 identifies measures to be completed according to type of respondent.

With respect to time costs, we do not know the professional backgrounds or employment status of respondents and therefore we have no knowledge about hourly wages. We have chosen $25 as an average for the purpose of calculating a time-cost estimate.

A.12 – 1 ESTIMATES OF ANNUAL BURDEN HOURS				
Type of Respondents	**Number of Respondents**	**Frequency of Response**	**Average Time per Response**	**Annual Hour Burden**
Adults*				
Adult study participants, single assessment	3,150	1	3	9,450
Adult study participants, two assessments	750	2	3	4,500
Parent proxies for child participants, single assessment	3,750	1	0.5	1,875
Parent proxies for child participants, two assessments	750	2	0.5	750
Children				
Single assessment	3,750	1	2.5	9,375
Two assessments	750	2	2.5	3,750
Totals				
	12,900*			29,700

*Some adults may participate both as a study participant and as a parent proxy if their child is also a study participant.

A.12 – 2 ANNUALIZED COST TO RESPONDENTS				
Type of Respondents	**Number of Respondents**	**Frequency of Response**	**Hourly Wage Rate**	**Respondent Cost**
Adults	3,900	1-2	$25.00	$348,750.00
Parent proxies	4,500	1-2	$25.00	$65,625.00
Children	4,500	1-2	$0.00	$0.00
			Total	$414,375.00

A.12 – 3 Summary of Measures Completed According to Type of Respondent			
	Adult participant *	**Child participant (age range)**	**Proxy for participating child (age range of child)** *
Battery of Toolbox Measures			
Sensation domain			
Automated Audiometry from the NIH Toolbox (AANT)	X	X	
Hearing Handicap Inventory (HHI)	X		
Words-in-Noise (WIN)	X	X	
Adult Odor Identification	X		
Pediatric Odor Identification		X	
University of Pennsylvania Smell Identification Test (UPSIT)	X	X	
Pain Assessment Ages 3-4		X (3-4)	X (3-4)
Pain Assessment Ages 5-7		X (5-7)	X (5-7)
Pain Assessment Ages 8-12		X (8-12)	X (8-12)
Pain Assessment Ages 13-17		X (13-17)	
Pain Assessment Ages 18-85	X		
Forced-Choice Sucrose Test	X	X(5-17)	
Toolbox Taste Test	X	X (12-17)	
Dynamic Visual Acuity (DVA)	X	X	
Vision Survey	X	X(7-17)	
Tactile Discrimination Test	X	X(7-17)	
Brief Kinesthesia Test	X	X (7-17)	
Cognition domain			
Dimensional Card Sort	X	X	
Flanker	X	X	
Imitation Based Assessment of Learning (IBAM)	X	X	
List Sorting	X	X	
Oral Symbol Digit Modalities Test	X	X (8-17)	
Pattern Comparison	X	X	
Rev Auditory-Verbal Learning Test (RAVLT)	X	X (8-17)	
Reading Recognition	X	X	
Vocabulary	X	X	
Bateria III Picture Vocabulary (Spanish only)	X	X(3-17)	
Word Accentuation (Spanish only)	X	X(7-17)	

A.12 – 3 Summary of Measures Completed According to Type of Respondent			
	Adult participant *	**Child participant (age range)**	**Proxy for participating child (age range of child)** *
Emotion domain			
Instructions	X	X (8-17)	X (3-12)
Negative Affect – Age 13-17 SELF		X (13-17)	
Negative Affect – Age 18 plus SELF	X		
Negative Affect – Age 3-7 PROXY			X (3-7)
Negative Affect – Age 8-12 PROXY			X (8-12)
Negative Affect – Age 8-12 SELF		X (8-12)	
Positive Affect – Age 3-7 PROXY			X (3-7)
Positive Affect – Age 8-12 PROXY			X (8-12)
Positive Affect – Age 8-12 SELF		X (8-12)	
Positive Affect – Age 13-17 SELF		X (13-17)	
Positive Affect – Age 18 plus SELF	X		
Social Relationships Age 3-7 PROXY			X (3-7)
Social Relationships Age 8-12 PROXY			X (8-12)
Social Relationships Age 8-12 SELF		X (8-12)	
Social Relationships Age 13-17 SELF		X (13-17)	
Social Relationships Age 18 up SELF	X		
Stress and Coping Age 8-12 PROXY			X (8-12)
Stress and Coping Age 8-12 SELF		X (8-12)	
Stress and Coping Age 13-17 SELF		X (13-17)	
Stress and Coping Age 18 up SELF	X		
Motor functioning domain			
Dexterity 9-hole Pegboard	X	X	
Endurance 2Minute Walk Test (2MWT)	X	X	
Locomotion 4-meter Walk Test	X	X (5-17)	
Strength Grip Strength Dynamometry	X	X	
Strength Knee Extension	X	X	
Balance Accelerometer Measure	X	X	
Additional Measures			
Additional Somatosensation Questions	X	X(13-17)	X(3-17)
Additional Audition Olfaction Taste	X	X(10-17)	X(3-17)

A.12 – 3 Summary of Measures Completed According to Type of Respondent			
	Adult participant *	**Child participant (age range)**	**Proxy for participating child (age range of child)** *
Questions			
Handedness Assessment	X	X(3-17)	X(When needed)
Cognition Information Form	X		X(3-17)
Health Care Access and Utilization	X		X(3-17)
Instrumental Activities of Daily Living (IADLs) Adults	X		
Occupation	X		
Applied Cognition Adult	X		
Pediatric Perceived Cognitive Function (PCF) Child		X (8-17)	X(8-17)
Pediatric PROMIS Physical Function Upper Extremity		X (8-17)	
Pediatric PROMIS Physical Function Mobility		X (8-17)	
Pediatric Functional Assessment of Chronic Illness Therapy Fatigue (FACIT-F)		X (8-17)	X (8-17)
PROMIS 29 Participant	X	X (13-17)	
Safety, Disability, Medical Condition and Miscellaneous Questions	X		X(3-17)
School Performance and Activities		X (13-17)	X (3-17)
Alcohol Use Questions	X	X(13-17)	
Education Questions	X		X (3-17)
Sociodemographic Form,	X		X(3-17)
Toolbox Language Screener	X	X (8-17)	X (3-7)
Test Anxiety Scale (TAS)	X	X (13-17)	
Falls Efficacy Scale-International (Short FES-I)	X		

*Note that if an adult participant is also serving as the proxy for a participating child, that adult's burden will be the combination of those two columns.

A.13 Estimate of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no costs to respondents other than their time to respond. Therefore, respondents are not expected to incur any capital and start-up costs or system maintenance costs in responding.

A.14 Annualized Cost to the Federal Government

The total cost of the entire Toolbox project is $25,185,667 over 5 years, or approximately $5,062,318 per year. This includes all developmental phases of the project, including this proposed data collection, and the deliverable of the final instrument package, related software, and operating procedures manual. The cost of this proposed one time data collection is $2,360,980, expected to be completed within one year, and includes the costs of subject recruitment, all data collection and follow-up, compensation payments to subjects, and other miscellaneous costs such as supplies, postage, and telecommunications.

A.15 Explanation for Program Changes or Adjustments

This is a new collection of information.

A.16 Plans for Tabulation and Publication and Project Time Schedule

A.16 – 1 Project Time Schedule

Activity	Time Schedule
Selection of potential participants	immediately after OMB approval
Administration of Toolbox measures to scheduled participants, initial assessment and test-retest reliability	1 month after OMB approval
3-month follow-up assessments	4 months after OMB approval
Calculate weights	5 months after OMB approval
Analysis	5-12 months after OMB approval
Presentation of Final Toolbox	13-14 months after OMB approval

Sample weighting will be completed by statistical weighting experts. As a post-stratification adjustment, weights will be calculated by the method of iterative proportional fitting, or raking, such that the weighted sample will have the same distribution of demographic variables as that in

the U.S. Census. Descriptive statistics will be calculated for the Toolbox measures to form the general population normative reference values. Weighted adjustments will allow the values collected in this sample to generalize to the target population defined in B.1. Summary tables for each of the Toolbox instruments will be prepared by age, sex and language. Descriptive statistics presented in the summary tables will include means and standard deviations, percentiles (e.g., minimum, 5^{th} percentile, 25^{th} percentile, median, 75^{th} percentile, 95^{th} percentile, maximum) and the frequency of respondents at the floor and ceiling. An explanatory document will be prepared to be used as a user's guide for the normative reference tables.

A.17 Reason(s) Display of OMB Expiration Date is Inappropriate

This study will display the expiration date for OMB approval of the information collection.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

The study complies with 5 CFR 1320.9, the Certification for Paperwork Reduction Act Submissions.