



Publications & Presentations Policies

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1 Introduction

The Jackson Heart Study (JHS) Publications and Presentations (P&P) Subcommittee is responsible for overseeing all aspects of scientific publications. This includes the formation of writing groups and review of proposals, the review of abstracts, and the final approval of manuscripts prior to journal submission. The goal of the P&P is to encourage the preparation of manuscripts and abstracts while providing oversight for their scientific quality and content.

The JHS P&P reviews all proposals, abstracts, and manuscripts that use JHS data* or are related to JHS design or methods. **All proposals must include a JHS representative.** A JHS representative is an investigator who is supported by the JHS Field Center or Coordinating Center, or a scientific leader of a JHS Working Group. JHS representatives have extensive knowledge and understanding of the JHS design and methodology, and subject-matter scientific expertise. The JHS strongly encourages the inclusion of Early Career Investigators and trainees on proposals.

The P&P policies are established to ensure the appropriate use of data from the JHS, timely completion of analyses, and adherence to the principles of authorship. Please review all sections of these P&P Policies prior to submission of a proposal, abstract, or manuscript. All correspondence related to P&P should be sent to jhspub@umc.edu.

*Note: For proposals approved by the JHS P&P subcommittee, the JHS Coordinating Center provides the datasets for analysis. If an investigator does not want to seek JHS P&P approval for their proposed research topic, JHS data may be requested from the Biologic Specimen and Data Repository Information Coordinating Center (BioLINCC) repository and the database of Genotypes and Phenotypes (dbGaP) through their respective processes. The data accessed using these repositories are subject to participant consent restrictions and some data may be excluded or truncated to protect confidentiality.

2 Publications & Presentations (P&P) Subcommittee

2.1 Role of the P&P Subcommittee

The role of the P&P subcommittee is:

- To ensure that abstracts, presentations, and publications that use JHS data are accurate and objective and do not compromise the scientific integrity of the study or stigmatize participants;
- To ensure that early career investigators, trainees, and fellows, participate in JHS publications;
- To establish procedures that allow for timely review of JHS publications and presentations;
- To prevent overlap of published material, approved proposals, and duplication of analyses;
- To stimulate scientific presentations and publications from investigators.

2.2 Composition of the P&P Subcommittee

The P&P Subcommittee consists of representatives from the JHS Scientific Working Groups, JHS Investigators, the JHS Director, the NHLBI Program Office, and other investigators appointed by the

Steering Committee. A Chair and Co-Chair for the P&P Subcommittee will be designated from the P&P Subcommittee membership by the Steering Committee.

2.3 Frequency of P&P Meetings

P&P Subcommittee meetings are held on the first and third Tuesday of the month at 2 p.m. CT (3 p.m. ET).

3 New Investigators

The JHS welcomes new investigators who are interested in using the JHS data for the first time to answer important scientific questions. Access to JHS data requires an approved proposal, and appropriate human subjects review (exempt, expedited, full review) by the investigator's institutional review board (IRB) or ethics board. Accordingly, the JHS strongly recommends that trainees/investigators who are planning to submit a proposal identify a JHS representative as a collaborator at the early stages of preparing a proposal. See **Appendix 1** for information for new investigators and **Appendix 2** for information about JHS representatives. Additionally, the evaluation criteria for proposals, abstracts, and manuscripts are provided in **Appendices 5, 7, and 9, respectively**.

4 Grant Applications that Propose Secondary Data Analysis

The JHS welcomes collaborations on grant applications that are proposing secondary data analysis. Investigators who are planning to submit grant applications for secondary data analysis must submit an ancillary study proposal for review and approval, prior to the submission of proposals. This will allow the JHS Coordinating Center to properly assess the scope and type of data needed, planned analyses, and any additional resources needed. The ancillary study guidelines and application is available on the website.

5 Procedures for Submitting a JHS Proposal

Proposals are required for all abstracts and manuscripts that use JHS data, including ancillary studies, or are related to JHS design or methods. A proposal is required to be submitted via the [JHS website](#) (requires account set-up and log-in credentials) that can also be accessed from the [JHS website](#). Please note that **JHS requires a proposal for each publication**.

The proposal must include a background, rationale, hypotheses to be addressed, key variables and how they will be defined, a statistical analysis plan, and references. The Lead Author initiates the proposal draft, prepares a list of co-authors, and obtains any suggestions for the proposal. In general, the P&P Subcommittee encourages proposals that can be completed within 24 months of approval by the P&P Subcommittee. Additionally, the Lead Author should have no more than three active proposals that they are leading and have not yet progressed to the penultimate draft stage. The evaluation criteria used by the P&P subcommittee is provided in **Appendix 5**.

All proposals must include a JHS representative (**Appendix 2**). A JHS representative is an investigator who is supported by the JHS Field Center or Coordinating Center or a scientific leader of a JHS Working Group. JHS representatives are subject-matter experts in their respective scientific disciplines; have knowledge and experience in working with JHS data; and are experienced in mentoring early career investigators and trainees in the development of abstracts, proposals, and manuscripts.

5.1 Potential Overlap

It is important to avoid overlap with manuscripts already in progress or published. Therefore, the Lead Author should review approved JHS proposals to ensure that the project is novel and does not duplicate an existing approved proposal or publication. Proposal titles are available on the external JHS website for general searching, and full proposals are accessible via the internal JHS website by JHS representatives. Related JHS manuscripts should be cited in the newly submitted proposal. The submitted proposal should list approved proposals with potential overlap and how this will be addressed. The Lead Author may be contacted for further discussion in cases of potential overlap.

5.2 Submission of a Proposal for Review

Proposals are submitted via the JHS website. The P&P Subcommittee advises that all information requested on the proposal form be provided at the time of submission for review. See **Appendix 4** for the proposal general template.

Enter the following proposal information directly into the [JHS website](#).

1. Proposal Title
P&P Subcommittee members adopted a P&P policy that requires authors to include the study name (The Jackson Heart Study) at the end of their paper title. The only exceptions to this policy are when the Journal restricts the number of words allowed in the title or the paper combines data from multiple studies.
2. Short Title (<50 characters)
3. Suggested Keywords (Please include Jackson Heart Study)
4. Type of manuscript (Core, Ancillary, Consortia)
5. Identify if the proposal is for a student/trainee research project. If so, identify a Mentor/Supervisor.
6. Lead Author: Contact information and Affiliation
7. Senior Author: Contact information and Affiliation
8. List of Co-Authors and Affiliations:
9. The Lead Author must attest that the listed co-authors have reviewed and **approved the final version** of the proposal prior to it being submitted to the P&P Subcommittee.
10. Identify JHS representative
11. Overview (maximum 250 words)
12. Rationale and Background (maximum 400 words)
13. Research Question/Hypothesis: Clearly state scientific questions to be addressed.
14. Data: List study visits and variables to be used, sample inclusions/exclusions.

15. Statistical Analysis Plan: Give a detailed description of the proposed statistical analysis (including pre-specification of primary, secondary, and exploratory analyses).
16. Identify any anticipated methodologic limitations or challenges and how they will be addressed (e.g., missing data, multiple testing, interval-censored data, limited power).
17. Is the research potentially sensitive or stigmatizing? If so, provide a rationale for performing in the JHS and describe appropriate protections.
18. References
19. Potential overlap with existing JHS proposals. The Lead Author is responsible for reviewing JHS manuscripts and proposals and identifying any potential overlap. If there is potential overlap, please describe how the proposal is different from those with potential overlap.
20. Disclosures/Conflicts of Interest: Describe the nature of any conflicts of interest.
21. Statistical Analysis: Location and designated person to conduct statistical analysis.
22. Upload supplemental files (*if applicable*)

Important reminders:

- Check the online information for accuracy as you complete each page of the application.
- When corrections are needed after submission, please log in to the online portal to make the necessary edits.
 - Once the submission is under review, no edits can be made to the proposal.
 - If an investigator needs to make substantive changes, the proposal may be withdrawn.
- Each proposal should result in one penultimate manuscript. If multiple penultimate manuscripts are planned, each planned manuscript must have its own approved proposal with a distinct tracking number.
- Abstracts require P&P review and approval prior to submission to conferences and scientific meetings.
- Manuscripts require P&P review and approval prior to submission to a journal.
- The proposal will expire and be closed if no manuscript is submitted for JHS review after two (2) years from the approval date. Extensions may be considered for investigators with extenuating circumstances.

For assistance or inquiries, email jhspub@umc.edu.

5.3 Proposal Review Process

Upon receipt of all required documentation, the Lead Author will receive an automated acknowledgment of submission from the P&P via email. The P&P Coordinator will review the proposal to verify that the submission is complete. The proposal will be assigned a JHS proposal number (P#) and added to the agenda for the next P&P Subcommittee call. For the scheduled P&P meeting to be considered for the applicable meeting. Please note that incomplete submissions will delay reviews. Allow for **1-2 weeks** after the assigned P&P meeting to obtain a formal communication of the committee's decision. For the scheduled P&P meeting to be considered for the applicable meeting. Please note that incomplete submissions will delay reviews. Allow for **1-2 weeks** after the assigned P&P meeting to obtain a formal communication of the committee's decision.

The P&P Subcommittee's review of the proposal will be summarized and sent to the Lead Author as (1)

approved, (2) revise and resubmit-administrative review, (3) revise and resubmit- full committee review, or (4) not approved. If revise and resubmit, a revised proposal with point-by-point responses to the review concerns must be submitted for re-review by the P&P Subcommittee. These instructions will be included in the email notification. Proposals that are not approved may not be resubmitted for review.

6 Amendment Requests

Should changes be needed for an approved proposal, the Lead Author must submit their request and justification in writing to jhsplib@umc.edu. Once the amendment request has been reviewed, the Lead Author will receive notification of the committee's decision. In some cases, a new proposal may be required. Examples of when an amendment request is necessary include:

- If new or revised hypotheses or research questions are proposed; or
- Additional requests for analysis or data not included in the original proposal.

7 Data and Materials Distribution Agreement (DMDA)

Prior to data release for an approved proposal, the investigator(s) must review and complete the JHS Data and Materials Distribution Agreement ([JHS DMDA](#)), including obtaining the signature of their authorized institutional official, and submit it to the JHS Coordinating Center. All co-authors who will need access to the data must have an active DMDA. An analytic data set will not be released if the DMDA is not on file at the JHS Coordinating Center. See **Appendix 10** for instructions on how to complete the DMDA, including obtaining the signature of their authorized institutional official, and submit it to the JHS Coordinating Center. All co-authors who will need access to the data must have an active DMDA. An analytic data set will not be released if the DMDA is not on file at the JHS Coordinating Center. See **Appendix 10** for instructions on how to complete the DMDA.

8 Procedures for Submitting a JHS Abstract

An abstract may not be submitted to any local, institutional, regional, national, or international scientific meeting prior to review and approval by the P&P Subcommittee. Any abstract submitted without this approval must be withdrawn. Submitted abstracts must be based on an approved proposal and must be submitted via the [JHS website](#) to the P&P Subcommittee for review at least **4 weeks** before the scientific meeting submission deadline. It is strongly advised that authors submit abstracts by this deadline to allow sufficient time for revisions if necessary. There is no guarantee that abstracts submitted after the P&P deadline will be reviewed prior to the conference deadline. Abstracts that include current employees of the National Heart, Lung, and Blood Institute (NHLBI) as authors/co-authors must be reviewed by NHLBI in addition to the JHS P&P prior to submission to a scientific meeting or conference.

8.1 Submission of an Abstract for Review

Abstracts are submitted via the [JHS website](#). See **Appendix 6** for the abstract submission template. The abstract must be within the scope of the approved proposal.

Enter the following abstract information directly on the Abstract Form in the [JHS website](#):

1. The P# of the approved JHS proposal. The abstract must be within the scope of the approved proposal.
2. Abstract title
3. Presenting Author: The name and contact information of the author who will present the abstract.
4. List of co-authors (Note: The Lead Author must attest that the listed co-authors have reviewed and **approved** the abstract prior to it being submitted to the P&P Subcommittee.)
5. Conference/scientific meeting information (conference name, submission deadline, conference location, conference dates)
6. Upload abstract

8.2 Abstract Review Process

Following the submission of all required documentation, the presenting author will receive an automated acknowledgment of submission from the P&P via email. The P&P Coordinator will notify the presenting author (via email) when the P&P Subcommittee review is complete and will provide the committee's decision. The P&P Subcommittee's review of the abstract will be summarized and sent to the presenting author as (1) approved, (2) revise and resubmit-administrative review, (3) revise and resubmit- full committee review, or (4) not approved. If revise and resubmit, a revised abstract with point-by-point responses to the review concerns must be submitted for re-review by the P&P Subcommittee. These instructions will be included in the email notification.

The abstract acceptance status (i.e., accepted for presentation or not accepted) should be sent to the P&P Coordinator via email at jhspub@umc.edu. If the abstract is submitted to multiple conferences (as allowed by some conference guidelines), notification of each submission and acceptance status should be sent to the P&P Coordinator.

9 Procedures for Submitting a JHS Manuscript

9.1 Submission of a Manuscript for Review

Once the penultimate manuscript is reviewed and approved by all co-authors, the Lead Author must submit the manuscript via the [JHS website](#) with the supporting documents listed below. See **Appendix 8** for the general template for manuscript submissions. The evaluation criteria used by the P&P subcommittee is provided in **Appendix 9**.

1. A memo/cover letter addressed to the P&P Subcommittee with:
 - Proposal number (P#),
 - Target journal, and Affirmation that all the co-authors have reviewed and approved the manuscript. Please note that the Lead Author should include a brief justification in their memo/cover letter to explain any changes in authorship from the approved proposal.

2. A Statement of Authors document, which includes co-authors' signatures and contributions, should be submitted as part of the manuscript submission. Completion of this form is required. See **Appendix 12** for an example of the Statement of Authors document.
3. A **lay summary** should be submitted using the JHS-approved lay summary template. See **Appendix 13** for the JHS lay summary template. Option: A “graphical” or “visual abstract” appropriate for a general audience may be submitted instead of the lay summary.
4. Copies of the analysis data set and codes used for data processing and analysis are required. The P&P Subcommittee may recommend data verification by the Coordinating Center.
5. The manuscript should include:
 - “Jackson Heart Study” in the title and summary, when possible.
6. Acknowledgment of funding sources for approved manuscripts:
 - “The Jackson Heart Study is supported by Contracts HHSN268201800010I, HHSN268201800011I, HHSN268201800012I, HHSN268201800013I, HHSN268201800014I, HHSN268201800015I from the National Heart, Lung, and Blood Institute (NHLBI) with additional support from the National Institute on Minority Health and Health Disparities (NIMHD).”
 - “This manuscript has been reviewed by JHS for scientific content.”
7. Disclaimer for approved manuscripts:
 - “The views expressed in this manuscript are those of the authors and do not necessarily represent the views of the National Heart, Lung, and Blood Institute (NHLBI); the National Institute on Minority Health and Health Disparities (NIMHD); the National Institutes of Health; or the US Department of Health and Human Services.”

9.2 Manuscript Review Process

Upon receipt of all required documentation, the Lead Author will receive an automated acknowledgment of submission from the P&P via email. The manuscript package (including the approved proposal, amendments, and manuscript) will be compiled by JHS staff and sent to two JHS reviewers for independent review. After those independent reviews are returned, the reviews are collated and the manuscript is added to the next P&P agenda for discussion. Allow for a **minimum of 4-6 weeks** for the independent reviews and final review by the P&P Subcommittee. The P&P Subcommittee’s review will be summarized and its decision reported back to the Lead Author as (1) approved, (2) revise and resubmit- administrative review, (3) revise and resubmit –full committee review, or (4) not approved. If the manuscript decision is to revise and resubmit, a revised manuscript with point-by-point responses to the review concerns will need to be submitted for re-review by the P&P Subcommittee. If a manuscript is not approved, it will not be re-reviewed by the P&P Subcommittee nor can it be submitted to a journal for consideration. These instructions will be included in the email notification.

9.3 Manuscripts with NHLBI Author/Co-authors

Manuscripts that include a current employee of the NHLBI as an author or co-author must be reviewed by NHLBI. In this case, the Lead Author should send the manuscript and the P&P approval letter via email to NHLBI at nhlbi_ebpdocs@nhlbi.nih.gov and copy the Project Officer, Dr. Sharon Smith at

smithsh1@mail.nih.gov before submission to a journal for publication. Note: Manuscripts that include employees of other NIH institutes and centers (e.g., National Institute on Minority Health and Health Disparities) do not require review by NHLBI.

9.4 Journal Submission

After the manuscript is approved by the P&P (and NHLBI if the manuscript has an NHLBI employee as an author), the author(s) can submit it to the target journal for consideration. If the journal requires new analyses (e.g., new variables, change in how variables defined) or substantive revisions to the manuscript text, please notify the P&P Coordinator to determine whether re-review by the P&P is required. If the manuscript is not accepted by the target journal and there are no substantive revisions, the Lead Author may submit to the next target journal.

The Lead Author must notify the P&P when the manuscript has been accepted by a journal. A reprint, copy, or link to the published PDF of the manuscript must be uploaded to the JHS P&P website under supplemental materials linked to the original proposal. In addition, the Lead Author must comply with the NIH Public Access Policy. (See section **9.5** and **Appendix 15** for more information).

9.5 NIH Public Access Policy

All JHS manuscripts must adhere to the NIH Public Access Policy. During journal submission, authors should select the NIH public access policy, if available, as some journals will deposit NIH-supported papers directly to PMC. If the journal does not deposit NIH-supported papers to PMC, the Lead Author shall submit to the NIH National Library of Medicine's (NLM) PubMed Central (PMC) an electronic version of the final manuscript, upon acceptance for publication, resulting from research supported in whole or in part with direct costs from NIH. NIH defines the author's final manuscript as the final version accepted for journal publication and includes all modifications from the publishing peer review process. The PMC archive will preserve permanently these manuscripts for use by the public, health care providers, educators, scientists, and NIH. The policy directs electronic submissions to the NIH/NLM/PMC at <http://www.pubmedcentral.nih.gov>. (See **Appendix 15** for the NIH Public Access Policy).

9.6 JHS Data Availability Statement

If requested, authors should use the following JHS Data Availability statement during journal submission:

Jackson Heart Study data may be requested from the Biologic Specimen and Data Repository Information Coordinating Center (BioLINCC) repository and the database of Genotypes and Phenotypes (dbGaP).

BioLINCC: <https://biolincc.nhlbi.nih.gov/studies/jhs/>

dbGaP: <https://www.ncbi.nlm.nih.gov/gap/>

9.7 JHS Preprint Policy

After a manuscript is approved by the P&P Subcommittee, authors may post the manuscript to a preprint server. A manuscript may not be submitted to a preprint server if it has not been approved by the P&P Subcommittee.

10 Consortia

JHS participates in several consortia including the following:

1. CardiogramPlusC4D (CAD GWAS)
2. Chronic Kidney Disease Prognosis Consortium (CKD-PC)
3. Cohorts for Heart and Aging Research in Genomic Epidemiology (CHARGE)
4. Collaborative Cohort of Cohorts for COVID-19 Research (C4R)
5. COMPASS (Stroke GWAS)
6. Cross-Cohort Collaboration (CCC)
7. GIANT (BMI and central adiposity GWAS)
8. Global Lipids Genetics Consortium (GLGC)
9. MAGIC-T2DGGI (Glycemic traits and T2D)
10. Population Architecture Using Genomics and Epidemiology (PAGE)
11. Polygenic Risk Methods in Diverse Populations (PRIMED)
12. Trans-Omics for Precision Medicine (TOPMed)

Consortia proposals and manuscripts are required to be submitted to the JHS P&P Subcommittee for approval. Please refer to each consortium's specific guidelines. For additional information, contact jhspub@umc.edu.

11 Proposal Progress

Proposals will be closed if no manuscript is submitted for P&P review within 2 years of approval. Closed proposals may not be re-opened and a new proposal with full committee review will be required for the research to recommence.

12 Manuscript Extension

For approved proposals that are about to expire and do not have a penultimate manuscript submitted, investigators may request a 6-month extension if there are extenuating circumstances.

Please note that adequate progress must be demonstrated for approval of the 6-month extension request. For more information on submitting an extension request, contact the P&P Coordinator at jhspub@umc.edu.

13 Contact Information

All correspondence and inquiries related to P&P should be sent to jhspub@umc.edu.

14 Appendices

- Appendix 1:** Information for New Investigators
- Appendix 2:** JHS Representatives
- Appendix 3:** JHS P&P Meeting Schedule & Submission Deadlines
- Appendix 4:** JHS Proposal Submission Template
- Appendix 5:** JHS Proposal Evaluation Criteria
- Appendix 6:** JHS Abstract Submission Template
- Appendix 7:** JHS Abstract Evaluation Criteria
- Appendix 8:** JHS Manuscript Submission Template
- Appendix 9:** JHS Manuscript Evaluation Criteria
- Appendix 10:** Instructions for Completing Data and Material Distribution Agreement (DMDA)
- Appendix 11:** Jackson Heart Study DMDA Template
- Appendix 12:** Statement of Authors Form
- Appendix 13:** Jackson Heart Study Lay Summary Template
- Appendix 14:** JHS Acknowledgement Statement and Disclaimer
- Appendix 15:** NIH Public Access Policy



VISIT THE JHS WEBSITE FOR MORE INFORMATION: [HTTPS://WWW.JACKSONHEARTSTUDY.ORG/](https://www.jacksonheartstudy.org/)

The JHS welcomes new investigators who are interested in using the JHS data for the first time to answer important scientific questions. Request for JHS data requires an approved proposal. Please note that proposals must be submitted using the [JHS online portal](#).

OVERVIEW OF STEPS IN THE SUBMISSION PROCESS FOR NEW JHS PROPOSALS

STEP 1- Determine Research Question/ Potential Overlap

- Determine if the needed variables are available in the JHS.
- The first author should identify and address any potential [overlap](#) between other approved proposals and published manuscripts.

STEP 2 – Co-authors

- All proposals must include a JHS Field Center/Coordinating Center investigator or a scientific leader of a JHS Working Group. See **Appendix 2** for information about the inclusion of JHS Representatives.
- In addition, all co-authors must review and approve the proposal prior to submission.

STEP 3- Proposal Submission

- Proposals must be submitted via the JHS website by selecting “New Submission” and entering the requested information directly on the online form. Please note first-time users must request a login account.
- The lead author will receive an automated confirmation following submission.

STEP 4- P&P Review

- Following review by the P&P committee, the lead author will receive the committee’s recommendation and any comments via email.

STEP 5- Data Request and Data and Materials Distribution Agreement (DMDA)

- Following approval, the lead author must complete the Data and Materials Distribution Agreement ([DMDA](#)). Once the DMDA is fully executed, the data will be released to the investigator.

STEP 6- Manuscript Development

- The writing team can move forward with analysis and manuscript preparation. Please note that manuscripts must be submitted to the P&P for review prior to journal submission. In addition, only one manuscript can be developed per approved proposal.

Appendix 2: JHS Representatives



JHS Representatives include JHS Working Group Co-Chairs and Field Center and Coordinating Center investigators who are subject-matter experts in their respective scientific disciplines; have knowledge and experience in working with JHS data; and are experienced in mentoring early career investigators and trainees in the development of abstracts, proposals, and manuscripts that are likely to receive a favorable decision by the JHS P&P Subcommittee.

The JHS Representatives are provided below.

Working Group Co-Chairs	
Arrhythmia Working Group	Drs. James Floyd
Biomarkers	Drs. Margaret Doyle, Nels Olson
Cardiovascular (CVD) Outcomes	Drs. Emily O’Brien, LaShaunta (Tay) Glover
Centers for Medicare and Medicaid Services Data	Drs. Yi Yang, Brad Hammill
Chronic Kidney Disease	Drs. Bessie Young, Clarissa Diamantidis
Obesity & Diabetes	Drs. Alain Bertoni, Joshua Joseph
Genetics	Drs. Laura Raffield, Leslie Lange
Healthy Aging	Drs. Lisa Barnes, Jennifer Manly, Priya Palta, Gwen Windham
Hypertension	Drs. Daichi Shimbo, Beth Lewis, Ogedegbe Olugbenga, Tanya Spruill
Nutrition and Physical Activity	Drs. Sameera Talegawkar, Robert Newton
Social Determinants of Health	Drs. Sharrelle Barber, Mario Sims
Field Center and Coordinating Center Investigators	
JHS Investigators / UMMC	Drs. Nancy Min, Christina Ezemenaka, Andrew Sims, Arnita Norwood, April Carson (Director, JHS)
JHS Investigators / WFUSM	Drs. Tina Davenport, David Reboussin, Sean Simpson, Mike Bancks, Brian Wells, Kristin Lenoir, Gary Beecham, Olivia Gilbert, Ramon Casanova, Alain Bertoni, Lynne Wagenknecht, Ralph D’Agostino, Leann Long (CC Director)



- The JHS P&P Committee meets the 1st and 3rd Tuesdays of each month.
- To allow sufficient time for processing and review, **the deadline for proposal submissions is noon Central Time (CT) on Monday of the week before the next P&P call.**
- The P&P Committee will follow a stringent policy of not reviewing proposals submitted after the P&P deadline until the next cycle.

NOTE: Meetings scheduled around major holidays or conferences are subject to change.



Jackson Heart Study Proposal Form

Instructions: Please read the JHS P&P Policies before completing the proposal form.

Please Note: Proposals must be submitted via the JHS Online System; this document is to provide a preview of the requested information. Areas within a grey box denote information to be entered directly into the online system and therefore, do not need to be completed in this template. Areas not within a grey box must be saved in a document and uploaded as a WORD or PDF attachment in the online platform.

Title Information

Proposal Title (Please include “Jackson Heart Study” in the title):

Short Title (<50 characters):

Suggested Keywords (Please include Jackson Heart Study):

Type of Proposal (**Select one**): Main Ancillary Consortia

- If Ancillary Study, please identify (**SELECT**) the Ancillary Study
- If Consortium Study, please identify (**SELECT**) the Consortium

Is this proposal for a student/trainee research project? Yes No

Type of Student/Trainee (**Select one**):

Undergraduate Graduate Student Doctoral Student Postdoctoral Fellow Other

If other, please specify:

Mentor/Supervisor Name: (**SELECT**)

Position/Title:

Institutional Affiliation:

Email:

Is this proposal related to the Trans-Omics for Precision Medicine (TOPMed) program?

Yes No

Author Information

The **Lead Author** is the person who will correspond and communicate with the JHS Coordinating Center.

Lead Author Name: (**SELECT**)

Position/Title:

Institutional Affiliation:

Email:

The **Senior Author** is the person who is ultimately responsible for the research in this proposal (can be the same as Lead Author).

Senior Author Name: **(SELECT)**

Position/Title:

Institutional Affiliation:

Email:

Co-author(s): Name, Affiliation, Email

Name	Institutional Affiliation	Email

Attestation Statement: _____ *As the Lead Author, I attest that each of the listed co-authors have reviewed and approved the version of the proposal being submitted to the JHS Publications and Presentations Committee.*

Please identify the JHS Field Center/Coordinating Center Investigator or Working Group Co-Chair representative for this proposal (see JHS P&P Policies for current list): **(SELECT)**

UPLOAD A PROPOSAL WITH THE FOLLOWING FORMAT AND ELEMENTS (WORD OR PDF)

Overview

Provide a brief overview of the proposal, describing the problem to be addressed and its scientific relevance (<250 words):

Rationale and Background

Please include discussion on relevance of Black and African American individuals to the proposed topic (400 words):

Study Aims and Hypotheses

List each study aim and corresponding hypothesis separately (add aims and hypotheses as needed)

Study Aim 1:

Hypothesis 1:

Study Aim 2:

Hypothesis 2:

Study Population

Inclusion criteria:

Exclusion criteria:

Data (visits and variables to be used)

Select data to be used in the proposal:

<input type="checkbox"/> Exam 1	<input type="checkbox"/> Exam 2	<input type="checkbox"/> Exam 3	<input type="checkbox"/> Exam 4
<input type="checkbox"/> AFU	<input type="checkbox"/> Adjudicated Events	<input type="checkbox"/> Ancillary Study	<input type="checkbox"/> Not Applicable

Provide details of variables to be used in the table format given below:

Exposure(s) (independent variable(s)):

Exposure Name	Description	Variable Type (e.g., binary, categorical, continuous, time to event)

Outcome(s) (dependent variable(s)):

Outcome Name	Description	Variable Type (e.g., binary, categorical, continuous, time to event)

Other variables (e.g., descriptive only, confounders, mediators, effect-modifiers):

Variable Name	Description	Variable Type (e.g., binary, categorical, continuous, time to event)

Statistical Analysis Plan- Give a detailed description of the proposed statistical analyses (including pre-specification of primary, secondary, and exploratory analyses). Sub-divide the analysis plan by the study aims listed above:

Identify any **anticipated methodologic limitations or challenges** and how they will be addressed (e.g., missing data, multiple testing, interval-censored data, limited power):

References (maximum 15)

Is the research potentially **sensitive or stigmatizing**? Yes No

If so, provide a rationale for performing in the JHS and describe appropriate protections.

Potential overlap with existing proposals.

The Lead Author is responsible for reviewing JHS proposals and manuscripts and identifying any potential overlap. If there is potential overlap, please describe how the proposal is different from those with potential overlap.

No similar proposals or manuscripts

Yes, the following similar proposals and/or manuscripts:

(For each identified proposal or manuscript, list the manuscript proposal number (e.g., P0143), title, Lead Author, and how potential overlap is being addressed).

P#	Title	Lead Author	Explain how potential overlap will be addressed.

Proposal Funding:

Is any of the work (e.g., chart review, data collection, analysis) for this proposal funded?

Yes No

If so, please provide the funding source and funding period.

Are you seeking funding to complete any work for this proposal? Yes No

If so, please provide the funding source and submission date.

Disclosures/Conflicts of Interest:

Do you or any coauthors on this proposal have a conflict of interest? Yes No

If so, please describe the nature of the conflict of interest:

Are these analyses to involve a for-profit corporation? Yes No Name of Corporation:

Please describe the nature of the financial interest with the listed corporation.

Do you or any coauthors on this proposal intend to patent any process, aspect, or outcome of these analyses? Yes No

Please describe plans for patents

Location and designated person to conduct statistical analyses:

JHS Coordinating Center

Other (Analyst Name, Institution, Contact Information)

Uploads (if applicable): (UPLOAD IN ASSOCIATED DOCUMENTS TAB)

Supplemental files (e.g., conceptual model, graphs, table shells, etc.)

**Thank you for your
submission.**

Appendix 5: JHS Proposal Evaluation Criteria

REVIEW CRITERIA: PROPOSAL

1	A clear statement of the nature of problem and rationale for investigating in the JHS cohort.
2	Research hypotheses are clear and appropriate.
3	Inclusion/exclusion criteria justified.
4	Exposure (independent), outcome (dependent), and relevant covariates described appropriately.
5	Statistical analysis plan is clear and appropriate.
6	Anticipated limitations identified with alternative strategies proposed.
7	Appropriate a priori specification of primary, secondary, and exploratory analysis.
8	Inclusion of a member from the appropriate JHS Working Group.
9	Absence of potential stigmatization issues
10	Confirmed that no potential overlap exists with manuscript proposals or papers already approved/published.



Jackson Heart Study Abstract Form

Instructions: Please read the JHS P&P Policies before completing the abstract form. Abstracts are submitted via the JHS P&P Website (link). The information below is a template of required elements.

Please Note: Abstracts must be based on / linked to an approved proposal; submissions should be made at least 4 weeks before the conference/scientific meeting deadline.

Abstract Title:

Is this abstract for a **student/trainee** research project? Yes No

Type of Student/Trainee (**Select One**):

Undergraduate Graduate Student Doctoral Student Postdoctoral Fellow Other
Other, please specify:

Mentor/Supervisor

Name:

Position/Title:

Institutional Affiliation:

Email:

Is this abstract related to the Trans-Omics for Precision Medicine (**TOPMed**) program?

Yes No

Presenting Author

Name:

Position/Title:

Institutional Affiliation:

Email:

Conference/Scientific Meeting:

Name of the conference/scientific meeting:

Location city:

Location State/Country:

Abstract Submission Deadline:

Meeting Start Date:

Meeting End Date:

Uploads

Abstract

Supplemental File(s) (if applicable)

Thank you for your submission.

Appendix 7: JHS Abstract Evaluation Criteria

REVIEW CRITERIA: ABSTRACT

- | | |
|---|---|
| 1 | Proposal: Abstract content aligns with JHS approved proposal. |
| 2 | Context: Rationale for the study is identified. The research question, or hypothesis is clearly stated. |
| 3 | Design: The basic design of the study is described (e.g., number of participants, inclusion criteria). |
| 4 | Methods: Primary exposure and outcome measurements are described. Statistical analysis is clear. |
| 5 | Results: The main findings are provided and quantified including confidence intervals or uncertainty measures. |
| 6 | Conclusions: Conclusions reported are supported by results presented in abstract. |



Instructions: Please read the JHS P&P Policies before completing the manuscript form. Manuscripts are submitted via the JHS P&P Website (link). The information below is a template of required elements.

Please Note: Manuscripts must be based on / linked to an approved proposal.

Title Information

Manuscript Title (Please include “Jackson Heart Study” in the title):

Short Title:

Suggested Keywords (Please include Jackson Heart Study):

Is this manuscript for a **student/trainee** research project? Yes No

Type of Student/Trainee (**Select One**):

Undergraduate Graduate Student Doctoral Student Postdoctoral Fellow Other

Other, please specify:

Mentor/Supervisor Name:

Position/Title:

Institutional Affiliation:

Email:

Is this manuscript related to the Trans-Omics for Precision Medicine (TOPMed) program?

Yes No

Author Information

Has there been a change in Lead, Senior, Quantitative Author or JHS Representative since the proposal was approved? Yes No

If yes, please provide a brief justification below and update all authors in the **Authors Tab**.

Attestation Statement: _____ (**Please Initial**) *As the Lead Author, I attest that each of the listed co-authors have reviewed and approved the version of the manuscript being submitted to the JHS Publications and Presentations Committee.*

Please indicate the **target journal**:

Uploads

Please upload the manuscript and supporting documents below:

- Cover Letter
- Lay Summary (JHS Lay Summary Template)
- Final Manuscript
- Statement of Authors (SoAs) form (JHS SoA Template)
- Final analysis code (Note: Upload as a zip file)
- Final analysis dataset (Note: Upload as a zip file)
- Supplementary files (if applicable)

- Manuscript includes **acknowledgment** of Jackson Heart Study Funding and **Disclaimer** (below)

Acknowledgment Statement

“The Jackson Heart Study is supported by Contracts HHSN268201800010I, HHSN268201800011I, HHSN268201800012I, HHSN268201800013I, HHSN268201800014I, HHSN268201800015I from the National Heart, Lung, and Blood Institute (NHLBI) with additional support from the National Institute on Minority Health and Health Disparities (NIMHD).”

“This manuscript has been reviewed by JHS for scientific content.”

If whole genome sequencing/TOPMed data is used, the following acknowledgment should also be included:

“The Jackson Heart Study (phs000964.v1.p1) whole genome sequencing was performed at the Northwest Genomics Center (HHSN268201100037C). Core support including centralized genomic read mapping and genotype calling, along with variant quality metrics and filtering were provided by the TOPMed Informatics Research Center (3R01HL-117626-02S1; contract HHSN268201800002I). Core support including phenotype harmonization, data management, sample-identity QC, and general program coordination were provided by the TOPMed Data Coordinating Center (R01HL-120393; U01HL-120393; contract HHSN268201800001I).”

Disclaimer Statement

“The views expressed in this manuscript are those of the authors and do not necessarily represent the views of the National Heart, Lung, and Blood Institute (NHLBI); the National Institute on Minority Health and Health Disparities (NIMHD); the National Institutes of Health; or the US Department of Health and Human Services.”

Thank you for your submission.

Appendix 9: JHS Manuscript Evaluation Criteria

REVIEW CRITERIA: MANUSCRIPT

1	The manuscript is consistent with the approved paper proposal. <ul style="list-style-type: none">• The paper does not “drift” into areas not proposed, particularly such that the publication of other papers on the topic would be compromised.
2	The Jackson Heart Study description is appropriate. <ul style="list-style-type: none">• Accurately describes the study in appropriate detail• Contains no significant errors
3	Analysis is appropriate. <ul style="list-style-type: none">• Statistical analysis is reasonable, although the reviewer may have used different methods• Alternate appropriate methods would not have resulted in substantially different conclusions.
4	Interpretation of results is appropriate. <ul style="list-style-type: none">• Conclusions do not extend inappropriately beyond the data.• Causal language and inappropriate clinical recommendations are avoided.
5	The manuscript is reasonably well-written. <ul style="list-style-type: none">• The Abstract is clear and accurate.• There are no significant grammatical, syntactical, or spelling errors that should have been corrected during earlier draft stages.
6	Study funding is properly acknowledged , per recommendations posted on the JHS website.
7	Absence of potential stigmatization issues.

NOTE: *The Jackson Heart Study Coordinating Center provides data and/or materials to the scientific community on behalf of the NHLBI according to the terms and conditions of the NHLBI Data and Materials Distribution Agreement (DMDA). Therefore, any requests to modify the terms and conditions of the DMDA must be submitted to the Jackson Heart Study Coordinating Center for subsequent submission to the NHLBI Data Access Committee for approval or disapproval.*

1. If you are requesting data and/or materials from the Jackson Heart Study (JHS) (i.e., for an ancillary study, or a manuscript), you will need to fill out a DMDA.

“Data” refers to any and all study information, records, statistics, facts, figures, and numbers, including without limitation to, laboratory, examination, and questionnaire results, and Genetic Analysis Data, images (e.g., without limitation to computed tomography scans, MRI scans), or primary signal data (e.g., ECG, spirometry tracings, polysomnography, accelerometry) and associated records either obtained directly from JHS participants or obtained from third parties as authorized by the participants pursuant to the contracts with the NHLBI, as well as those provided to the JHS by ancillary studies.

“Materials” refers to biological samples including, without limitation: urine, blood (or any part thereof), tissues, or extracted DNA from said biological samples pursuant to the contracts with the NHLBI, as well as biological samples provided to the JHS by ancillary studies.

2. The DMDA can be found on the Jackson Heart Study website: [JHS DMDA](#)
3. The PI should download the DMDA from the JHS website and complete the form. For a DMDA to be valid, it must have the following sections complete:

Section 1 “Materials:”

Please generally describe what is more explicitly specified in the approved Research Project. (If the Research Project involves data only, please enter “n/a” or leave blank).

Section 2 “Data:”

This agreement covers only data described in the approved Research Project. For secondary data analyses, include the type of data requested (e.g., genetics, omics, events, mortality, derived variables).

Section 3.1 “Research Project:”

JHS number & title of the approved ancillary study proposal or paper proposal(s).

Section 3.2 “Other Recipients:”

If materials are requested and any aspect of the Research Project related to materials is to be performed by an entity other than the Recipient (as explained in

section 4.2), identify the entities here. Please enter “n/a” or leave blank if not applicable.

Initial 1 “Recipient’s PI:”	Principal Investigator (PI) initials at the end of section 3.
Initial 2 “Recipient’s PI:”	Principal Investigator (PI) initials at the end of section 12.
Initial 3 “Recipient’s PI:”	Principal Investigator (PI) initials at the end of section 13.
Initial 4 “Recipient’s PI:”	Principal Investigator (PI) initials at the end of section 18.
Initial 5 “Recipient’s PI:”	Principal Investigator (PI) initials at the end of section 22.
Sign 1 “Recipient’s PI:”	Principal Investigator (PI). Data/materials will be transferred only to the PI, who assumes responsibility for students/staff participating in the Research Project (DMDA clause 5). Please notify the Coordinating Center with the names of any additional persons who will receive access (e.g., author or analyst on a paper).
Sign 2 “Recip.’s Authorized Rep:”	Institution (usually Business Office, Office of Research, Licensing & Technology, or Grants & Contracts - the signer must have local institutional authority to legally commit the institution to this agreement.)
Sign 3 “JHS CC:”	Completed by JHS Coordinating Center following all of the above
Sign 4 “NHLBI Rep.:”	[Materials only] Completed by JHS Coordinating Center following all of the above

Please send requests and completed agreements to jhspub@umc.edu.

***IRB REVIEW (DMDA clause #18):**

The DMDA *requires* review by the Recipient Institution’s IRB. Data and/or materials transferred will contain no personal identifiers. However, a slight possibility remains that individual participants could be identified given the volume of data. This additional IRB review is not needed by JHS investigators at JHS-contracted institutions whose project involves only data or biospecimens that are already covered by a local, current IRB-approved JHS contract.

Appendix 11: Jackson Heart Study DMDA Template
[JHS DMDA](#)



DEPARTMENT OF HEALTH AND HUMAN SERVICES

**Jackson Heart Study
Data and Materials Distribution Agreement**

The undersigned parties hereby enter into this Data and Materials Distribution Agreement (DMDA) on the date the last party hereto signs the SIGNATURE PAGE below (the "Effective Date").

INTRODUCTION

The Jackson Heart Study (JHS) is described at www.jacksonheartstudy.org.

To protect the confidentiality and privacy of JHS participants and their families, investigators granted access to Data and Materials must adhere to the requirements of this DMDA. Failure to comply with this DMDA could result in its termination, denial of further access to JHS or other National Heart, Lung, and Blood Institute (NHLBI) resources, and may leave violators subject to legal action on the part of JHS participants, their families, or actions brought by the United States of America (U.S. Government).

The undersigned parties entering into this DMDA include: the Recipient (defined in the next section), the NHLBI, and the Coordinating Center for the JHS, on behalf of the JHS and under the direction of the JHS Steering Committee.

DEFINITIONS

For purposes of this agreement:

"Data" refers to any and all study information, records, statistics, charts, figures, and numbers, including without limitation to, laboratory, examination, and questionnaire results, and Genetic Analysis Data, images (e.g., without limitation to computed tomography scans, MRI scans), or primary signal data (e.g., ECG, spirometry tracings, polysomnography, accelerometry) and associated records either obtained directly from JHS participants or obtained from third parties as authorized by the participants pursuant to the contracts with the NHLBI, as well as those provided to the JHS by ancillary studies.

"Genetic Analysis Data" refers to any and all information derived from genetic material and any and all data derived therefrom including statistical analyses linking data from genetic materials with other study data.

"Materials" refers to biological samples including without limitation to: urine, blood (or any part thereof), tissues, or extracted DNA from said biological samples pursuant to the contracts with the NHLBI, as well as biological samples provided to the JHS by ancillary studies.

"Recipient" refers to the institution or other entity receiving access to the JHS Data and/or Materials requested for the Research Project identified in section 3 below as described in the attached research application.

"Recipient's Principal Investigator (PI)" refers to the Research Project director for the Recipient.

"Research Project" refers to the project described in the attached research application.

"Resultant Data" refers to analyze Data derived in whole or in part by Recipient from Data and/or Materials provided under this DMDA.



“JHS Study Investigator” is a research investigator who works with the JHS either as an employee of the NHLBI or through a current and active award (including contracts, grants, or other transactions) or consulting agreement with the NHLBI or one of its contractors.

TERMS AND CONDITIONS

The Parties hereto agree as follows:

1. Materials. JHS and NHLBI agree to transfer to Recipient the Materials described below, including the types of samples, amount, and concentration per sample (when applicable), the number of individuals from whom samples are to be provided, and whether samples are nonrenewable or from a renewable resource (e.g., DNA from immortalized cell lines) for use by the Recipient’s PI to conduct the Research Project as summarized in section 3 below.

[Redacted area]

2. Data. JHS agrees to provide Recipient with Data described as follows:

[Redacted area]

JHS will provide Recipient with the name and contact information of Study Investigators and all other investigator(s) who generated such Data.

Example

3. Research Project.

3.1 These Materials and Data will be used by Recipient’s PI solely for use in conducting the Research Project, as named and described in the attached research application (insert Research Project name below):

[Redacted area]

3.2 If any aspect of the Research Project, is to be performed by an entity other than the Recipient as permitted by section 4.2, such entity is to be named below:

[Redacted area]

Recipient agrees that it will not employ, contract with, or retain any person, directly or indirectly, who is listed in the federal government’s Excluded Parties List (EPL) System for Award Management (SAM) (<https://sam.gov/content/exclusions>). Recipient agrees to notify JHS within 30 days of such person’s debarment or disqualification under this DMDA.

3.3 This DMDA covers only the Research Project set forth in Section 3.1. Recipient must submit a separate DMDA for each Research Project for which Data and/or Materials are requested.

Representations. Recipient and Recipient’s PI expressly certify that the contents of any statements made or reflected in this document are truthful and accurate.

RECIPIENT'S PI INITIALS: **4. Non-Transferability.** This DMDA is not transferable.

4.1 Recipient and Recipient's PI agree that substantive changes made to the Research Project, and/or appointment by Recipient of another principal investigator and/or transfer of Recipient's PI to another institution or other entity to complete the Research Project will require execution of a separate DMDA. Except as provided in section 4.2 below, Recipient may not distribute Data or Materials to any other individual or entity, regardless of the intended use of such Data or Materials. Nothing in this section precludes Recipient from publishing results of the Research Project through the usual channels of scientific publication.

4.2 Recipient and Recipient's PI may transfer or cause to be transferred Materials to an institution or institutions or other entities not affiliated with Recipient but with which Recipient has either a fee-for-service or subcontract agreement or specific authorization from the NHLBI for performance of assays and/or genetic analyses for the Research Project as identified in section 3.2.

4.3 A separate DMDA is not required if the derived Data are either returned to the Recipient and Recipient's PI or are deposited for Recipient and Recipient's PI in a publicly accessible repository maintained by the NHLBI upon completion of the assays. No Data are to be provided to such institutions or other entities unless a separate DMDA has been approved by JHS and NHLBI. The Recipient and Recipient's PI adhere to the study's policy regarding retention and destruction of material and data.

5. Conduct of Research Project. Recipient's PI is responsible for conducting the Research Project and shall be responsible for assuring that any co-investigator(s) or contractor(s) comply with the terms of this DMDA.

6. Publication. JHS and NHLBI request that the Recipient's PI provide to the authorized representative for the JHS Coordinating Center (named below) a copy of any abstract ten (10) days in advance of submission for publication and any manuscript or other disclosure document thirty (30) days in advance of submission for publication, in order to permit review and comment and ensure compliance with the confidentiality requirements of this DMDA. Please refer to the NHLBI Supplement to the NIH Policy for Data Management and Sharing (<https://www.nhlbi.nih.gov/grants-and-training/policies-and-guidelines/nhlbi-policy-for-data-sharing>).

7. Acknowledgments. Recipient and Recipient's PI agree to acknowledge the contribution of JHS in any and all oral and written presentations, disclosures, and publications resulting from any and all analyses of Data or Materials, in accordance with the guidelines established by the study.

7.1 Collaborations. If a manuscript resulting from the Research Project has Study Investigators as co-authors, then the manuscript must be submitted for review by the JHS.

7.1.a If the manuscript is approved by the JHS, the Recipient and Recipient's PI agree to include the following language in an acknowledgment.

"The Jackson Heart Study is supported by Contracts HHSN268201800010I, HHSN268201800011I, HHSN268201800012I, HHSN268201800013I, HHSN268201800014I, HHSN268201800015I from the National Heart, Lung, and Blood

Institute (NHLBI) with additional support from the National Institute on Minority Health and Health Disparities (NIMHD).”

“This manuscript has been reviewed by JHS for scientific content.”

7.1.b If the manuscript is not approved by the JHS and the Recipient and Recipient’s PI wish to proceed to publish without inclusion of Study Investigators as co-authors, the Recipient and Recipient’s PI agree to include the following language in an acknowledgment.

“The Jackson Heart Study is supported by Contracts HHSN268201800010I, HHSN268201800011I, HHSN268201800012I, HHSN268201800013I, HHSN268201800014I, HHSN268201800015I from the National Heart, Lung, and Blood Institute (NHLBI) with additional support from the National Institute on Minority Health and Health Disparities (NIMHD).”

“This manuscript was not approved by the JHS. The opinions and conclusions contained in this publication are solely those of the authors, and are not endorsed by the JHS or the NHLBI and should not be assumed to reflect the opinions or conclusions of either.”

7.2 Other Studies. If the Research Project does not involve collaboration with Study Investigators, then the Recipient and Recipient’s PI agree to include the following language in an acknowledgment.

“The Jackson Heart Study is supported by Contracts HHSN2682018000010I, HHSN2682018000011I, HHSN2682018000012I, HHSN2682018000013I, HHSN2682018000014I, HHSN2682018000015I from the National Heart, Lung, and Blood Institute (NHLBI) with additional support from the National Institute on Minority Health and Health Disparities (NIMHD).”

“This manuscript was not prepared in collaboration with investigators of the JHS and does not necessarily reflect the opinions or conclusions of the JHS or the NHLBI.”

7.3 Ancillary Study Investigator Acknowledgments. If Data include data provided to the JHS by other ancillary study investigators, Recipient and Recipient’s PI also agree to acknowledge the contribution of those other ancillary study investigators in any and all oral and written presentations, disclosures, and publications resulting from any and all analyses of such Data.

8. Non-Identification/Participant Anonymity. Recipient and Recipient’s PI agree that Materials and/or Data will not be used, either alone or in conjunction with any other information, in any effort to determine the individual identities of any of the participants from whom Data and/or Materials were obtained or derived.

9. Use Limited to Research Project. Recipient and Recipient’s PI agree that Data, Materials, their progeny, or derivatives thereof will not be used in any experiments or procedures unless said experiments or procedures are disclosed and approved as part of the Research Project.

10. Use in Human Experimentation Prohibited. Recipient and Recipient’s PI agree that Materials, their progeny, and derivatives thereof will not be used in experimentation or research involving of any kind with human participants.



11. Compliance with Participants' Informed Consent. Recipient and Recipient's PI agree that Data and/or Materials, their progeny, and derivatives thereof will not be used for any purpose contrary to a participant's applicable signed informed consent document(s). Recipient and Recipient's PI agree to consult with Study Investigators and ascertain, specifically and in detail, the terms and conditions of applicable JHS informed consent documents.

12. No Distribution, Confidentiality, and Avoidance of Waste. Recipient and Recipient's PI agree to retain control over Data, Materials and their progeny, and derivatives thereof. Recipient and Recipient's PI further agree not to transfer Data, Materials and their progeny, and derivatives thereof, with or without charge, to any other entity or individual, except for Data and/or Materials as provided for in section 4.2 above. In addition to the provisions set forth in section 19 below, Recipient and Recipient's PI agree to keep Data confidential, encrypted (if stored in an electronic medium), and off of publicly available Data storage platforms. Recipient and Recipient's PI agree to make reasonable efforts to avoid contamination or waste of Materials.

RECIPIENT'S PI INITIALS:

13. Resultant Data to be Provided to JHS and NHLBI. Every twelve (12) months, Recipient and Recipient's PI agree to provide JHS with a report based on the Resultant Data. This report shall include a description of the activities performed and Resultant Data obtained up to the reporting date. Recipient and Recipient's PI agree to provide Resultant Data to JHS in accordance with applicable NIH and NHLBI data sharing policies in place as of the effective date of this agreement. Recipient and Recipient's PI agree that JHS and NHLBI may distribute all such Resultant Data through established NHLBI procedures to any institutions requesting access for their qualified scientific investigators. Recipient and Recipient's PI will provide Resultant Data in the electronic format specified by NHLBI or JHS. If errors in family structure, including paternity, are identified, Recipient and Recipient's PI agree to contact the Coordinating Center Authorized Representative (named below), at the time such errors are identified, to receive detailed instructions on how and to whom to provide such information. Recipient and Recipient's PI agree to refrain from disclosing identified errors to anyone other than individual(s) specifically identified and authorized by JHS and NHLBI.

RECIPIENT'S PI INITIALS:

14. Costs/No Warranties. Cost for Materials distribution will be determined on a case by case basis. Costs are subject to change following written notification from JHS with the approval of NHLBI. NO WARRANTIES, EXPRESS OR IMPLIED, ARE PROVIDED AS TO THE MERCHANTABILITY OR FITNESS FOR ANY PURPOSE OF THE MATERIALS AND/OR DATA PROVIDED TO RECIPIENT UNDER THIS AGREEMENT.

15. Recipient's Responsibility for Handling Materials. Recipient and Recipient's PI acknowledge that Materials may carry viruses, latent viral genomes, and other infectious agents. Recipient and Recipient's PI agree to treat Materials as if they were not free of contamination, and affirm that Materials will be handled by trained persons under laboratory conditions that afford adequate biohazard containment. By accepting Materials, Recipient assumes full responsibility for their safe and appropriate handling.

16. Non-Endorsement, Indemnification. Recipient and Recipient's PI agree not to claim, infer, or imply United States Government endorsement of the Research Project, the entity, or personnel

conducting the Research Project, or any resulting commercial product(s) except as described in section 7.

Recipient and Recipient's PI agree to hold the United States Government, JHS, and all investigator(s) who generated Data and Materials, and the agents and employees of each of them harmless and release them from all liabilities, demands, damages, expenses, and losses arising out of Recipient or Recipient's PI's negligence.

17. **Accuracy of Data.** Recipient agrees that the United States Government and JHS are not responsible for the accuracy of Data or the provenance or integrity of Materials provided.

18. **Recipient's Compliance with Recipient IRB's Requirements.** Recipient and Recipient's PI agrees to use the Data and/or Materials only in conjunction with the Research Project that has been reviewed by the Recipient's Institutional Review Board (IRB) or similar human subjects oversight body in accordance with Department of Health and Human Services regulations at 45 CFR Part 46. Recipient and Recipient's PI agrees to comply fully with all such conditions and with the participants' informed consent documents, and any additional conditions that may be imposed by the JHS IRB(s). Recipient agrees to report promptly to the JHS and NHLBI any unanticipated problems or proposed changes in the Research Project. Recipient also agrees to report to Recipient's IRB any unanticipated problems or changes in the Research Project that involve additional risks to participants or others. Recipient remains subject to applicable state and local laws and regulations and institutional policies that provide additional protections for human subjects.

Example

RECIPIENT'S INITIAL

19. **Recipient's Responsibility to follow Data Security Best Practices.** Recipient is aware of computer and Data security best practices and will follow them for receipt, storage and use of Data and Resultant Data. An example of best practice guidelines can be found in http://www.ncbi.nlm.nih.gov/projects/gap/pdf/dbgap_2b_security_procedures.pdf.

20. **Amendments.** Amendments to this DMDA must be made in writing and signed by authorized representatives of all signatory Parties hereto.

21. **Termination.** This DMDA shall terminate at the earliest of: the completion of the Research Project; five (5) years after the effective date of this DMDA; abandonment of the Research Project; or violation by Recipient of any provisions of this DMDA not remedied within 30 days after the date of written notice by NHLBI and JHS of such violation, debarment or disqualification.

Upon termination of this DMDA:

Recipient agrees to destroy all copies of all Data received from JHS and consult with the JHS and the NHLBI regarding the disposition of all remaining Materials. Recipient will verify that the JHS data have been destroyed in a written or electronic communication to the JHS Coordinating Center.

22. **Disqualification, Enforcement.** Failure to comply with any of the terms of this DMDA may result in disqualification of Recipient and Recipient's PI from receiving additional Data and/or Materials. The United States Government and/or JHS may have the right to initiate legal actions at law or in equity

against the Recipient for violating or manifesting an intent to violate the confidentiality requirements of this DMDA, the limitations on the use of the Data or Materials provided, or both. Proceedings may be initiated against the violating party, or legal representatives, and assigns, for a restraining injunction, compensatory and punitive damages, mandamus, and/or any other proceeding at law or in equity, including obtaining the proceeds from any intellectual property or other rights that are derived in whole or in part from the breach of the confidentiality requirements or use limitations of this agreement. In addition, Recipient and Recipient's PI acknowledge that a breach or manifesting an intent to breach the confidentiality requirements or use limitations of this DMDA may subject Recipient and Recipient's PI to legal action on the part of JHS participants, their families, or both.

RECIPIENT'S PI INITIALS:

23. Prior Distribution Agreements. By execution of this DMDA, Recipient certifies to the best of its knowledge that it is in compliance with the terms and conditions of all its existing DMDAs with JHS and/or the NHLBI.

Required signature begins on the next page

Example



SIGNATURE PAGE

RECIPIENT'S PRINCIPAL INVESTIGATOR:

Read and Understood by the Recipient's Principal Investigator:

I agree to abide by the terms and conditions laid out in this agreement and acknowledge that I am steward of the data and/or materials for the duration of this agreement and am responsible for my own actions and those that I supervise or that are working under my direction.

[Redacted box]

Name and Title of Recipient's Principal Investigator

[Redacted box]

Mailing Address of Recipient's Principal Investigator

[Redacted box]

Email Address of Recipient's Principal Investigator

[Redacted box]

Telephone and Fax Number of Recipient's Principal Investigator

[Redacted box]

Signature of Recipient's Principal Investigator and Date

[Redacted box]

Example

RECIPIENT'S AUTHORIZED REPRESENTATIVE:

[Redacted box]

a [non-profit] OR [for-profit] corporation/institution

Name of Recipient (Corporation/Institution)

organized under the laws of (State/Country):

[Redacted box]

with a principal address at:

[Redacted box]

[Redacted box]

Name and Title of Recipient's Authorized Representative

[Redacted box]

Signature and Date of Recipient's Authorized Representative



National Heart, Lung,
and Blood Institute

DEPARTMENT OF HEALTH AND HUMAN SERVICES

COORDINATING CENTER FOR JACKSON HEART STUDY (JHS)

[Redacted box]

Name and Title of JHS Coordinating Center Authorized Representative

[Redacted box]

Signature and Date of JHS Coordinating Center Authorized Representative

NHLBI (for Materials only):

[Redacted box]

Name and Title of NHLBI JHS Representative

[Redacted box]

Signature and Date of NHLBI JHS Representative

This Distribution Agreement is entered into as of: [Redacted box] (effective date)

Example

Appendix 12: Statement of Authors Form

**Statement of Authors (SoAs) upon Submission of a Manuscript to Publications and Presentations Subcommittee
Jackson Heart Study**

Paper #: Title:

I agree that each of the co-authors has made contributions as noted below and that these contributions are sufficiently substantive to merit authorship.

1. First Author:	<input type="text"/>	Signature: <input type="text"/>	Date: <input type="text"/>
** Each co-author should select your contribution(s) to this manuscript and sign **			
2. Co-Author:	<input type="text"/>	Signature: <input type="text"/>	Date: <input type="text"/>
Contribution:	<input type="checkbox"/> concept and design <input type="checkbox"/> acquisition, analysis, or interpretation of data <input type="checkbox"/> drafting of the manuscript <input type="checkbox"/> critical review of the manuscript for important intellectual content <input type="checkbox"/> statistical analysis <input type="checkbox"/> obtained funding <input type="checkbox"/> administrative, technical, or material support <input type="checkbox"/> supervision		
3. Co-Author:	<input type="text"/>	Signature: <input type="text"/>	Date: <input type="text"/>
Contribution:	<input type="checkbox"/> concept and design <input type="checkbox"/> acquisition, analysis, or interpretation of data <input type="checkbox"/> drafting of the manuscript <input type="checkbox"/> critical review of the manuscript for important intellectual content <input type="checkbox"/> statistical analysis <input type="checkbox"/> obtained funding <input type="checkbox"/> administrative, technical, or material support <input type="checkbox"/> supervision		
4. Co-Author:	<input type="text"/>	Signature: <input type="text"/>	Date: <input type="text"/>
Contribution:	<input type="checkbox"/> concept and design <input type="checkbox"/> acquisition, analysis, or interpretation of data <input type="checkbox"/> drafting of the manuscript <input type="checkbox"/> critical review of the manuscript for important intellectual content <input type="checkbox"/> statistical analysis <input type="checkbox"/> obtained funding <input type="checkbox"/> administrative, technical, or material support <input type="checkbox"/> supervision		
5. Co-Author:	<input type="text"/>	Signature: <input type="text"/>	Date: <input type="text"/>
Contribution:	<input type="checkbox"/> concept and design <input type="checkbox"/> acquisition, analysis, or interpretation of data <input type="checkbox"/> drafting of the manuscript <input type="checkbox"/> critical review of the manuscript for important intellectual content <input type="checkbox"/> statistical analysis <input type="checkbox"/> obtained funding <input type="checkbox"/> administrative, technical, or material support <input type="checkbox"/> supervision		
6. Co-Author:	<input type="text"/>	Signature: <input type="text"/>	Date: <input type="text"/>
Contribution:	<input type="checkbox"/> concept and design <input type="checkbox"/> acquisition, analysis, or interpretation of data <input type="checkbox"/> drafting of the manuscript <input type="checkbox"/> critical review of the manuscript for important intellectual content <input type="checkbox"/> statistical analysis <input type="checkbox"/> obtained funding <input type="checkbox"/> administrative, technical, or material support <input type="checkbox"/> supervision		
7. Co-Author:	<input type="text"/>	Signature: <input type="text"/>	Date: <input type="text"/>
Contribution:	<input type="checkbox"/> concept and design <input type="checkbox"/> acquisition, analysis, or interpretation of data <input type="checkbox"/> drafting of the manuscript <input type="checkbox"/> critical review of the manuscript for important intellectual content <input type="checkbox"/> statistical analysis <input type="checkbox"/> obtained funding <input type="checkbox"/> administrative, technical, or material support <input type="checkbox"/> supervision		
8. Co-Author:	<input type="text"/>	Signature: <input type="text"/>	Date: <input type="text"/>
Contribution:	<input type="checkbox"/> concept and design <input type="checkbox"/> acquisition, analysis, or interpretation of data <input type="checkbox"/> drafting of the manuscript <input type="checkbox"/> critical review of the manuscript for important intellectual content <input type="checkbox"/> statistical analysis <input type="checkbox"/> obtained funding <input type="checkbox"/> administrative, technical, or material support <input type="checkbox"/> supervision		
9. Co-Author:	<input type="text"/>	Signature: <input type="text"/>	Date: <input type="text"/>
Contribution:	<input type="checkbox"/> concept and design <input type="checkbox"/> acquisition, analysis, or interpretation of data <input type="checkbox"/> drafting of the manuscript <input type="checkbox"/> critical review of the manuscript for important intellectual content <input type="checkbox"/> statistical analysis <input type="checkbox"/> obtained funding <input type="checkbox"/> administrative, technical, or material support <input type="checkbox"/> supervision		

Example

(Continue authors on the next page if needed.)

NOTE: The signed SoAs are due when the manuscript is submitted to P&P for review. Digital signatures are accepted.

Appendix 13: Jackson Heart Study Lay Summary Template

TEMPLATE: STANDARD FORMAT FOR LAY SUMMARIES OF JHS PUBLICATIONS

*Note: In order to monitor reading level to meet the criteria (should be 10th-grade level or below), use [Flesch Kincaid Readability Test](#)

Lay Title:

Original Title:

By: (Original Authors):

Introduction (8-9 lines):

Purpose (2-4 lines):

Method (3-5 lines):

Conclusion (3-5 lines):

Implications (3-5 lines):

Formatted for Posting on JHS Public Website by: _____ Date _____

Appendix 14: JHS Acknowledgment Statement and Disclaimer

Acknowledgment Statement

- “The Jackson Heart Study is supported by Contracts HHSN268201800010I, HHSN268201800011I, HHSN268201800012I, HHSN268201800013I, HHSN268201800014I, HHSN268201800015I from the National Heart, Lung, and Blood Institute (NHLBI) with additional support from the National Institute on Minority Health and Health Disparities (NIMHD).”

“This manuscript has been reviewed by JHS for scientific content.”

If whole genome sequencing/TOPMed data is used, the following acknowledgment should also be included:

- “The Jackson Heart Study (phs000964.v1.p1) whole genome sequencing was performed at the Northwest Genomics Center (HHSN268201100037C). Core support including centralized genomic read mapping and genotype calling, along with variant quality metrics and filtering were provided by the TOPMed Informatics Research Center (3R01HL-117626-02S1; contract HHSN268201800002I). Core support including phenotype harmonization, data management, sample-identity QC, and general program coordination were provided by the TOPMed Data Coordinating Center (R01HL-120393; U01HL-120393; contract HHSN268201800001I).”

Disclaimer Statement

- “The views expressed in this manuscript are those of the authors and do not necessarily represent the views of the National Heart, Lung, and Blood Institute (NHLBI); the National Institute on Minority Health and Health Disparities (NIMHD); the National Institutes of Health; or the US Department of Health and Human Services.”

Appendix 15: NIH Public Access Policy
<https://sharing.nih.gov/public-access-policy>

NIH Public Access Policy – PubMed Central (PMC) for JHS What is it?

- A federal U.S. Law which ensures that the public has access to the published results of NIH-funded research at the [Home - PMC - NCBI \(nih.gov\)](https://www.ncbi.nlm.nih.gov/pmc/), a free digital archive of full-text biomedical and life sciences papers available online without a fee.
- Requires that such papers are publicly available no later than 12 months after publication. Provided that the NIH shall implement access policy in a manner consistent with copyright law.

Who is responsible?

- Corresponding authors of peer-reviewed manuscripts that use data from directly-funded studies such as JHS and that were accepted after April 7, 2008.
- JHS grantee/contractors: Papers submitted to PMC will be assigned a PMCID that must be cited by the JHS grantee/contractors in all future NIH applications, proposals or progress reports submitted to NIH. If a JHS grantee has failed to materially comply with the terms and conditions of award, NIH may suspend the grant, pending corrective action, or may terminate the grant for cause. In 2013, NIH implemented New Enhanced Compliance measures allowing the Institute to delay processing of non-competing continuation grant awards if publications arising from that award are not in compliance with the NIH public access policy.
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 - **Method B (author pays journal or publisher to submit):** Journal or publisher submits final published article within 12 months of publication – no further author action required.
 - **Method C (neither Journal nor Publisher participate):** Author must manually submit final accepted version of manuscript upon acceptance and link all relevant grant and contracts to the manuscript. Additional designated coauthors must log in and approve manuscript submission.
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3. **(Method C only):** If you are a responsible corresponding author, create or login to an account at <http://www.nihms.nih.gov/> and upload the manuscript upon acceptance to PMC, referencing all required and relevant JHS grants and contracts.
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