

**JACKSON HEART STUDY ANCILLARY STUDY PROPOSAL FORM**

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

JHS Admin Use Only: ASN #

1. Date: Click or tap to enter a date.
2. Title of study:
3. Keywords:
4. Ancillary Study Principal Investigator(s):
   1. Name:
   2. Institutional affiliation:
   3. Address:
   4. Phone number:
   5. E-mail address:
5. JHS Field Center or Coordinating Center Representative:
   1. Name:
   2. Institutional affiliation:
   3. Address:
   4. Phone Number:
   5. E-mail address:
6. Other Ancillary Study Co-investigators:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Co-Investigator (Last name, First name)** | **Institution Affiliation** | **Phone number &**  **E-mail address** | **Responsibility** | **Percent Effort** |
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1. **Are there any potential areas of overlap?** Please contact the JHS ancillary study staff and JHS Field Center or Coordinating Center representative to confirm. If there are potential areas of overlap, please state how this will be addressed.
2. **Collaboration approval:** Does this ancillary study use data from or rely on the use of data from another approved ancillary study? Yes  No

If yes, please provide the Ancillary Study name and number.

1. **Funding:**
2. Source: 
   * If NIH, specify funding mechanism:
   * Note: If direct costs ≥ $500K in any year, prior approval from NIH is required. Additional time for ancillary study review will be needed to meet the required milestones for seeking and obtaining NIH prior approval.
3. Grant due date:
4. Proposed grant start date:
5. Proposed grant end date:
6. Does this study involve the support or collaboration of a for-profit entity?

Note: For-profit involvement requires that participants who did not consent to their data being used by private companies be excluded.

1. **Sample Size:** Explicitly state the size and any special characteristics of the participant sample.
2. Proposed sample size
3. Proposed inclusion criteria
4. Proposed exclusion criteria
5. **Participant involvement:** Will participants be contacted, interviewed, or examined?

Yes  No

If yes, please list participant involvement and estimate the time required for each measure (e.g., questionnaire, specimen collection, physical measurement) in the table below. *Note: Each questionnaire must be listed separately in the table and uploaded with this application.*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Measure** | **Contact Type Required** | **Estimated Time** | **If questionnaire,**  **is it validated?** | **If questionnaire, is permission to use or a license agreement required?** | **If questionnaire, provide reference for its development and scoring.** |
| e.g., CES-D 20-item scale | In-person or phone | 15 minutes | Yes | No permission to use is required. Available in public domain. | Radloff, L. S. (1977). The CES-D Scale: A self-report depression scale for research in the general population. Applied Psychological Measurement, 1(3), 385–401. |
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1. **Biological Specimens:** Do you propose to use stored specimens or collect new samples?

Yes  No

If yes, please list the proposed analyte, specimen type required for each analyte (serum, plasma, citrate, urine, DNA), volume of specimen, exam cycle and numbers of participants.

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| --- | --- | --- | --- | --- |
| **Analyte** | **Type of specimen** | **Exam Cycle** | **Amount of specimen** | **Number of participants** |
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1. Total volume of each sample type you would like sent:
2. Do you propose to request a total sample volume that exceeds 250 microliters (µl) and/or samples from Exam 1 (baseline)? Yes  No

If yes, please provide justification.

1. Are re-frozen samples acceptable? Yes  No

If yes, please indicate whether there are any limits on the number of freeze-thaw cycles.

1. Laboratory performing analysis:
2. Lab Investigator Name:
3. Lab Institutional affiliation, if any:
4. Address:
5. Phone number:
6. E-mail address:
7. Means of specimen delivery to the laboratory:
8. Storage resources (e.g., emergency power for freezers:
9. Bar code reader available: Yes  No
10. List method of analyses for each analyte requested in the table below.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Test** | **Assay** | **Method of Analysis (e.g., ELISA, HPLC) (include manufacturer)** | **Lower Limit** | **Upper Limit** | **Low CV** | **High CV** |
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1. If a proposed assay or kit is not well-validated or relatively unknown, specify additional details here:
   1. Name of test:
   2. What is the test for and what does it provide for the JHS?
   3. References for method:
   4. Kind of specimen required:
2. Projected timeline for:
   1. Pulling and shipping samples:
   2. Sample analysis:
   3. Return of samples to lab:
   4. Have you corresponded with the JHS core lab about this ancillary study?

Yes  No

1. Please specify plans for disposition of any residual specimen.
2. **Images:** Do you propose to have access to images such as CT scans, ECG, MRI, ultrasound?

Yes  No

If yes, describe imaging materials requested in table below.

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| --- | --- | --- | --- |
| **Image Type** | **Exam Cycle** | **Format requested** | **Additional information?** |
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1. Does your study require raw data files from the parent study or data that is access-restricted (e.g., CMS data)? Yes  No

If yes, specify and provide justification.

1. **JHS Coordinating Center Involvement:** Describe the estimated effort and time required of JHS Coordinating Center staff for the proposed ancillary study activities in the table below.

|  |  |  |
| --- | --- | --- |
| **Activity** | **Estimated effort or time** | **Comments** |
| Local regulatory approvals (e.g., IRB) and required study reporting |  |  |
| Sample selection and coordination with central biorepository |  |  |
| Data collection forms review |  |  |
| Create and test data collection project |  |  |
| Quality assurance and quality control |  |  |
| De-identified data set preparation |  |  |
| Statistical analysis |  |  |
| Data management and integration into parent study dataset |  |  |
| Other (Specify: ) |  |  |
| Other (Specify: ) |  |  |

1. **JHS Field Center Involvement:** Describe the estimated effort and time required of JHS Field Center staff for the proposed ancillary study activities in the table below.

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| --- | --- | --- |
| **Activity** | **Estimated effort or time** | **Comments** |
| Participant recruitment |  |  |
| Administer interviews |  |  |
| Conduct measurements |  |  |
| Collect blood or urine specimens |  |  |
| Prepare and disseminate participant results letters |  |  |
| Medical records review or abstraction |  |  |
| Other (Specify: ) |  |  |
| Other (Specify: ) |  |  |

1. **Genetic Information**: Does your proposal plan to use genetic data (defined as any data from participant’s DNA)?

Yes  No

If yes, please answer the following items.

1. What gene(s) will be investigated?
2. Will genetic information be used to address a primary aim or secondary aim of the JHS?

Primary aim (heart and vascular disease)

Secondary aim (other health conditions)

1. Should genetic results be reported to participant’s physicians? Base your response on your knowledge of existing literature and current practices regarding increased risk and availability of treatment for adverse outcomes associated with the gene mutations to be studied. Describe the plan for addressing any relevant clinical or other (ethical, legal, or social) implications of the findings.
2. If your proposal requires genetic informed consent, provide the estimated number of participants who have the appropriate consent.
3. **Clinical Implications**: Will the findings have clinical implications? If so, describe the plan for reporting results to participants and providing recommendations for follow-up.
4. **Quality Control**: If new data is being collected or new variables being generated, describe the quality control process that will be implemented.
5. **Patent Intent**: Do you intend to use the data to patent any process, aspect or outcome of the analysis?
6. **Rationale and Impact:** What is the advantage of conducting this ancillary study with the JHS cohort (versus other cohorts)?
7. **Assurances:**  Please provide the following assurances (check each):

Confidentiality of JHS participants will be maintained.

The Ancillary Study PI will abide by all JHS policies and procedures.

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

The Ancillary Study PI will develop and submit a manual of procedures, if required,

and quality control plans for their ancillary study.

Data collected by the Ancillary Study, with complete documentation, will be provided to the JHS Coordinating Center for review. This submission will include newly generated data with clear labels, units (if applicable), documentation of methods, guidance for using the data in analyses, and programming code for checking and verifying any calculated or derived variables. After the submission has been reviewed and passes data quality checks, the Ancillary Study Investigators will receive an integrated file containing data from the parent study. The ancillary study PI is given the first and exclusive opportunity to analyze, present and publish data collected by the ancillary study. The JHS Coordinating Center will make ancillary study data available for use by other investigators in accordance with the timelines and conditions outlined by the parent study contract and NHLBI. Collaboration with ancillary study investigators who collected the data will be 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.

<https://www.nhlbi.nih.gov/grants-and-training/policies-and-guidelines/nhlbi-policy-for-data-sharing-from-clinical-trials-and-epidemiological-studies>

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

Please provide a research narrative (maximum 5 pages not including references) for the proposed study, and include the following:

1. Abstract (maximum 1 page)

Summarize background information and literature, and state how they lead to the questions(s) of interest. Include a concise justification and explanation of the research question(s) to be addressed. Conclude by stating the aim of the ancillary study and summarizing the method(s) that will be used to address the question(s).

1. Specific Aims (maximum 1 page)

Identify the research questions or hypotheses to be addressed by the ancillary study.

1. Significance

Explain in detail, the significance of the planned work. Explain why this information is lacking with regard to the ancillary study question(s), and how the proposed study will address that gap. Finally, explain how the methods and/or information from the JHS will address the ancillary study question(s). Acknowledge any limitations or concerns related to the proposed methods, and explain how they have been or will be dealt with.

1. Approach
2. Study population – Describe the sample of interest (e.g., the entire JHS cohort or subgroups). Include the anticipated time frame of participant involvement (if any).
3. Methods – Describe information to be collected and any methods or equipment to be used. Included detailed explanations and protocols for each method used. Explain how the information from the method or equipment will address the question(s). Describe data needed from JHS parent study and how defined (e.g., exposure, outcomes, covariates).
4. Statistical Analysis – Explain how each study hypothesis will be analyzed. Include any current hypotheses or information that might influence the approach to the analysis or the question.
5. Power Calculations
6. References