

SOLICITATION

SECTION A - SOLICITATION

<p>1. Request For Proposal (RFP) Number: EH06-201</p>	<p>2. Issue Date: 01/09/09</p>
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3. **TITLE:** Establishing Nationally Representative Norms for the NIH Toolbox for Assessment of Neurological and Behavioral Function

<p>4. ISSUED BY: ENH Research Institute Center on Outcomes, Research and Education 1001 University Place, Suite 100 Evanston, IL 60201</p>	<p>5. SUBMIT OFFERS TO: See Attachment B</p>
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6. Proposals for furnishing the supplies and/or services will be received at the place designated and quantity specified in Attachment B until **3:00 p.m., CST, February 23, 2009.**

FOR INFORMATION CALL:

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7. Table of Contents on following page.

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SECTION A – LIST OF ATTACHMENTS

SOLICITATION ATTACHMENTS

Attachment A: Contract Clauses

Attachment B: Packaging and Delivery of Proposal

Attachment C: Proposal Intent Response Sheet

BUSINESS PROPOSAL ATTACHMENTS

Attachment D: Small Business Subcontracting Plan

Attachment E: Contact Points

Attachment F: Representations and Certifications

INFORMATIONAL ATTACHMENTS

Attachment G: Proposed Instrument List

SECTION B - INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS

1. GENERAL INFORMATION

A. CONTRACT AWARD

ENH Research Institute (ENHRI) intends to award a contract or contracts resulting from this solicitation to the responsible offeror(s) whose proposal(s) represents the best value after evaluation in accordance with the factors and subfactors in the solicitation. As a subcontractor to the Toolbox project, the resultant contract will be flow-down from ENHRI's prime contract from the NIH and will include all applicable FAR clauses. See Attachment A.

- 1) ENHRI may reject any or all proposals if such action is in ENHRI's interest.
- 2) ENHRI reserves the right to make multiple awards if, after considering the additional administrative costs, it is in ENHRI's best interest to do so.

B. TYPE OF CONTRACT

It is anticipated that the award from this solicitation will be a cost reimbursement type, completion contract with a period of performance of 18 months, and that incremental funding will be used.

C. PREPARATION COSTS

This solicitation does not commit ENHRI to pay for the preparation and submission of a proposal.

2. INSTRUCTIONS TO OFFERORS

A. GENERAL INSTRUCTIONS

INTRODUCTION

The following instructions will establish the acceptable minimum requirements for the format and contents of proposals.

(1) Contract Type and General Clauses

A completion type, cost-reimbursement contract will be awarded. Any resultant contract shall include the clauses applicable to the selected offeror's organization and type of contract awarded as required by Public Law, Executive Order, or acquisition regulations in effect at the time of execution of the proposed contract.

(2) Authorized Official and Submission of Proposal

The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this solicitation. The proposal shall be marked, addressed, and submitted in the number of copies specified in Attachment B

entitled PACKAGING AND DELIVERY OF THE PROPOSAL. Proposals must be typewritten, paginated, reproduced on letter size paper and must be legible in all required copies. To expedite the proposal evaluation, all documents required for responding to the solicitation should be placed in the following order:

I. COVER PAGE

Include solicitation title, number, name of organization, identification of the proposal part, and indicate whether the proposal is an original or a copy.

II. TECHNICAL PROPOSAL

It is recommended that the technical proposal consist of a cover page, a table of contents, and the information requested in the Technical Proposal Instructions.

III. BUSINESS PROPOSAL

It is recommended that the business proposal consist of a cover page, table of contents, and the information requested in the Business Proposal Instructions and SECTION A, List of Attachments.

(3) Separation of Technical and Business Proposals

The proposal must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other. The technical proposal must include direct cost and resources information, such as labor-hours and categories and applicable rates, materials, subcontracts, travel, etc., and associated costs so that the offeror's understanding of the project may be evaluated. However, the technical proposal should not include pricing data relating to individual salary information, indirect cost rates or amounts, fee amounts (if any), and total costs. The technical proposal should disclose your technical approach in as much detail as possible, including, but not limited to, the requirements of the technical proposal instructions.

(4) Standards for Privacy of Individually Identifiable Health Information

The Department of Health and Human Services (DHHS) issued final modifications to the "Standards for Privacy of Individually Identifiable Health Information," the "Privacy Rule," on August 14, 2002. The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information and is administered and enforced by the DHHS Office for Civil Rights (OCR).

Decisions about the applicability and implementation of the Privacy Rule reside with the contractor and his/her institution. The OCR Web site (<http://www.hhs.gov/ocr/>) provides information on the Privacy Rule, including a complete Regulation Text and a set of decision tools on "Am I a covered entity?" Information on the impact of the HIPAA Privacy Rule on NIH processes involving the review, award, and administration of grants, cooperative agreements and contracts can be found at: <http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html>.

B. TECHNICAL PROPOSAL INSTRUCTIONS

(1) Technical Discussions

A detailed work plan must be submitted indicating how each aspect of the specific tasks is to be accomplished. Your technical approach should be in as much detail as you consider necessary to fully explain your proposed technical approach or method. The technical proposal should reflect a clear understanding of the nature of the work being undertaken. The technical proposal must include information on how the project is to be organized, staffed, and managed. Information should be provided which will demonstrate your understanding and management of important events or tasks.

The proposal of multiple/alternative methods of completing the RFP tasks are welcomed when accompanied by an explanation of the pros/cons of each method, including budget ramifications.

(2) Background

The overall goal of the Toolbox project is to develop unified, integrated methods and measures of four domains of neurological and behavioral functioning (cognitive, emotional, motor and sensory) for use in large epidemiological studies where functioning is monitored over time. These large studies may be longitudinal cohort studies or they may be clinical trials evaluating the effectiveness of interventions and treatments. The Toolbox measures could also be incorporated in large cross-sectional epidemiological studies.

The target population for the Toolbox project is defined as persons aged 3 to 85 years dwelling in the community (U.S. civilian, non-institutionalized population). In addition, participants will be restricted to those capable of following instructions given in English or Spanish and understanding the informed consent process. There may be other restrictions as well related to the completion of individual tests (e.g., adequate functionality to perform specific tasks).

There are different phases of development anticipated in the Toolbox project, each with unique sampling needs: pretesting/pilot testing, validation and calibration (which may result in further refinement of measures), and norming (which should be based on the final measures). Some domains will need to pretest (or “try-out”) new or modified instruments in very small convenience samples. Pilot testing will involve small samples in order to evaluate the administration procedures on new or modified instruments and/or gather preliminary data to assess their measurement properties. Validation will involve moderately-sized samples to obtain more precise information about measurement properties. Depending on the measure, calibration based on item response theory may occur prior to, during, or after validation. The domains are cognitive, emotional, motor and sensory function. Subdomains under sensory function include audition, olfaction, taste, somatosensation, vestibular balance and vision.

The final phase (“Norming”) will involve a large sample for the purpose of establishing comparative norms. **The purpose of this request for applications (RFA) is to solicit proposals from experienced survey contractors to conduct some or all of the tasks required to**

establish nationally representative norms for the Toolbox measures (Norming).

Additional descriptive materials regarding the Toolbox effort are posted at www.nihtoolbox.org.

Sample Size

Norms will be computed by age, gender and language strata, and each stratum will contain a minimum of 100 adult subjects or 50 pediatric subjects.

Norming: Adults

Age	English		Spanish		Total
	Male	Female	Male	Female	
18 - 29	100	100	100	100	400
30 - 39	100	100	100	100	400
40 - 49	100	100	100	100	400
50 - 59	100	100	100	100	400
60 - 69	100	100	100	100	400
70 - 79	100	100	100	100	400
80 - 85	100	100	100	100	400
Total	700	700	700	700	2800

Norming: Children*

Age	English		Spanish		Total
	Male	Female	Male	Female	
3	50	50	50	50	200
4	50	50	50	50	200
5	50	50	50	50	200
6	50	50	50	50	200
7	50	50	50	50	200
8	50	50	50	50	200
9	50	50	50	50	200
10	50	50	50	50	200
11	50	50	50	50	200
12	50	50	50	50	200
13	50	50	50	50	200
14	50	50	50	50	200
15	50	50	50	50	200
16	50	50	50	50	200
17	50	50	50	50	200
Total	750	750	750	750	3000
*An alternative sampling plan may be proposed if significant cost savings would be recognized.					

(3) Technical Specifications

Independently, and not as an agent of ENHRI, the Contractor shall furnish services, qualified professional and technical personnel, material, equipment and facilities not otherwise provided by ENHRI under the terms of this contract as needed to perform the work set forth below.

Specific Tasks

Individual tasks involved in establishing norms are outlined below. Budgets must provide separate estimates for each of the six tasks listed below.

Task 1. Select Testing Sites

Contractors will propose a methodology for selecting testing sites where participants will complete all of the Toolbox measures. Some Toolbox measures can be self-administered via computer (i.e., computer-assisted self interviewing - CASI), while others will be technician administered or technician assisted. The testing facilities should have a quiet, private room where testing can take place and there must be ready access to minimum space of 60 feet to accommodate the walk test, which is the most space intensive measure in the Toolbox. The walk test may be conducted in a public area. Testing facilities should have internet access for data transfer and should be accessible for persons with disabilities.

Contractors shall specify the number of testing sites to be selected. Contractors shall demonstrate

the extent to which the selected testing sites or the samples they will be recruiting from testing sites are geographically representative of the contiguous 48 states. Contractors shall also demonstrate the extent to which they can provide a diverse sample and the degree to which the sample will match the U.S. general population composition. Testing sites should be selected to provide a mix of race groups, socioeconomic levels, and communities (i.e., rural, suburban, urban). Sites may be bilingual and capable of testing both English- and Spanish-speaking participants, or sites can be identified separately for testing only English- or Spanish-speaking participants. A mix of bilingual and monolingual testing facilities would also be acceptable. It will not be necessary to provide sign language capabilities for participants with hearing impairments.

The contractor will be responsible for obtaining IRB approval. The Toolbox team will assist with the preparation and submission of IRB paperwork, as needed. Academic sites can be considered as potential testing facilities. The contractor shall demonstrate their ability to obtain IRB approval for multiple sites (including academic sites, if applicable) in a timely fashion. Preference will be given to proposals ensuring geographic representation.

To ensure consistent quality of data collected across all testing sites, contractor should provide plans for site monitoring during the recruitment process.

Task 2. Identify, Screen and Recruit Participants

Sample selection: Contractors shall propose a probability methodology for drawing a sample from communities surrounding the selected testing sites. The maximum and average distances respondents may need to travel to the testing sites should be specified. Provisions for participant transportation, if any, should be described and included in the budget.

If random digit dialing (RDD) is to be used to identify participants, the contractor shall specify what additional methods will be employed to contact residents of selected households who are not successfully reached by phone. If RDD is to be used alone with no supplemental methods of contact, the contractor must demonstrate that the resulting sample will be representative of the community from which it is drawn and not subject to selection bias due to telephone technology (e.g., cell-phone only households, caller ID and call screening) that may limit the likelihood of successful contact for randomly selected numbers.

Contractors shall specify the maximum number of participants per household to be sampled. Proxy respondents will be required for several measures (e.g., emotional functioning) administered to the pediatric participants ages 3 - 7. No proxy respondents for adult participants will be allowed.

Contractors shall describe methods they will employ to maximize response rates and deal with issues of non-response. They shall also describe the method to be used to calculate the response rates for the various sub-populations (e.g., English-speaking adults/children, Spanish-speaking adults/children, elderly etc.), and rough estimates of the anticipated response rates shall be provided.

Screening and Recruitment: Contractors shall develop the eligibility screening instruments, participant recruitment materials and training materials. Detailed descriptions of eligibility screening and recruitment procedures should be provided. All Toolbox measures and instructions

will be translated into Spanish prior to norming. However, contractors will be responsible for translating screening materials and participant recruitment materials into Spanish. Contractors will also be responsible for providing necessary computer hardware and software programming needed to conduct the screening and to schedule and track respondents. The contractor will be responsible for recruiting and training bilingual staff to conduct the screening.

Exclusion Criteria

The only exclusion criteria for the norming phase of the Toolbox project are age (less than 3 or over 85), language and cognitive impairment. A person will be considered ineligible for participation if s/he has insufficient cognitive functioning to provide informed consent or if s/he is unable to follow instructions in English or Spanish. The contractors shall describe their methodology for ascertaining whether a sampled person is ineligible due to cognitive impairment or insufficient language skills.

Initial Questionnaire

An initial questionnaire will be administered prior to the completing the Toolbox measures. This questionnaire will include standard sociodemographic questions and questions to ascertain the presence of any injuries or disabilities that might prevent the completion of a certain Toolbox measure so that participants can be directed to complete some measures but not others (e.g., to screen a blind person out of the vision test battery). Time permitting, this questionnaire may also contain questions on medical history and health behaviors that can be used as covariates when analyzing the normative data.

Contractors are asked to recommend when this questionnaire should be completed relative to the participant's visit to the testing facility. Specifically, should it be administered (in full or in part) prior to the testing appointment and if yes, what is the recommended mode of administration? Should it be administered (in full or in part) when the participant arrives at the testing facility? Contractors shall recommend the maximum practical time they believe participants would be willing to spend completing this initial questionnaire without adversely affecting overall participation rates or causing undue burden. We ask that contractors estimate the cost to administer an initial questionnaire that takes the maximum practical time to complete. The Toolbox team will develop an initial questionnaire that complies with the completion time limit recommended by the contractor. Upon request from the contractor, the initial questionnaire will be made available by the Toolbox team in web-enabled format, print and/or CASI.

Task 3. Administration of Toolbox Measures for Establishing Normative Data

Contractors may propose to conduct the testing in the norming phase of the Toolbox project. All testing equipment for each site, including computers for CASI, will be provided by the Toolbox project. It is anticipated that the average time required for adults to complete the Toolbox measures will be between 2.5 and 3 hours. This does not include the initial questionnaire described under #2 above. The Toolbox measures for the pediatric sample are anticipated to take on average 1.5-2.5 hours to complete for children ages 3 - 7 and 2.5 - 3 hours for children 8 - 18 (not including break time). The projected number of adult and child participants tested per week at each site should be specified.

Toolbox project team members will provide training on the administration of Toolbox measures to the site personnel; however, contractors may propose to organize and/or host the training

sessions. Toolbox project team members will be responsible for site visits during the norming phase to ensure appropriate protocols for administering Toolbox measures are being followed.

Timing of Testing the Toolbox Measures

In order to accommodate a diverse population that includes persons who are students, employed, out of work, retired etc., a flexible testing schedule that includes evening and weekend appointments should be designed. Contractors shall discuss an approach for accommodating a variety of schedules.

Task 4. Longitudinal Administration of Toolbox Measures for Assessing Test-retest Reliability and Sensitivity to Change

The norming sample will be utilized to establish test-retest reliability and sensitivity to change for all Toolbox measures. Therefore, the measures will need to be re-administered to a subset of the norming sample. For test-retest reliability, 250 children and 250 adults will complete the entire battery of Toolbox measures one week after the initial administration. For sensitivity to change, all Toolbox measures will be administered to 250 children and 250 adults six months after the initial administration. It is not necessary that the subsamples for assessing test-retest reliability and sensitivity to change be the same people.

Task 5. Determine Sample Weights

Following collection of the normative data, the contractor will determine sample weights that will be assigned to the data in order for the norms to be “nationally representative.” The application should describe a general methodology for calculating sample weights.

Task 6. Generation and Submission of Deliverables

Weekly tracking reports will be submitted to the Toolbox team showing the number of subjects screened, recruited and tested. These reports will also track refusals. A final report describing the methodology used for each task completed by the contractor and the results will be submitted. Any data collected by the contractor (e.g., screening questionnaire) will be provided to Toolbox team in SAS format upon completion of the norming phase. Finally, sampling weights will be provided.

Timeline

The contractors will submit as part of the application a timeline for each task they propose to do. The contractors should be prepared to commence screening and recruitment of participants in August 2010. All norming activities must be completed by September 2011, including delivery of reports, data and sampling weights. This 13-month timeline for norming does not include the longitudinal assessments for ascertaining test-retest reliability and sensitivity to change. Those longitudinal activities, including delivery of data in SAS format, must be completed by March 2012.

Schedule

Provide a schedule for completion of the work and delivery of items specified in the statement of

work. Performance or delivery schedules shall be indicated for phases or segments, as applicable, as well as for the overall program. Schedules shall be shown in terms of calendar months from the date of authorization to proceed or, where applicable, from the date of a stated event, as for example, receipt of a required approval by ENHRI.

Qualifications

Contractors should indicate past experience with collecting both survey data and technician administered/assisted measures. Normative data will be established for English- and Spanish-speaking participants.

Key Personnel

Describe the experience and qualifications of personnel who will be assigned for direct work on this program. Information is required which will show the composition of the task or work group, its general qualifications, and recent experience with similar equipment or programs. Special mention shall be made of direct technical supervisors and key technical personnel, and the approximate percentage of the total time each will be available for this program.

Resumes of all key personnel are required. Each must indicate educational background, recent experience, and specific or technical accomplishments.

Other Considerations

Record and discuss specific factors not included elsewhere which support your proposal. Using specifically titled subparagraphs, items may include listing any agreements and/or arrangements with subcontractor(s). Provide as much detail as necessary to explain how the statement of work will be accomplished within this working relationship.

C. BUSINESS PROPOSAL INSTRUCTIONS

(1) Basic Cost/Price Information

The business proposal must contain sufficient information to allow ENHRI to perform a basic analysis of the proposed cost or price of the work. This information shall include the amounts of the basic elements of the proposed cost or price. These elements will include, as applicable, direct labor, fringe benefits, travel, materials, subcontracts, purchased parts, shipping, indirect costs and rate, fee, and profit.

A detailed budget must accompany the proposal. In addition to the hard copy of the budget, please include one disk containing the budget files in Excel format with your business proposal. The following costs are assumed by the Toolbox project and **do not** need to be reflected in the budget.

- Equipment and computers needed to administer Toolbox measures
- Programming computer-administered Toolbox measures
- Translation of Toolbox measures and instructions into Spanish

Translation of consent forms into Spanish

Site visits by Toolbox project team members to ensure testing protocols are being followed

All other costs necessary to successfully complete the norming tasks must be specified.

(2) Cost and Pricing Data

1. General Instructions

A. You must provide the following information on the first page of your pricing proposal:

- (1) Solicitation, contract, and/or modification number;
- (2) Name and address of offeror;
- (3) Name and telephone number of point of contact;
- (4) Name of contract administration office (if available);
- (5) Type of contract action (that is, new contract, change order, price revision/redetermination, letter contract, unpriced order, or other);
- (6) Proposed cost; profit or fee; and total;
- (7) Whether you will require the use of Government property in the performance of the contract, and, if so, what property;
- (8) Date of submission; and
- (9) Name, title and signature of authorized representative.

B. As part of the specific information required, you must explain your estimating process, including--

- (1) The judgmental factors applied and the mathematical or other methods used in the estimate, including those used in projecting from known data; and
- (2) The nature and amount of any contingencies included in the proposed price.

(3) Cost Elements

Depending on your system, you must provide breakdowns for the following basic cost elements, as applicable:

1. Materials and services. Provide a consolidated priced summary of individual material quantities included in the various tasks, orders, or contract line items being proposed and the basis for pricing (contractor quotes, invoice prices, etc.). Include raw materials, parts, components, assemblies, and services to be produced or performed by others. For all items proposed, identify the item and show the source, quantity, and price. Conduct price analyses of all subcontractor proposals.
2. Direct Labor. Provide a time-phased (e.g., monthly, quarterly, etc.) breakdown of labor hours, rates, and cost by appropriate category, and furnish bases for estimates. Offerors are advised that no direct labor cost amounts may exceed the salary cap in effect as determined by the government. LINK TO EXECUTIVE SCHEDULE SALARIES: <http://www.opm.gov/oca/09tables/indexSES.asp>

**Note to Offerors: The current Fiscal Year Executive Level I Salary Rate should be adhered to in the preparation of your proposal. All costs associated with any resultant contract award shall be in compliance with the current Fiscal Year 2009 Executive Level I Salary rates.*

3. Indirect Costs. Indicate how you have computed and applied your indirect costs, including cost breakdowns. Show trends and budgetary data to provide a basis for evaluating the reasonableness of proposed rates. Indicate the rates used and provide an appropriate explanation.
4. Other Costs. List all other costs not otherwise included in the categories described above and provide bases for pricing.
5. Other Administrative Data

Subcontractors

If subcontractors are proposed, please include a commitment letter from the \ subcontractor detailing:

- 1) Willingness to perform as a subcontractor for specific duties (list duties).
- 2) What priority the work will be given and how it will relate to other work.
- 3) The amount of time and facilities available to this project.
- 4) Information on their cognizant field audit offices.
- 5) A complete cost proposal in the same format as the offeror's cost proposal.

Additionally, if the proposal amount will exceed \$500,000, a small business subcontracting plan will need to be completed. (ATTACHMENT D)

(4) Proposer's Annual Financial Report

A copy of the organization's most recent annual report must be submitted as part of the business proposal.

(5) Representations and Certifications

One copy of the Representations and Certifications (ATTACHMENT F) shall be completed and be signed by an official authorized to bind your organization. Additionally, a completed copy of the Representations and Certifications shall be submitted from any proposed subcontractor.

(6) Past Performance

Offerors shall submit the following information as part of their BUSINESS proposal.

A list of the last 5 contracts completed during the past THREE years and THE LAST

5 **CONTRACTS AWARDED** currently in process that are similar in nature to the solicitation workscope. Contracts listed may include those entered into by the Federal Government, agencies of state and local governments and commercial concerns. Offerors that are newly formed entities without prior contracts should list contracts and subcontracts as required above for all key personnel.

Include the following information for each contract or subcontract:

1. Name of Contracting Organization
2. Contract Number (for subcontracts, provide the prime contract number and the subcontract number)
3. Contract Type
4. Total Contract Value
5. Description of Requirement
6. Contracting Officer's Name and Telephone Number
7. Program Manager's Name and Telephone Number
8. Standard Industrial Code

The offeror shall submit comparable information on all subcontractors that the offeror proposes to perform a major subcontract under this effort. For the purpose of this solicitation, a "major subcontract" is defined as one that is over \$500,000.

The offeror may provide information on problems encountered on the identified contracts and the offeror's corrective actions.

Each offeror will be evaluated on its performance under existing and prior contracts for similar products or services. ENHRI is not required to contact all references provided by the offeror. Also, references other than those identified by the offeror may be contacted by ENHRI to obtain additional information that will be used in the evaluation of the offeror's past performance.