ANCILLARY STUDY GUIDELINES

Purpose

The Jackson Heart Study (JHS) encourages investigators to propose and conduct ancillary studies that further the aims of the JHS and contribute to scientific productivity. Such studies enhance the value of the JHS and ensure the continued interest of the diverse group of investigators who are critical to the successes of the study. Ancillary studies provide an exceptional opportunity for investigator to conduct additional projects within an already existing cohort.

Timeline for submitting an Ancillary Study

Genetic and Biospecimen proposals	12 weeks prior to grant deadline
Biospecimen Proposals	12 weeks prior to grant deadline
Proposal Involving Participants	12 weeks prior to grant deadline

For secondary data analysis proposals, please refer to the Publication and Presentations Guidelines.

SECTION I: Ancillary Study Submission and Review Procedures

A. Submission of Ancillary Study Proposal

1. Investigators are required to notify the JHS Chief Science Officer (CSO) or the Chairperson of the Ancillary Studies Subcommittee (ASSC) of their **intent** to submit an ancillary study prior to submission. In addition, the Principal Investigator (PI) must complete the Ancillary Concept Form. The JHS Ancillary Study Resource Unit will review this material and provide feedback on potential resource needs such as budget, personnel and other substantive matters to the investigators before the proposal may be submitted.

2. After receiving feedback from the Jackson Heart Study, the Principal Investigator should complete the Ancillary Study Proposal Form available on the JHS website www.jacksonheartstudy.org and attach the requested narrative.

3. The PI is responsible for obtaining all Co-investigators Agreement Statements, indicating that the Co-investigators have read and are in agreement with the proposal. (See example of Co-investigator agreement statement)

B. Communication to Principal Investigator

1. Upon submission of the AS proposal, an e-mail will be generated to notify the PI that JHS has received the AS proposal.

2. If an AS proposal is determined to be incomplete, the JHS Coordinator will return the incomplete proposal to the PI and the JHS investigator.

3. Complete proposals will be reviewed by the Ancillary Studies Subcommittee (ASSC) within 30 days of submission to JHS. ASSC meetings occur bi-monthly, the schedule is posted at www.jacksonheartstudy.org.

4. The PI will receive notification from the ASSC Chairperson of the results of the review and the appropriate next steps.

Ancillary Study Subcommittee Decisions:

a. **Approved**: The proposal will be sent for further review and approval to the JHS Steering Committee (SC) and, if approved by the JHS SC, then to National Heart, Lung and Blood Institute (NHLBI).
b. **Approved pending revisions:** PI should submit a response to comments from the ASSC before final approval from ASSC. Once approval is obtained, the proposal will be forwarded to the JHS SC and to NHLBI for further review and approval.
c. **Reconsider after revisions:** The PI must revise the proposal based upon the ASSC recommendations and resubmit to the ASSC within 30 days of notification.
d. **Disapproved**: The PI will receive no further consideration. The PI has the option of developing and submitting a new proposal.

5. After an AS proposal is approved by the JHS SC, the PI will receive written notification from the SC Chairperson of the results of the JHS SC review.

6. The PI will also receive written notification from NHLBI of the results of their review.

Note: **A proposed ancillary study should not be submitted for funding until formal written notification is received from NHLBI. PIs submitting ancillary study proposals for funding without NHLBI approval will be asked to withdrawn their application and resubmit after receiving NHLBI approval**.

B. Resubmission Process

1. PIs of proposals that are **approved pending revisions** must address **minor** revisions within **15 days** of receipt of the communication from the ASSC Chairperson and resubmit revisions via online system.

2. PIs of proposals that are **reconsidered after revisions** must address the revisions within **30 days** of receipt of the communication from the ASSC Chairperson and resubmit revisions via online system.

Section II: Post-Approval Procedures

Overview

Once an ancillary study proposal has been approved by the JHS and the NHLBI, the ancillary study investigator may submit his/her study proposal to a funding agency. Once funding is secured and prior to initiating the study, the PI must complete and submit the following documents to the JHS ASSC Coordinator (jhsanc@umc.edu): Institutional Review Board (IRB) approval letter, Data and Materials Distribution Agreement (DMDA), a Data Request Form, and copy of award notification, and the final protocol that will be implemented. A detailed description of the post-approval procedures are outlined below:

1. Participant Consent and Institutional Review Board Approval:

If separate consent is necessary, this must be obtained from each cohort member who will participate in the ancillary study. The consent document should clearly identify the ancillary study as one being performed in addition to the main study and inform participants that their participation in the ancillary study is not necessary for them to continue in the Jackson Heart Study.

IRB approval for the ancillary study at the PI's home institution is his/her responsibility and must be obtained before initiation of the study. The PI is required to provide documentation of IRB approval by his/her home institution by sending a copy of the IRB approval letter to the AS Coordinator. Further, the PI must provide documentation that all investigators have current IRB and HIPPA certification by their home institution.

For any protocol modification, the PI must obtain IRB approval from his or her home institution. (Review #4 Changes in Protocol, Data Request, or Funding Source)

2. Data and Materials Distribution Agreement:

A DMDA must be completed and submitted to the JHS Ancillary Study Coordinator before the PI can request JHS data and/or materials. The DMDA is available on the JHS website at www.jacksonheartstudy.org. Once the DMDA is fully executed a copy will be sent to the PI.

3. Statistical Computing Request Form (Data Request Form):

To request data and materials, the PI must complete the online Variables Needed Request Form (Variables Needed). The request form should be completed with input from the JHS collaborating co-investigator and include specific variable names and/or variables to be derived for the purpose of this study. Forms, Manuals of Operation, and data dictionaries are available on the JHS website for use during this process.

4. **Changes to the Protocol, Data Request, or Funding Source**:

Once an ancillary study is approved, there can be no changes in the protocol type, amount of data requested, or funding source without prior approval from the JHS ASSC, SC, and NHLBI. To make modifications to an approved ancillary study, the PI must submit a request to the ASSC Chairperson in the form of a letter identifying the proposed modifications. Some modifications may require the submission of a new ancillary study proposal if modifications change the scope of the study.

Subsequent IRB approvals is necessary for approved protocol modifications prior to implementation. The PI should seek approval from the home institution and send documentation of approval to the AS Coordinator.

Changes in the DMDA may be required as well. If a previously approved ancillary study is to be submitted to a funding agency that differs from that specified in the original proposal, the PI must inform the ASSC by submitting a revised application along with a cover letter indicating the change.

5. Rapid Approval for Novel SNPs:

Any investigator with an approved ancillary study for genotyping may submit a written request to the JHS ASSC Chairperson to genotype additional SNPs that have been found to be associated with the focus phenotypes of that ancillary study. A copy of the original approved ancillary study must accompany the letter and a progress report on the findings of the initial study.

6. Progress Report:

Investigators with approved ancillary studies are required to complete progress reports via the online system to the AS Coordinator semi-annually. Copies of the progress reports will be forwarded to the JHS SC and NHLBI.

7. Publication Guidelines:

Manuscript proposals, abstracts, manuscripts and slide presentations emanating from ancillary studies are subject to the same approval process as other JHS publications and presentations. These guidelines are available in a document entitled "Jackson Heart Study Guidelines for Publications and Presentations". When a manuscript proposal, emanating from an ancillary study, is submitted, the primary author should indicate on the Manuscript Proposal Form the Ancillary Study from which it emanates. All manuscripts emanating from an ancillary study must submit a manuscript proposal to the JHS Publications and Presentations Subcommittee.

SECTION III: Policies

A. NHLBI Policies

1. **Data Sharing:** Upon completion of the study, data collected in an ancillary study should be made available to the JHS Coordinating Center for use by other investigators and to NHLBI for inclusion in the NHLBI's limited access data program. Limited access data refers to trial or study data, with certain deletions and recoding that are released to requesting institutions and investigators for specific purposes and with certain restrictions and conditions. Limited access data from ancillary studies will be made available in accordance with NHLBI policy for Distribution of Data https://biolincc.nhlbi.nih.gov/home/.

2. **Data Collection:** Ancillary Study PIs are required to sign the NHLBI/JHS DMDA before data collection can begin.

3. **Approval Process:** The JHS ASSC, JHS SC, and NHLBI must approve all ancillary study proposals prior to implementation.

4. **Funding:**

   - Ancillary Studies seeking funding through NIH and the direct costs exceed $500,000 should review policies on the NHLBI website http://www.nhlbi.nih.gov/funding/policies/500kweb.htm .
   - Ancillary study receiving support from a for-profit entity must complete a Third Party agreement.
   - Ancillary study investigators must not enter into any verbal or written contract agreements with industries or private individuals that will provide funding for activities related to the JHS data without prior review and written approval from the JHS SC and NHLBI.

5. **Integrating Data into JHS Database**: Ancillary Study PIs will be given the first opportunity to analyze and publish data collected under the auspices of their ancillary study. Twelve (12) months after data collection and editing have been completed, ancillary study data are to be provided to the JHS for integration into the main JHS database and for use by other JHS investigators.

6. **Cost and Participant Burden:** The PI will define and should estimate the cost and the burden on participants.

7. **Non-Interference with Core Examination**: Study data collection must not interfere with the conduct of the core examination.

8. **Sequence with Core Examination:** Ancillary studies may be proposed before and/or after contract award as scientific opportunities arise.

9. **Confidentiality and Consent**: Analysis of study samples, within or outside the primary JHS investigator group, will be conducted in full compliance with procedures for ensuring participant confidentiality and in accordance with written informed consent as provided by the participants. Development of appropriate consent documents will include adequate notification of study subjects that sharing of study samples outside the JHS investigative group is anticipated.

B. JHS Policies

1. **Priority:** Ancillary studies are subject to the same policies, reviews and approvals as the core JHS protocol. The highest priority will be given to studies which:

    a. Have the highest scientific merit
    b. Do not interfere with the main study objectives
    c. Produce the least burden on participants
    d. Have objectives directly related to the study
    e. Require the unique characteristics of the cohort

2. **Compatibility with JHS Goals:** Ancillary Studies must be compatible with JHS goals which are located on JHS website at www.jacksonheartstudy.org.

3. **JHS Investigator:** A JHS investigator, other than the JHS Director, must be involved as either the PI or included as a co-investigator in **every** ancillary study proposal. The JHS investigator is responsible for assuring the study's continuing compatibility with the JHS. All communications regarding the ancillary study should be copied to the JHS investigator.

4. **Capacity Building:** An important aspect of the JHS is the development of African American scientists in the area of cardiovascular disease research. For this reason, proposed ancillary studies must include an African American scholar as either the PI, or as a collaborator. The JHS encourages the involvement of African American graduate and undergraduate students in ancillary studies in order to build minority student capacity in research.

5. **K-Awards and Related Research**: The ASSC supports requests for data to be used in applications for K- Awards and related research projects. In keeping with the philosophy and practice of scientific excellence, the ASSC requires that these requests be submitted in the form of an ancillary study proposal.

6. **Two-Year Limit:** If a study proposal does not receive funding within in two (2) years of its approval by the ASSC, the ancillary study must be resubmitted as a new proposal. Otherwise the study proposal will be considered closed.

7. **Use of JHS Resources:** Funds from the core JHS contract may not be used to support an ancillary study. Ancillary study investigators must obtain sufficient funding for all aspects of the ancillary study. This support will be used to cover ancillary study related expenses associated with:

    - data processing and data analysis such as selecting the sample; preparing and documenting analysis files and providing statistical support; preparation of forms or software; and checking ancillary study data for errors or quality

    - rental of clinic or office space

    - use of JHS staff for activities such as recruiting participants, interviewing participants,

obtaining informed consent, and/or collecting blood and urine samples or other data and processing and shipping biological samples

If the ancillary study proposal includes plans to use JHS resources, the PI of the ancillary study must make arrangements with the JHS Director and/or CSO. All communication regarding use of JHS resources must include a JHS investigator involved in the ancillary study and the JHS Director and /or CSO.