

STRONG HEART STUDY ANCILLARY STUDY AND SUB-STUDY

GUIDELINES

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 via the Strong Heart Study Website (<http://strongheartstudy.org/Research/AncillaryandSub-Studies/ProposeanAncillaryorSub-study.aspx>) and then will automatically be forwarded to Dr. Shelley A. Cole, Chair of the SHS Steering Committee, for SHS Steering Committee review. 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://strongheartstudy.org/ContactUs.aspx>.

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://strongheartstudy.org/ContactUs.aspx>.

A proposal is required to be submitted via the Strong Heart Study Website (<http://strongheartstudy.org/Research/AncillaryandSub-Studies/ProposeanAncillaryorSub-study.aspx>) and then will automatically be forwarded to Dr. Shelley A. Cole, Chair of the SHS Steering Committee, for SHS Steering Committee review. 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.

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