

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval

For

Other Than Full and Open Competition

1. Contracting Activity:

Veteran Health Administration (VHA)
Service Area Office (SAO) – East
323 North Shore Drive, Suite 500
Pittsburgh, PA 15212

Portland VA Medical Center, NCO 20
3710 SW US Veterans Hospital Rd
Portland, OR 97239

2. Nature and/or Description of the Action Being Processed:

2237 Number: 648-14-2-172-0202

This is a request for Other Than Full and Open Competition for a Firm Fixed Price Contract for research services with Boys Town National Research Hospital (BTRNH), a Non-Profit entity, in accordance with FAR 6.302-3.

3. Description of Supplies/Services Required to Meet the Agency's Needs:

As part of the VA Rehabilitation Research and Development (RR&D) Service-funded project titled "Comprehensive Wide Bandwidth Test Battery of Auditory Function in Veterans", the proposed contract is with Boys Town National Research Hospital (BTRNH) as outlined in project application sub-award and approved by VA RR&D for: supply technology in the form of a wideband test battery of middle-ear and cochlear function to evaluate auditory function in Veterans. The contractor will augment the existing test battery to include software development of a sequentially adaptive procedure to measure the acoustic-reflex threshold and a synchronized spontaneous otoacoustic emission test, with software support for an Etymotic ER 10B+ probe for all otoacoustic emission tests. will participate in the interpretation of automated test results from a battery of multiple tests measured by a single system that may be helpful in evaluating the auditory status of Veterans. will be the Research Programmer under this contract.

Estimated total period of performance: 07/01/14 – 06/30/18

Estimated Values:

Base Year	07/01/14 - 06/30/15	\$ 118,388.00
Option Yr 1	07/01/15 - 06/30/16	\$ 121,940.00
Option Yr 2	07/01/16 - 06/30/17	\$ 125,598.00
Option Yr 3	07/01/17 - 06/30/18	\$ 129,366.00

Total estimated Price: \$ 495,292.00

These estimates are based off of personnel expenses, including salary and fringe benefits, for the Senior Scientist and the Research Programmer. The Senior Scientist will require 25% effort and the Research Programmer will require 60% effort. Each period of performance will have two (2) CLINs; Senior Scientist salary/fringe and Research Programmer salary/fringe.

Comprehensive Wide Bandwidth Test Battery of Auditory Function in Veterans

The goal of this research is to evaluate a comprehensive test battery of new wide-bandwidth, i.e., wideband (WB), acoustical tests of auditory function in the differential diagnosis of middle ear, cochlear and retrocochlear pathologies in a population of Veterans. WB tests refer to ear canal tests using sound responses measured from 0.2 kHz to frequencies as high as 8 kHz, a bandwidth that is critical both for speech and non-speech perception. There will be tests in the battery for middle ear assessment using power absorption, cochlear assessment using otoacoustic emissions (OAEs) and the acoustic stapedius reflex (ASR) using middle ear power absorption. Results will be compared with a standard single-frequency clinical immittance test battery routinely used in the assessment of auditory function in Veterans. Task 1 seeks to evaluate the accuracy of the WB test battery in the differential diagnosis of middle-ear pathology and related conductive hearing loss by comparing the sensitivity and specificity of the WB battery to the traditional immittance battery for the following disorders: otosclerosis, serous otitis media, cholesteatoma, and tympanic membrane (TM) perforation. Task 2 seeks to develop and evaluate an improved, automated WB acoustic reflex threshold test relative to traditional single-frequency reflex threshold testing. Task 3 seeks to validate the use of TEOAE and SSOAE tests in Veterans to assess cochlear status, and evaluate their test performance in classifying ears with normal hearing and sensorineural hearing loss. Finally, Task 4 seeks to compare the diagnostic accuracy of the full WB test battery with the full single-frequency admittance test battery to detect any type of hearing loss including sensorineural, conductive and mixed. The hypothesis is that the WB test battery is more accurate than the traditional immittance test battery in identifying ears with normal auditory status and ears with a range of risks for auditory pathology.

This will be a multi-site research project with data collection at two VA sites: The Portland VA Medical Center, National Center for Rehabilitative Auditory Function (NCRAR) and the Mountain Home VA Medical Center. Wideband tests will be developed in collaboration with _____ of the Boys Town National Research Hospital (BTNRH). Human subjects will be recruited for this study that have had hearing evaluations from the VA Audiology Clinics at the Portland VAMC and Mountain Home VAMC. The VA Medical Centers will be responsible for the recruiting. These subjects will respond to flyers or be part of a human subject volunteer registry established at each site. Since the focus on the proposal is to evaluate the use of at WB test battery in comparison with the traditional battery in evaluating patients seen at VA Audiology clinics, the recruitment of subjects from clinic populations is critical. Across the 4 years of the study, a total 640 subjects will be recruited, 320 from each site. This number of subjects will be required to obtain sufficient numbers of subjects with a variety of hearing disorders and pathologies to allow a comparison of results for traditional and wideband tests. All subjects will receive the same clinical and WB

test battery. The clinical immittance test battery will consist of 226 Hz tympanometry and ASR threshold testing. The WB battery will consist of ambient pressure and tympanometric absorbance tests, an automated ASR threshold test, a transient OAE test, and a synchronous-spontaneous OAE test that will also be developed in the first year of the study. Data will be analyzed to compare the utility of the WB and single-frequency tests in the differential diagnosis of conductive, mixed, and sensorineural hearing loss in Veterans. Any improvements found in the diagnostic performance of the WB test battery compared to current clinical procedures would provide an integrated set of auditory tests to more effectively and efficiently evaluate auditory function in Veterans.

4. Statutory Authority Permitting Other than Full and Open Competition:

- () (1) Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per FAR 6.302-1;
- () (2) Unusual and Compelling Urgency per FAR 6.302-2;
- (X) (3) Industrial Mobilization, Engineering, Developmental or Research Capability or Expert Services per FAR 6.302-3;
- () (4) International Agreement per FAR 6.302-4;
- () (5) Authorized or Required by Statute FAR 6.302-5;
- () (6) National Security per FAR 6.302-6;
- () (7) Public Interest per FAR 6.302-7.

5. Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):

has broad training in acoustical physics with expertise in digital signal processing and hearing science. His hearing research program using human subjects at the University of Washington and BTRH has been continuously supported by the NIH since 1988. His laboratory has developed new screening and diagnostic tests of clinical middle-ear function that inform knowledge of normal function, provide insight into maturational processes, and have led to insights regarding middle-ear dysfunction. His role on the project will be to supply technology in the form of a wideband test battery of middle-ear and cochlear function to evaluate auditory function in Veterans. He will work with the investigative team to augment the existing test battery to include a sequentially adaptive procedure to measure the acoustic-reflex threshold and a synchronized spontaneous otoacoustic emission test. will also be involved in interpreting the test battery results.

and his colleagues have developed proprietary software for use with the Interacoustics Wideband Research System (a commercial device) in the form of a wideband test battery of middle-ear and cochlear function to evaluate auditory function in Veterans. from the Portland VAMC has been working with on their current NIH project for which has developed several proprietary tests of middle ear and cochlear function that will continue to be updated and used in our assessment of Veterans in the VA Merit review study. In addition, he and his scientific programmer, will be modifying the software to make additional measurements of wideband otoacoustic emissions (OAE) and to adapt the wideband acoustic reflex test to obtain automatic acoustic reflex thresholds to meet the needs of the funded research proposal. Software modifications to achieve the study goals will be ongoing throughout the project. There is no other researcher or software developer for this project who could provide the type of deliverables needed for this study. Moreover will analyze data and modify research system

functionality based on data analysis. Because of this, he and his scientific programmer are absolutely essential to the conduct of this research project.

6. Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:

The efforts of [redacted] and his colleagues at Boys Town National Research Hospital is a continuation of collaboration with [redacted]. An intent to sole source was posted to FBO on 03/07/14 and closed on 03/17/14. No responses were received, further confirming that Boys Town is the only source capable of satisfying this requirement.

7. Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:

The proposed contractor is a Non-Profit Research Hospital. The Government is only paying for the contractor's actual direct costs for this contract. The contractor shall submit a price proposal for the labor categories proposed, which will be compared to the IGCE for price reasonableness purposes. Labor prices will be compared against the Consumer Price Index. The Contracting Officer will determine price as fair and reasonable at time of award and also upon any option periods being exercised.

8. Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:

An intent to sole source was posted to FBO on 03/07/14 and closed on 03/17/14. No responses were received, further confirming that Boys Town is the only source capable of satisfying this requirement.

9. Any Other Facts Supporting the Use of Other than Full and Open Competition:

[redacted] and Boy's Town staff have previously collaborated on [redacted].

The new VA Rehabilitation Research and Development project titled, "Comprehensive Wide Bandwidth Test Battery of Auditory Function in Veterans" is a continuation of NIH studies on the VA RR&D level for utilizing the proprietary software and developing uses for the Veteran population.

10. Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:

None.

11. A Statement of the Actions, if any, the Agency May Take to Remove or Overcome any Barriers to Competition before Making subsequent acquisitions for the supplies or services required:

The Research Office will continue to monitor requirements and developments in the market. It is not clear whether a need for similar resources will be required by [redacted] in the near future.

12. Requirements Certification:

I certify that the requirement outlined in this justification is a Bona Fide Need of the Department of Veterans Affairs and that the supporting data under my cognizance, which are included in the justification, are accurate and complete to the best of my knowledge and belief.

13. Approvals in accordance with FAR 6.304

- a. **Contracting Officer's Certification (required):** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.
- b. **NCM/PCM (Required \$3K and above):** I certify the justification meets requirements for other than full and open competition.