

NOTICE OF INTENT: 75N98026Q01205

Sole Source Justification and Notice Authority

FAR 6.302-1 — Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements

Contracting Activity:

National Human Genome Research Institute (NHGRI), National Institutes of Health (NIH)

Proposed Contractor:

University of Florida

Description of Requirement

The National Human Genome Research Institute (NHGRI) intends to award a contract to the **University of Florida** to provide critical clinical research support for the recruitment and acquisition of biological samples from participants enrolled in a specific disease registry maintained at the University of Florida. The samples will be used to support ongoing NIH research protocol **10-HG-0065**, which investigates the causes, detection, and prevention of genetic disorders, including **Malignant Hyperthermia Susceptibility (MHS)**.

This research is authorized under the NIH statutory authorities for research concerning the causes, detection, and prevention of disease, including **42 U.S.C. § 285(a)(1)** and **42 U.S.C. § 284(b)(1)(A)(ii)**. Research addressing MHS also has significant implications for public health and for ensuring combat readiness in the Armed Forces, consistent with **DoDI 6130.02, Volume 2**, and **Executive Order No. 14,183, 90 FR 8757**.

The University of Florida will provide the participant recruitment and clinical research support necessary to identify eligible individuals through the established MHS registry, obtain informed consent, coordinate biological sample collection, maintain sample tracking, and facilitate shipment of collected samples to NIH.

Only One Responsible Source: University of Florida

NHGRI requires clinical research support from **Dr. Nikolaus Gravenstein, Professor of Anesthesia at the University of Florida School of Medicine**, and access to the established patient registry maintained at the University of Florida. Dr. Gravenstein has played an instrumental role in supporting the scientific objectives of the NIH project to identify causal genetic mutations responsible for susceptibility to malignant hyperthermia.

The requirement depends upon access to participants enrolled in Dr. Gravenstein's established MHS registry. The registry provides a unique and established population of individuals with relevant clinical histories who may be eligible for enrollment in NIH protocol 10-HG-0065. The University of Florida is therefore uniquely positioned to serve as the primary referral and recruitment source for this research.

The contractor will provide personnel to solicit participation among eligible individuals in the registry, provide and obtain informed consent documentation, coordinate biological sample collection, maintain sample identification and tracking, and arrange shipment of samples to NIH. These activities require established access to the registry, familiarity with the participant population and associated clinical information, and continuity with the ongoing NIH research effort.

Obtaining these services from another source would require establishing an alternative participant population and recruitment mechanism and would not provide the same direct access to the established registry or the continuity necessary to support the ongoing research protocol. The University of Florida possesses the existing infrastructure, registry access, clinical expertise, and established relationship with the relevant participant population necessary to satisfy the Government's requirements.

Accordingly, pursuant to **FAR 6.302-1**, the Government intends to solicit and negotiate with only one source because the University of Florida is the only responsible source capable of satisfying the specific clinical research support requirements without substantial duplication of effort, delay, or disruption to the ongoing research.

This notice is **not a request for competitive quotations or proposals**. However, interested small businesses, including **8(a), Historically Underutilized Business Zone (HUBZone), Service-Disabled Veteran-Owned Small Business (SDVOSB), veteran-owned, women-owned, and small disadvantaged businesses**, may submit a written capability statement demonstrating their ability to perform the requirements described above.

Capability statements must provide sufficient information to demonstrate the firm's ability to provide access to an appropriate participant population, conduct participant recruitment and informed-consent activities, coordinate biological sample collection and tracking, and facilitate shipment of samples to NIH while meeting the requirements of NIH protocol 10-HG-0065.

Submission of a capability statement does not constitute a commitment by the Government to compete the proposed acquisition. Any determination to compete the requirement will be made solely at the discretion of the Government.

An award is anticipated approximately **five (5) days after the closing date of this notice**, unless the Government determines that another responsible source is capable of meeting the requirement.

Interested parties shall submit capability statements by email to:

danielt@mail.nih.gov

Responses must be received **no later than 9:00 a.m. EDT on September 21, 2026**.

Reference Notice No. 75N98026Q01205 in all correspondence.