STRONG HEART STUDY ANCILLARY STUDY AND SUB-STUDY

GUIDELINES AND PROPOSAL FORM

The Strong Heart Study (SHS) welcomes investigators to propose ancillary studies or sub-studies that are related to cardiovascular disease and its risk factors using resources that can be provided by the SHS.

I. Ancillary studies

An **ancillary study** requires additional participant contact, for example, administration of a questionnaire, personal interview, physical examination, etc., and separate funding. Ancillary study proposals must be approved by the SHS Steering Committee, the participating tribes, institutional IRB and the Indian Health Service IRBs.

A proposal is required to be submitted to Dr. Shelley A. Cole (scole@txbiomed.org), Chair of the SHS Steering Committee. An ancillary study proposal form must be completed and the required narratives attached.

Investigators who are not affiliated with SHS need to work with a SHS investigator (PI or co-investigator). A directory of current SHS investigators is located on the SHS website at http://strongheart.ouhsc.edu.

Submission Deadlines: Investigator-initiated Ancillary Study proposals must be submitted to the SHS no later than three months prior to the due date of the funding agency. Ancillary proposals in response to an RFA must be submitted to the SHS as soon as possible or no later than six (6) weeks prior to the due date of the funding agency.

If summary statistics or other data are needed from the SHS Coordinating Center (CC), at least four (4) weeks will be allowed for the CC to provide the information. Agreement with the SHS CC about the costs needed to perform such tasks is negotiable.

At least two-weeks prior to the grant submission deadline, a near-final draft of the proposal will need to be submitted to the SHS *collaborators* to allow review for potential errors and omissions regarding participant contact and data availability.

At least two -weeks prior to the grant submission deadline, the final draft of the Resource Sharing Plan (including Data Sharing and Genomic Data Sharing plans if applicable) must be sent to the SHS Steering Committee for review.

II. Sub-studies

A sub-study does not require participant contact. It uses the SHS repository data and/or specimens to study cardiovascular disease and its related risk factors. Separate funding may be required, for example, if the sub-study requires additional lab tests. Sub-study proposals must be approved by the SHS Steering Committee.

Investigators who are not affiliated with SHS need to work with a SHS investigator (PI or co-investigator). A directory of current SHS investigators is located on the SHS website at http://strongheart.ouhsc.edu.

A proposal is required to be submitted to Dr. Shelley A. Cole (scole@txbiomed.org), Chair of the SHS Steering Committee. A sub- study proposal form must be completed and the required narratives attached.

Submission Deadlines: **Investigator-initiated Sub-Study proposals must be submitted to the SHS no later than two (2) months prior to the due date of the funding agency. Sub-Study proposals in response to an RFA must be submitted to the SHS as soon as possible or no later than six (6) weeks prior to the due date of the funding agency.**

If summary statistics or other data are needed from the SHS Coordinating Center (CC), at least four (4) weeks will be allowed for the CC to provide the information. Agreement with the SHS CC about the costs needed to perform such tasks is negotiable.

III. Data Distribution Requirements for Both Ancillary Studies and Sub-studies

The following data distribution requirements are for both ancillary studies and sub-studies.

A data distribution agreement or a specimens distribution agreement must be signed by the proposing investigators after the proposal has been approved by the SHS Steering Committee. If using SHS genetic or pedigree data, an additional data access and distribution agreement for genetic data must be signed.

PART 1: Basic Study Information and Projected Impact on SHS

1) **Title of Study:**

2) **Principal Investigator:** {Name, Academic Rank (if applicable), Institutional Affiliation, Address, Phone and Fax Numbers and E-Mail Address}

   Please indicate if the principal investigator attended the following workshop: ___Yes ___No

   NHLBI Population Studies Workshop - Jackson Heart Study and Strong Heart Study, July 28-31, 2013, National Institute of Health, Bethesda, Maryland.

3) **SHS Investigator, with expertise in related field of science, included on proposal and their role:**

4) **Co-Investigators:** (Include in the table below name of co-investigator, academic rank (if applicable), institutional affiliation, address, telephone and fax numbers and e-mail address)

Co-Investigator	**Academic Rank & Institution**	**Address**	**Phone/Fax Numbers & e-mail address**	**Role on Study**	**Percent effort**

5) **American Indian Investigators:** Include a description of the plan for the inclusion/development of minority investigators as a part of the study team.

6) **Funding:**
   a) Source:
   b) If NIH, list the funding mechanism:
   c) Grant Due Date:
   d) Proposed Study Start Date: End Date:
   e) Grant Title (if different from study title):
   f) Does this study involve support or collaboration of a for-profit corporation?
      YES_____ NO_____
      If yes, has a Third-Party Agreement been initiated? YES_____ NO_____
   g) Do you intend to use the data to patent any process, aspect or outcome of the analysis?

      YES_____ NO_____

   h) Estimated direct costs per year (please provide an estimate even if a final figure is not available)

FY01	FY02	FY03	FY04	FY05
$	$	$	$	$

7) **Use of SHS Resources:** Indicate in the table below all SHS resources that you will use, estimated amount of time, cost that will be allocated, and proposed source.

SHS Resource	**Activity**	**Estimated Time**	**Estimated Cost**	**Proposed Funding**

				Source
Coordinating Center	Sample Selection			
Coordinating Center	Data set preparation			
Coordinating Center	Preparation of forms or software			
Coordinating Center	Check study data for errors and/or quality			
Coordinating Center	Statistical Analysis of data for manuscripts			
Coordinating Center	Verify results of statistical analysis conducted by study investigators			
Field staff	Obtain Consent			
Field staff	Recruit participants			
Field staff	Collect blood, urine, blood pressure, anthropometric data or data via questionnaires			
Field Staff	Process and ship biological specimens			
Office or Clinic Space	Study site			
PML Laboratory	Retrieve stored specimens			
Genetics Center	Retrieve stored specimens			
Genetics Center	Access or retrieve stored genetic data			
Other				

8) **Sample Size:** Justification for sample size and proposed inclusion and exclusion criteria

9) **Participant Involvement:** Will participants be contacted, interviewed or examined?
NO_____ YES_____

If Yes, describe the amount of participant time required, projected discomfort and proposed stipend.

10) **Biological Specimens:** Does your study require the use of blood, urine, serum, DNA or other biological specimen?
YES_____NO_____

If archived specimens will be required, please complete the following:

A. List of tests to be measured and specific kinds of specimen required for each analyte (serum, plasma, urine, DNA), volume of specimen, and numbers of participants.

a. Test:

b. Kind of specimen:

c. Amount of specimen and justification for amount:

d. Number of participants:

B. Exam Phase requested:

C. Location of Laboratory performing analysis.

a. Address:

b. Investigator Contact numbers:

c. Means of specimen delivery to the laboratory:

d. Storage resources: Emergency power for freezers etc.

e. Bar code reader available: YES___ NO_____

D. Method of analyses for each measurement requested (list).

a. Test(s):

b. Method of analysis: ELISA, RIA, HPLC…

E. Reproducibility (Percent intra-assay variability) of each measurement.

F. Upper and lower limit of analytical range of each measurement.

G. Number and kind of SHS archived applicable specimens currently in the research laboratory.

H. Disposition of any residual specimen.

I. Acknowledgement that policies and conditions specified by the SHS will be followed.

J. Specific Measurements for a new analyte/marker.

a. Name of test:

b. What is the test for and what does it provide for the SHS?

c. References for the method:

d. Kind of specimen required:

11) SHS Reading Center Involvement: Will your ancillary study involve the use of echocardiography, ECG, carotid, or popliteal ultrasound data?

YES_____ NO_____

If yes, please describe the materials required for your study.

12) Intervention: Does this study propose an intervention?

YES_____ NO_____

If yes, please briefly describe the planned intervention.

13) SHS Data: Summarize the SHS data (demographics, risk factors, events etc.) and analysis (descriptive statistics, regression analysis, figures, etc.) needed for your ancillary study.

14) Genetic and Pedigree Information:

a) Does your proposal contain the generation of new or use of existing genetic data (defined as data from any of the following: participants' DNA, RNA or pedigree (family) relationships?

NO___ (skip to question 15) YES___ (please see questions 14b-f)

b) Does the funding source for your study require genetic data sharing?
c) What genetic information is proposed to be used?
d) Is the genetic information collected for pooling with other cohorts for a specified genetic consortium? (name the consortium)_____
e) The P.I. must complete and sign the Data Access and Distribution Agreement for SHS Genetic Data.

15) **Clinical Implications:** Will the findings have clinical implications? If so, describe the plan for reporting results to participants and providing recommendations for follow-up.

16) **Rationale and Impact:** Why do you propose to conduct the study within SHS? Why not use other populations?

a) Advantage of conducting the study within the SHS cohort?

b) Impact on ongoing SHS study or other ancillary studies

17) **Overlap With Existing SHS Ancillary Study or Sub-study:** The PI has reviewed existing SHS ancillary studies or sub-studies and found
a) No similar ancillary study or sub-study _____
b) The following ancillary study/studies and sub-study/studies with similarities (List the ancillary study and sub-study number, title and PI and specify the potential overlaps/similarities):

18) **Assurances:** Please provide the following assurances (check each)
_____ The Study PI will report progress of the study as requested.

_____ Confidentiality of SHS participants will be maintained

_____ Data collected by the Ancillary Study or Sub-study, with documentation, will be provided to the SHS Coordinating Center for integration into the main database, one year after data collection has been completed. The ancillary study PI is given the first and exclusive opportunity to analyze, present and publish data collected by the ancillary study, with certain conditions, when appropriate. Collaboration with the study investigators who collected the data is required. A study PI who wishes to extend the period of protected use must send a written request with justification to the Steering Committee for review. SHS manuscript proposal policies will be followed in all cases.

PART 2: Description of the Proposed Ancillary Study or Sub-study

Please provide a description of the proposed study. The completed narrative should not exceed twelve (12) pages, per PHS 398 format (excluding literature citations and appended questionnaires and forms). The narrative should include the following: project summary, relevance, specific aims, research strategy (significance, innovation, and approach), references and resource sharing.

a) In the **summary,** state the application's broad, long-term objectives and specific aims. Describe concisely the research design and methods for achieving the stated aims.

b) In addressing **relevance,** describe the relevance of this research to the aims of the SHS.

c) Under **specific aims**, state concisely the goals of the proposed study and summarize the expected outcome(s), including the impact that the results of the proposed study will exert on the research field.

d) In addressing **research strategy**, address significance, innovation and approach separately. If you have multiple aims, you may address significance, innovation and approach for each aim individually, or you may opt to do so collectively for all of the specific aims.

e) When addressing **significance;**
- Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.
- Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.
- Describe how the concepts, methods, technologies, treatments, services or preventive interventions that drive this field will be changed if the proposed aims are achieved.

f) When addressing i**nnovation**;
- Explain how the application challenges and seeks to shift current research or clinical practice paradigms.
- Describe any novel theoretical concepts, approaches or methodologies, instrumentation or intervention(s) to be developed or used, and any advantage over existing methodologies, instrumentation or intervention(s).

g) When addressing **approach**;
- Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Include how the data will be collected, analyzed and interpreted as well as any resource sharing plans as appropriate.
- Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.

- If the project is in the early stage of development, describe any strategy to establish feasibility and address the management of any high risk aspects of the proposed work.
- Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised.

h) **References**

i) When addressing **resource sharing**;

- The plan should specify that one year after data collection a copy of any new data collected by the Ancillary Study will be provided, with documentation, to the SHS Coordinating Center for integration into the SHS database.
- If collecting genetic data, the plan must agree with the existing data sharing policy agreed upon by the SHS and participating tribes.

Checklist and Timeline for Ancillary Study and Sub-study Proposal Submission:

Materials to submit	**PI Submits to SHS SC**	**Step 1** (time for review)	**Step 2**	**Step 3**	**Step 4**	**Step 5**	**Step 6** (post approval)	**Step 7** (post approval)
1. Proposal	X	SC review (6 weeks)	Inform PI of SC decision Including lab decision	Obtain tribal approvals **3 months for ancillary studies and 2 months for sub-studies**	SHS review of penultimate version of proposal (2-weeks prior to grant submission deadline)	PI submits proposal to funding agency	PI completes IRB & other applications and obtain approvals	PI begins study
2. Cover letter	X							
3. Signature Sheet	X							
4. Lab Application (if bio-specimens are to be used)	X	Lab review (2 weeks)						

Terms:
SC – Steering Committee
IRB – Institutional Review Board
Other applications – Data and materials distribution agreement