

Justification for Other than Full and Open Competition

“Source Selection Information – see FAR 2.101 and 3.104”

1. Identification of the agency and contracting activity.

- a. Federal agency and contracting activity.** National Institutes of Health (NIH), Office of the Director (OD), Office of Management (OM), Office of Acquisition and Logistics Management (OALM), Office of Logistics and Acquisition Operations (OLAO), Office of Acquisitions (OA)
- b. Sponsoring organization.** National Institute on Deafness and Other Communication Disorders (NIDCD), .Office of the Director (OD), Division of Intramural Research (DIR), Office of the Scientific Director, Office of the Clinical Director
- c. Project Officer Information.**
 - **Project Officer Name** Ralph A. Lopez
 - **Mailing Address.** 35A Convent Drive, GF-118, Bethesda, MD 20892
 - **E-mail Address.** lopezra@mail.nih.gov
 - **Telephone Number.** 301-402-3365

2. Nature and/or description of the action being approved.

a. Acquisition purpose and objectives.

The purpose of this new requirement is to acquire clinical otolaryngology and research expertise, and professional support from a university based otolaryngology department affiliated with an academic medical center in order to meet the objectives of the National Institutes on Deafness and Other Communication Disorders (NIDCD). For this new contract requirement, JHU shall provide clinical otolaryngology surgeon-scientists with subspecialty qualifications in neurotology, head and neck surgical oncology, facial plastics and microvascular reconstruction, and rhinology/skull base surgery. The JHU shall provide additional professional and ancillary support, clinic and adjacent hospital facilities to conduct collaborative translational research and provide standard care in support of the clinical research program of the NIDCD DIR. In addition, infrastructure to support training of the next generation of NIDCD clinical researchers in human communication disorders shall be provided.

This acquisition will be for the direct use and benefit of the government. The contract mechanism has been selected to provide the government with a broadened research base and increased productivity through better utilization of the NIH intramural clinic, laboratory space, and expertise.

b. Project background.

The NIDCD DIR has undertaken an expansion of an integrated laboratory and clinical research program requiring otolaryngologist-head and neck surgeon-scientists, fellowship trained otolaryngology sub-specialists, and support staff. The newly expanded NIDCD DIR clinical research program will develop a translational clinical research program with emphasis on genetic and acquired disorders of human communication affecting hearing, balance, smell, taste, voice, speech and language. Recent scientific advances in genomics, cell biology, and immunology, have created new opportunities to more rapidly translate these findings to interventions to impact the health of persons with disorders affecting human communication. Translational clinical studies represent the practical implementation of basic discoveries and critical experiments that refine and define new questions to be addressed by non-clinical investigation. As such, a synergistic relationship exists between NIDCD's basic science and clinical studies. Successful translation of basic research requires coordination of the efforts by laboratory investigators, statisticians, physician-scientists, clinicians, and other patient-care providers. Strong linkages between the bench and the Clinical Research Program enhance the likelihood of success.

Currently, the services are being provided under the Intergovernmental Personnel Act (IPA) Mobility Program; there were no previous contracts in place. The IPA Mobility Program provides for the temporary assignment of personnel between the Federal Government, state and local governments, colleges and universities etc. NIDCD partnered with Johns Hopkins University via the NIDCD Otolaryngology Surgeon-Scientist Program (OSSP) and have jointly recruited and invested approximately four (4) or more years of support for otolaryngology surgeon scientists with the different specialties and specific research qualifications required for clinical patient care and specific NIDCD research projects.

To support the needs of this expansion, it is in the best interest of the Government to continue the partnership between the NIDCD at the NIH and JHU, by issuing a new contract for a 5-year period, to JHU's otolaryngology department. JHU is the only an academic medical center that meets the requirements and have the only qualified surgeon-scientists and fellowship trained subspecialists that possess protocol specific experiences with NIDCD surgical patients. The contractor will support development and conduct of NIDCD DIRs translational and clinical research program, and provide all otolaryngology-head and neck surgical patient care at the NIH Clinical Research Center (CRC), located in Bethesda, Maryland.

3. Description of the supplies or services required to meet the agency's needs (including the estimated value).

a. Project title. Clinical Research, Professional, Ancillary Support Services and Facilities for NIDCD

b. Project description. (For complete description see statement of work (SOW) attached). To provide clinical research, professional and ancillary support, surgery, and facilities to conduct translational research and to maintain the clinical research program of the NIDCD DIR. In addition this contract shall provide the infrastructure for training the next generation of NIDCD clinical researchers in human communication disorders.

- **Requirement type.**

- ☐ Research & development (R&D)
- ☒ R & D support services
- ☐ Support services (non-R&D)
- ☐ Supplies/equipment
- ☐ Information technology (IT)
- ☐ Construction
- ☐ Architect-engineer (A & E) services
- ☐ Design-build
- ☐ Other (specify):

- **Type of action.**

- ☐ New requirement
- ☒ Follow-on
- ☐ Other (specify): _____

- **Proposed contract/order type.**

- ☐ Firm-fixed-price
- ☐ Other fixed-price (specify, e.g., fixed-price award-fee, fixed-price incentive-fee): _____
- ☐ Cost-plus-fixed-fee
- ☐ Other cost reimbursement (specify, e.g., cost-plus-award-fee, cost-plus-incentive-fee): _____
- ☐ Time and materials
- ☒ Indefinite delivery/Indefinite quantity – Hybrid (fixed price and time and materials)
- ☐ Other (specify): _____
- ☐ Completion Form ☐ Term form

- **Acquisition identification number.**

c. Total estimated dollar value and performance/delivery period. The minimum order is \$250.00 and the maximum ordering limit will be \$15,000,000 for a 5-year period; FY22 through FY26.

4. Identification of the statutory authority permitting other than full and open competition.

- ☐ This acquisition is conducted under the authority of 41 United States Code (U.S.C.) 3304(a)(3), as set forth in Federal Acquisition Regulation (FAR) 6.302-1(a)(2).
- ☐ This acquisition is conducted under the authority of section 4202 of the Clinger-Cohen Act of 1996.
- ☐ This acquisition is conducted under the authority of the Services Acquisition Reform Act of 2003 (41 U.S.C. 428a).

5. Demonstration that the proposed contractor(s) unique qualifications or the nature of the acquisition requires use of the authority cited.

- a. Name and address of the proposed contractor.** Department of Otolaryngology-Head and Neck Surgery at the Johns Hopkins University-Suburban Hospital and Clinics, Bethesda, MD, and Johns Hopkins University Hospital and Clinics, Baltimore MD.
- b. Nature of the acquisition and proposed unique qualifications of the contractor.** The nature of the acquisition is to procure the services of Otolaryngology surgeon-scientists and other professional personnel from JHU's Department of Otolaryngology-Head and Neck Surgery that possess historical knowledge and expertise with the specific services already being provided by the NIDCD. To accomplish the goals of the NIDCD Otolaryngology Surgeon-Scientist Program (OSSP), the JHU's surgeon-scientists are proposed as the only source based on an essential requirement for their surgeon-scientists four-year history ; historical knowledge of protocols and patient surgery; their skills, expertise, close adjacency to the NIH; , and because only the Department of Otolaryngology Head and Neck Surgery at Johns Hopkins University-Suburban Hospital and Clinics, Bethesda, MD meet the clinical care of research participants requiring surgery.

Through JHU's partnership with NIDCD via the OSSP, the only JHU otolaryngology surgeon scientists possesses the historical clinical and scientific knowledge, clinical-surgical skills, and expertise in conducting current NIDCD research protocols. They are currently Associate Protocol Investigators, and know and understand the rationale, objectives, design, and methodologies of current research protocols; including customized surgical procedures, statistical considerations, and organization of ongoing NIDCD and NIH research projects. Awarding to another hospital would jeopardize the continuity and integrity of ongoing research by generating inaccurate outcomes, and potentially endanger the health and lives of active protocol participants. The accuracy and consistency of research activities is necessary, including clinical evaluation and testing, through the lifecycle of research protocols, in order for the e measurement to provide accurate clinical outcomes and the reason why NIH is a world leader in research.

Furthermore, research participants may experience clinical disorders and post-surgical complications from surgeries performed at the Clinical Center that affect the head and neck. These include life threatening airway obstruction and bleeding, for which necessary response time of a needed specialist or ambulance transport to the specialist and hospital facility is 5-8 minutes. Research shows that hypoxia, the lack of oxygen to the brain and heart exceeding 5 minutes, can rapidly cause severe brain damage or death.

The Johns Hopkins University-Suburban Hospital is the only University affiliated hospital with otolaryngology department and staff trained, as part of the OSSP, with subspecialty qualifications required to meet this essential time requirement. They will manage adverse events and medical emergencies requiring otolaryngology services for the entire NIH. It's estimated that otolaryngologists see 20-40 patients per week, perform 1-2 surgeries, and are on call 24/7.

The JHU-SH can also provide rapid access for patients to other sub-specialty care not available at the NIH Clinical Center, including stroke, heart attack, vascular surgery and interventional radiology, which may be life-threatening complications of head and neck disorders and surgery. Patient survival and outcomes from these emergencies are improved when they can be transferred to an adjacent hospital and receive these services within less than 30 minutes.

In summary, only JHU otolaryngology surgeon-scientists with both subspecialty clinical qualifications and research training, experience and publication record are necessary to fulfill the dual requirement for clinical care and research supporting the NIDCD mission. The JHU has the only existing otolaryngology surgeon-scientists at JHU Suburban Hospital with the required subspecialty qualifications in neurotology, head and neck surgical oncology, facial plastics and microvascular reconstruction, and rhinology/skull base surgery. Further, only the existing JHU-SH otolaryngology surgeon-scientists possess the demonstrated capabilities of meeting these dual requirements by initiating research and providing clinical care supporting NIDCD through Interagency Professional Agreements.

The backing of an established and world renowned Department of Otolaryngology-head and neck surgery is important for ensuring a higher level of clinical and research expertise, ancillary and administrative support. The JHU Department of Otolaryngology, Hospital, and Clinics in Baltimore provides the administrative leadership, oversight, and support for the JHU staff and facilities at Suburban Hospital and NIDCD. The department is the closest ranked among top departments nationally among Universities in clinical and research expertise and research funding. The department provides a multidisciplinary tumor board weekly including JHU Suburban staff to provide comprehensive case review and recommendations, triage patients to standard care, and clinical trials at JHU and NIH. Patients requiring medical or radiation oncology standard therapy can be seamlessly referred to appropriate standard care not provided as part of NIH research studies.

6. **Description of the efforts made to ensure that offers are solicited from as many potential sources as practicable. Indicate whether a BetaSam.gov notice was or will be publicized as required by FAR Subpart 5.2 and, if not, which exception under FAR 5.202 applies.** A Sources Sought Notice directed at small businesses was posted in BetaSam.gov on January 3, 2022 for 15 days. No capability statements were received.
7. **Determination by the Contracting Officer that the anticipated cost/price to the Government will be fair and reasonable.** An Independent Government Cost Estimate (IGCE) has been developed based on cost history and current market conditions and program expectations. However, to ensure that the price proposed will be fair and reasonable, the data from the IGCE will be compared with the proposal received by the JHU. An award will be made only if during negotiations, it is shown that the anticipated cost to the government will be fair and reasonable.
8. **Description of the market research conducted (see FAR Part 10) and the results, or a statement of the reasons market research was not conducted.** The NIDCD market research includes (c) reviewing literature published by qualified organizations, including renown certified specialists in otolaryngology head and neck surgery from the American Association of Medical Colleges for medical school faculty, and Veterans Administration; (d) contacting the NIDCD Clinical Director and Administrative Officer who are the program officials who have surveyed University and private practice in the local marketplace; and (e) convening a pre-solicitation conference to exchange information with the marketplace.
9. **Any other facts supporting the use of other than full and open competition.** The NIDCD has determined that factors cited under the aforementioned justifications in 5.b. cannot be met by other local Universities or providers. Foremost, there is no other department or hospital as close as JHU Suburban that can meet the patient care and safety requirements for the most critical time-sensitive emergencies described while providing the full scope of otolaryngology subspecialist clinical and research expertise required.

The JHU Suburban department faculty has both the clinical otolaryngology subspecialty and research expertise and accomplishments required to support the NIDCD clinical research program. These include faculty with education, subspecialty fellowship training, expertise and scholarly publication records in basic and clinical research related to neurotology, head and neck surgical oncology, facial plastics and microvascular reconstruction, and rhinology/skull base surgery. Surgeon scientists with such dual qualifications are scarce and JHU has assembled an outstanding faculty who are the only ones capable of fulfilling the requirement outlined in the statement of work. Examples of the areas of research expertise include development of gene therapy for hearing and balance disorders; establishing methods to reduce chemotherapy related hearing loss; and combining surgery, immune and molecular targeted therapy for head and neck neoplasms and allergic sinusitis that affect human communication. Additionally, the faculty are integrated with the department faculty at the main JHU Hospital in Baltimore, MD, which provide added multidisciplinary clinical tumor board expertise; and advisory research expertise of other JHU faculty supported by human communications and cancer centers of excellence.

10. Listing of sources, if any, that expressed, in writing, an interest in the acquisition.

No responses to market research was received.

11. Statement of the actions, if any, the agency may take to remove or overcome any barriers to competition before any subsequent acquisition for the required supplies or services.

Currently, there is no other University department or hospital located across the street from the NIH, which have the only surgeon-scientists with the required expertise in all the subspecialties and can meet all the requirements for patient safety and care, qualified surgeon scientists in all the subspecialties and research fields required. Therefore, at this time, the NIDCD cannot predetermine whether or not they can overcome the barriers to compete this requirement in the future.

12. Program office certification.

This is to certify that the portions of this justification that have been developed by the undersigned program office personnel, including supporting information and/or data verifying the Government's minimum needs, schedule requirements and other rationale for other than full and open competition, are accurate and complete.

Official	Name & Title	Signature	Date
Project Officer	Ralph A. Lopez, Deputy Chief, IRAB, DIR, NIDCD		
Project Officer's Immediate Supervisor	Lynne E. Penn, Chief, IRAB, DIR, NIDCD		
Head of the Sponsoring Program Office	Carter VanWaes, M.D., Clinical Director, NIDCD		

13. Contracting Officer Certification.

This is to certify that the justification for the proposed acquisition has been reviewed and that to the best of my knowledge and belief the information and/or data provided to support the rationale and recommendation for approval is accurate and complete.

Official	Name & Title	Signature	Date
Contracting Officer	Aseia Chaudhry		

14. Chief of the Contracting Office and Head of the Contracting Activity signature(s).

Official	Name & Title	Signature	Date
Chief of the Contracting Office	Darnese Wilkerson, Director, Office of Acquisitions, OM, OD, NIH		
Head of the Contracting Activity	Diane J. Frasier, Director, Office of Acquisition and Logistics Management, OM, NIH		

15. **Competition Advocate signature.**

Official	Name & Title	Signature	Date
Competition Advocate	Sherry Mills, M.D., M.P.H. Director Office of Extramural Programs, OER, NIH		

16. **HHS Senior Procurement Executive signature.**

Official	Name & Title	Signature	Date
HHS Senior Procurement Executive			