

Ancillary Studies to the Strong Heart Study (SHS) Phase VII Exam Guidelines for Pre-review of Submissions to the SHS Steering Committee

SHS VII Ancillary Study Proposal Submissions for Pre-review:

At least two weeks before an intended presentation to the SHS Steering Committee, please submit the following to the SHS Steering Committee Chair (Dr. Shelley Cole: scole@txbiomed.org) and Ancillary Studies Coordinator (Dr. Tauqeer Ali: Tauqeer-Ali@ouhsc.edu).

A. Summary (2-3 pages of text) of your proposal including *all* of the following:

1. Title
2. Intended proposal submission date to funding agency
3. Funding organization, specific funding announcement (if applicable)
4. Principal Investigator, list of key investigators, and their email addresses
5. Specific Aims
6. Short paragraph on general significance
7. Methods summary
8. Table/list of data to be collected, study procedures and assessment of participant burden.
Please include a summary table that lists the categories of data to be collected and the procedures or assessments. An example table is provided at the end of these guidelines.
9. Statement on how this will benefit American Indian health and would be of interest to the SHS communities.

B. NIH Biosketch of Principal Investigator and any key investigators including a description of their role on this project.

SHS VII Ancillary Study Presentations:

Ancillary Study presentations, may occur in person or by videoconference at the monthly SHS Steering Committee videoconference calls (first Tuesday of the month at 4:00pm ET) or at the in-person Steering Committee meetings tentatively scheduled for mid-November 2019 in Bethesda, Maryland and early March in Phoenix, Arizona.

Format: Oral presentations will be limited to **10 minutes, with 10-15 minutes for discussion**. Presenters should briefly address each of the proposal areas listed in Part A above.

SHS approvals: Studies that are recommended to move forward will need to complete the SHS Ancillary Study Proposal submission forms and requirements at least 2 to 3 months prior to their submission. Earlier submissions are recommended.

<https://strongheartstudy.org/Research/Ancillary-and-Sub-Studies/Propose-an-Ancillary-or-Sub-study#385531864-ancillary-studies>

Additional Information:

SHS Phase VII Basic Exam Components: For planning purposes, the components of the basic core examination will include the following: recruitment, informed consent, blood pressure and anthropometry measurements, phlebotomy and spot urine for key lab analytes (serum lipid profile, plasma glucose, whole blood HbA1c; and urinary creatinine and albumin) and sample storage for future research use, and questionnaires to update personal and medical history and current medications use.

SHS Phase VII Exam Timing:

- Planning of exam components, obtaining IRB and Tribal Approvals:
February 15, 2021 to February 14, 2022
- Phase VII exam:
February 15, 2022 to February 14, 2024

SHS description: strongheartstudy.org

General questions: contact SHS Principal and lead investigators
<https://strongheartstudy.org/Contact-Us#383111813-directory-of-investigators>

Proposal Item 8: Example table summarizing data to be collected, proposed study procedures and assessments, and timing.

<i>Summary of Data to be Collected, Procedures and Assessments</i>	<i>Baseline</i>	<i>Time Point 1</i>	<i>Time Point 2</i>	<i>Time Point 3</i>	<i>Time Point 4</i>	<i>Time Point 5</i>	<i>Time Point 6</i>
<i>Demographics</i>							
<i>Diagnostic</i>							
<i>Medical History</i>							
<i>Clinical tests</i>							
<i>Samples</i>							
<i>Intervention</i>							
<i>Follow-up</i>							
<i>Overall burden for timepoint</i>							