**JACKSON HEART STUDY ANCILLARY STUDY PROPOSAL FORM**

**Date of Submission:**

**ASN:**

**PART 1: Basic Study Information and Projected Impact on JHS**

1. **Title of Study:**
2. **Principal Investigator(s):**  (Include in the table below name of Principal Investigator, institution affiliation, address, telephone and e-mail address)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Principal Investigator (Last name, first name)** | **Institution Affiliation/Address** | **Phone number &**  **E-mail address** | **Responsibility** | **Percent Effort** |
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1. **Co-Investigators:** (Enter name of co-investigator, institution affiliation, address, telephone and e-mail address)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Co-Investigator (Last name, First name)** | **Institution Affiliation/Address** | **Phone number &**  **E-mail address** | **Responsibility** | **Percent Effort** |
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1. **Minority Investigators:** Include a description of the plan for the inclusion/development of minority investigators as a part of the ancillary study team.
2. **Funding:**
3. Source:

If NIH, list all funding mechanisms:

1. Grant Due Date:

If funded, provide reason for this application.

1. Proposed Study Start Date:       End Date:
2. Grant Title (if different from study title):
3. 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

1. Do you intend to use the data to patent any process, aspect or outcome of the analysis?

YES  NO

If yes, describe plans for such patent:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **FY01** | **FY02** | **FY03** | **FY04** | **FY05** |
|  |  |  |  |  |

1. Estimated direct costs per year (please provide an estimate even if a final figure is not

available):

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

| **JHS Resources** | **Activity** | **Estimated**  **Time** | **Estimated**  **Cost** | **Proposed Funding**  **Source** |
| --- | --- | --- | --- | --- |
| Coordinating Center | Sample selection |  |  |  |
| Coordinating Center | Data set preparation |  |  |  |
| Coordinating Center | Preparation of forms or database |  |  |  |
| Coordinating Center | Development of quality assurance/quality control procedures |  |  |  |
| Coordinating Center | Quality control check of ancillary study data |  |  |  |
| Coordinating Center | Statistical analysis of data for manuscripts |  |  |  |
| Coordinating Center | Verification of results of statistical analysis conducted by ancillary study investigators |  |  |  |
| Field Center | Obtain consent |  |  |  |
| Field Center | Recruit participants |  |  |  |
| Field Center | Conduct interviews, collect questionnaire data |  |  |  |
| Field Center | Conduct measurements (e.g., blood pressure, anthropometrics, height, weight) |  |  |  |
| Field Center | Collect blood or urine specimens |  |  |  |
| Field Center | Data entry |  |  |  |
| Field Center | Copy of medical records |  |  |  |
| Central Laboratory | Process and ship biological specimens |  |  |  |
| Other | Office or clinic space |  |  |  |

1. **Sample Size:**
2. Justification for proposed sample size.
3. Justification for proposed inclusion criteria.
4. Justification for proposed exclusion criteria.
5. **Participant Involvement:** Will participants be contacted, interviewed or examined?

YES  NO

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

Note you must contact the AS Coordinator if participant contact is required.

1. **Biological Specimens:** Does your ancillary study require the use of blood, urine, serum DNA or other biological specimen?

YES  NO

If yes, please attach archived specimens application.

Click the [link](https://www.jacksonheartstudy.org/Portals/0/Documents/ASN/JHS_Labapplication_Template.docx?ver=2017-01-13-113739-620) to Lab request document

Note all assay results must be sent directly to the JHS Coordinating Center.

1. **JHS Reading Center Involvement:** Will your ancillary study involve the use of CT and/or MRI Scans, echocardiography, ECG, carotid ultrasound, spirometry or retinal photography data?

YES  NO

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

If the reading center is involved the results of the data should be directly sent to the coordinating center.

1. **Intervention:** Does this study propose an intervention?

YES  NO

If yes, please briefly describe the planned intervention.

1. **JHS Data:** Does this study require variables/measures (demographics, risk factors, covariates, events, or etc.) from the JHS main study database?

Requested data:

1. **Genetic Information** (defined as any data from a participant’s DNA):
2. Does your proposal require the use of genetic data?

Yes  (please see questions 13 b-f) No  (skip to question 15)

1. Name the gene(s) or SNPs to be investigated.
2. Is the genetic information used to address the primary or secondary aims of the JHS?

YES  NO

1. Will the genetic results be reported to the participants?

YES  NO

If yes, please base your response on existing literature and current practices regarding returning genetic results to participants in cohort studies.

1. Is the genetic information collected for pooling with other cohorts for a specified genetic consortium? YES  NO

If yes, please list name of consortia.

1. If your proposal requires genetic informed consent, state the estimated number of participants who have the appropriate consent.
2. **Clinical Implications:** Will the findings have clinical implications? If so, describe the plan for reporting results to participants and providing recommendations for follow-up.

1. **Rationale and Impact:** Why do you propose to conduct the study within JHS versus another population?
2. Advantage of conducting the study within the JHS cohort?
3. Impact on ongoing JHS study or other ancillary studies?
4. **Overlap With Existing JHS Ancillary Study:**  Please contact AS Coordinator to verify if there is overlap:
5. No similar ancillary study
6. The following ancillary study/studies with similarities (List the ancillary study number,

title, PI and specify the potential overlaps/similarities):

1. **Extension of Work Described in Active JHS Manuscript Proposal:** The PI has reviewed active JHS manuscript proposals and found:
2. No similar active manuscript proposal
3. The following active manuscript proposal/proposals with similarities (List the

manuscript proposal number, title, lead author and specify the potential overlaps/similarities):

1. **Assurances:**  Please provide the following assurances (check each):

The Ancillary Study PI will report progress of the study as requested.

Confidentiality of JHS participants will be maintained.

Data collected by the Ancillary Study, with documentation, will be provided to the JHS Data Management Unit for integration into the main database. This will include documentation of newly collected data with labels, and/or laboratory results as well as documentation on methods, visits and units used with specific instructions for using the data in analyses such as exclusions that were applied. After that has been done, the Ancillary Study Investigators will receive the integrated file containing data from the main study. 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. Ancillary study data are available for additional uses by other investigators one year after the data has been submitted to the Data Management Unit. Collaboration with the ancillary study investigators who collected the data is encouraged. An ancillary study PI who wishes to extend the period of protected use must send a written request with justification to the Steering Committee for review. JHS manuscript proposal policies will be followed in all cases. In addition, limited access data will be made available to the public in accordance with the NHLBI Policy for Distribution of Data (<https://biolincc.nhlbi.nih.gov/home/> ) effective October 1, 2005. “Limited Access data” refers to study data, with certain deletions and recoding, which are released to requesting institutions and investigators for specific purposes, with certain restrictions and conditions. This policy requires that data from ancillary studies be included in the JHS limited access data set submitted to NHLBI no later than 3 years after completion of the ancillary study (or 2 years after the ancillary study data is finalized for use in publication, whichever comes first).

**PART 2: Description of the Proposed Ancillary Study**

Please attach research narrative, including the following (please do not exceed 10 pages, excluding references): Relevance, specific aims, research strategy (significance, innovation, and approach), summary and references.

Attach Signature(s) Sheet: