

PRE-SOLICITATION NOTICE
STRONG HEART STUDY (SHS) – FIELD CENTERS FOR THE LEGACY COHORT

Type: Pre-Solicitation

Notice Number: 75N92026R00011

Title: Strong Heart Study (SHS) – Field Centers for the Legacy Cohort

Classification Code: A – Research & Development

NAICS Code: 541715, Research and Development in the Physical, Engineering, and Life Sciences (except Nanotechnology and Biotechnology)

Posted Date: 10/15/2026

Response Date: 10/30/2026

Primary Point of Contact: Jonathan Lear, Contracting Officer, john.lear@nih.gov

Contracting Office Address:

Department of Health and Human Services, National Institutes of Health, Office of Acquisition and Logistics Management (OALM), Research and Development and Professional Services – Division B, 6701 Rockledge Drive, RKL2, Bethesda, MD 20817 UNITED STATES.

Introduction:

The National Heart, Lung, and Blood Institute (NHLBI) intends to procure research and development services to support three (3) Field Centers (FCs) for the Strong Heart Study (SHS) Legacy Cohort. The Field Centers will continue longitudinal follow-up and morbidity and mortality surveillance of the established SHS cohorts, conduct two limited clinical examinations, support Tribal community engagement and research capacity-building activities, and perform related scientific and operational activities. The purpose of this announcement is to provide a Pre-Solicitation Notice for the anticipated release of the solicitation identified above.

THIS NOTICE ADDRESSES THE SHS LEGACY COHORT FIELD CENTERS ONLY. THIS IS A SYNOPSIS. THIS IS NOT A SOLICITATION.

Background:

The Strong Heart Study (SHS) is a long-running longitudinal observational study of two (2) combined cohorts followed prospectively: the original SHS cohort recruited from 1989 to 1991 and the Strong Heart Family Study (SHFS) cohort recruited from 1998 to 1999. The original and family cohorts together form the largest multicenter, prospective epidemiological study of cardiovascular disease (CVD) in American Indians (AIs). The study's main objective is to examine the etiology and natural history of cardiovascular disease in AIs.

Overall, there have been seven (7) phases of the study, with each phase corresponding to a multi-year project period. The current phase, Phase VII, began in 2019 and is expected to end in 2027 and includes infrastructure support, morbidity and mortality surveillance, data analysis, dissemination activities, and a clinical examination. More information about the SHS is available at <https://strongheartstudy.org/>.

The SHS has collected clinical and phenotypic data from its participants over six (6) clinical examinations and up to 35 years of follow-up. Data on risk factors; biochemical analytes; lifestyle factors, including diet and physical activity; cardiac structure and function; vascular, pulmonary and gall bladder function; CVD events; and causes of death are available for

PRE-SOLICITATION NOTICE
STRONG HEART STUDY (SHS) – FIELD CENTERS FOR THE LEGACY COHORT

approved research and community use. Genetic data are also available for approved community and research use.

In addition to generating a wealth of data on CVD and other disorders in AIs, the SHS has supported numerous scientific and public health accomplishments. These include publication of hundreds of medical and scientific articles; support for approximately 45 young AI investigators and students; establishment of risk prediction algorithms and guidelines for use by Indian Health Service and other health care providers; advances in understanding diabetes and other CVD risk factors; and support for numerous independently funded ancillary studies. Also noteworthy are the high level of community engagement and retention of participants throughout the clinical examinations and the low levels of loss to follow-up.

It is anticipated that three (3) Field Center contracts will be awarded to continue morbidity and mortality surveillance in the SHS Legacy Cohort and to conduct two limited examinations of living Legacy Cohort participants. The Field Centers will collaborate with a separately procured SHS Coordinating Center responsible for study coordination, data management, and statistical support. A separate acquisition is also underway for Field Centers to establish a New Cohort.

Objectives:

The scientific objectives of this proposed acquisition are to: (1) enhance statistical power to perform analyses of predictors of clinical events; (2) investigate the high risk of cardiovascular disease and related conditions in this population; and (3) enable investigations of new risk factors or interactions among factors that inform disease pathophysiology.

The operational objectives are to: (1) conduct two limited clinical examinations of living Legacy Cohort participants; (2) continue follow-up of consented participants in the SHS original and family cohorts to increase the number of clinical endpoints and enable long-term characterization of aging trajectories, resilience, and morbidity- and mortality-related outcomes; (3) foster scientific collaborations by serving as a platform for independently funded ancillary study examination components; (4) support Tribal community engagement activities by fostering partnerships with community representatives and stakeholders, including Tribal leaders; (5) produce and disseminate research findings to scientific and lay communities; and (6) increase research capacity in Tribal communities and support training of junior investigators, especially Native American investigators.

The SHS will continue to serve as a platform for in-depth ancillary studies that may be funded outside of the SHS contracts. Once funded and approved, ancillary studies will be operationally integrated into the main study in accordance with applicable SHS policies and approvals.

Project Requirements:

The important overall technical requirements associated with this proposed acquisition for the SHS Legacy Cohort Field Centers include the following:

1. Attend a virtual kick-off meeting with the NHLBI Project Office and Contracting Office. (Task Area A)

PRE-SOLICITATION NOTICE
STRONG HEART STUDY (SHS) – FIELD CENTERS FOR THE LEGACY COHORT

- 2.** Obtain and maintain applicable Tribal/community reviews and approvals of the planned research. (Task Area A)
- 3.** Conduct regular participant follow-up and retention activities and perform clinical events investigation and ascertainment. (Task Area A)
- 4.** Support Tribal/community engagement activities and maintain partnerships with community representatives and stakeholders, including Tribal leaders. (Task Area A)
- 5.** Establish and participate in a Community Advisory Board/Group and support dissemination and implementation activities. (Task Area A)
- 6.** Implement community-based pilot research projects to increase research capacity in participating Tribal communities. (Task Area A, Subtask A.1)
- 7.** Develop, implement, and evaluate a recurring short-term Summer Immersion Research Experience for high school students from participating Tribal communities. (Task Area A, Subtask A.2)
- 8.** Organize, attend, and manage Community Symposium activities for Tribal/community leaders and representatives during the contract period. (Task Area A)
- 9.** Provide training and mentoring opportunities for junior and early-career investigators, fellows, students, and Tribal community members. (Task Area A)
- 10.** Participate collaboratively in the SHS Steering Committee, Observational Studies Monitoring Board, and other applicable study committees. (Task Area A and applicable Task Areas)
- 11.** Facilitate quality control and quality assurance activities for cohort follow-up, clinical examinations, data collection, and biospecimens in coordination with the Coordinating Center and applicable study committees. (Task Area A and applicable Task Areas)
- 12.** Participate actively in data analysis and prepare and disseminate scientific summaries, presentations, publications/manuscripts, reports, and community-facing study findings. (Task Area A and applicable Task Areas)
- 13.** Prepare for and conduct the Phase VIII limited clinical examination of surviving and willing SHS participants, including protocol development and review, staff training and certification, pilot testing, recruitment, examination implementation, quality control, and exam closeout. (Task Area B, including B.1 and B.2)
- 14.** Prepare for and conduct the Phase IX limited clinical examination of surviving and willing SHS participants, including protocol development and review, staff training and certification, pilot testing, recruitment, examination implementation, quality control, and exam closeout. (Task Area C, including C.1 and C.2)

PRE-SOLICITATION NOTICE
STRONG HEART STUDY (SHS) – FIELD CENTERS FOR THE LEGACY COHORT

15. If deemed necessary by the Government, perform study closeout and/or transition activities, including orderly transfer of applicable study data, records, protocols, documents, and other study materials while maintaining required confidentiality and security. (Task Area D)

16. Prepare and submit required technical, financial, Section 508, progress, and other reports and monthly invoices in accordance with the solicitation and resulting contract/task orders. (All applicable Task Areas)

Anticipated Contract Structure and Period of Performance:

The Government anticipates awarding three (3) Indefinite-Delivery/Indefinite-Quantity (IDIQ) contracts for the SHS Legacy Cohort, Field Centers. The anticipated ordering period is ten (10) years, from approximately November 15, 2027 through November 14, 2037. Task orders will be issued to support the Task Areas and Subtasks described in the solicitation. The anticipated award date and periods of performance are subject to change.

For planning purposes, the current SOW anticipates: Task Area A, Core Field Center Operations, over the 120-month ordering period; Subtask A.1, four (4) non-severable 30-month task orders within an overall 102-month program period; Subtask A.2, ten (10) non-severable 12-month task orders over a total potential 120-month period; Task Area B, Phase VIII, with a 40-month period consisting of B.1 examination preparation (9 months) and B.2 examination conduct and closeout (31 months); Task Area C, Phase IX, with a 24-month period consisting of C.1 examination preparation (9 months) and C.2 examination conduct and closeout (15 months); and Task Area D for study closeout and/or transition activities, if deemed necessary by the Government. These periods and structures are subject to the final solicitation.

Solicitation Information:

This is not a Request for Proposal (RFP), and the Government is not committed to award a contract pursuant to this announcement. The RFP is expected to be posted to the Government-wide Point of Entry at SAM.gov approximately 15 calendar days after the date of this notice. This date is subject to change.

Interested parties are responsible for monitoring SAM.gov for release of the solicitation and any amendments. No solicitation package is available at this time.