NHLBI HeartShare Program
Abstract, Presentation, Publication, and Data Request Policies and Procedures

Contents

1. Overview

The HeartShare Study is an innovative program funded by the US National Heart, Lung, and Blood Institute (NHLBI) at the National Institutes of Health (NIH). We seek to better understand the biological basis of heart failure with preserved ejection fraction (HFpEF) by using cutting edge technologies, big data, and artificial intelligence, with the ultimate goal of finding new ways to prevent and treat HFpEF. The success of the HeartShare Study will be judged, partly, on the number and quality of its scientific publications and presentations. The purpose of the policies established herein is to encourage important analyses and facilitate publications while providing guidelines that assure appropriate use of any HeartShare Study data, timely completion of manuscripts, and adherence to the principles of authorship. The HeartShare Study publications and ancillary studies process is overseen by the Publication and Ancillary Studies (PAS) Committee, the structure and membership of which is defined in this policy.

Website: www.HeartShareStudy.org
Email: HeartShareStudy@northwestern.edu
Twitter: @HeartShareStudy

A. Definitions of HeartShare Study Components

- **CC**: Clinical Center, NHLBI has named six CCs, the Foundation for the National Institutes of Health (FNIH) has named a seventh CC through the Accelerating Medicines Partnership Heart Failure (AMP HF) Program.
- **DTC**: Data Translation Center at Northwestern University Feinberg School of Medicine. Consists of the Administrative and Outreach Core, Cohort Core, Data Portal Core, and Data Management Core.
- **NHLBI**: National Heart, Blood, and Lung Institute, a division of the National Institutes of Health, the funding agency for the Program.
- **PAS Committee**: Publications and Ancillary Studies Committee, a subcommittee responsible for administering the HeartShare Program Publications Policy, with final adjudication by the Steering Committee. It is made up of a representative from each HeartShare Study site, the DTC, AMP HF partners, NHLBI, and Co-Chairs.
- **SC:** Steering Committee, responsible for final approval of publications proposed by HeartShare Program members and is made up of the principal investigator(s) at each HeartShare Study site, the DTC, AMP HF partners, NHLBI, and the two Co-Chairs.

B. Objectives of the PAS Committee

- To encourage publication submissions – particularly collaborative works involving multiple HeartShare Program sites.
- To ensure and expedite orderly and timely presentations to the scientific community of all pertinent data resulting from HeartShare Program studies.
- To ensure scientifically accurate presentations and papers from HeartShare investigators.
- To maintain a complete up-to-date list of HeartShare Program presentations and publications, and to distribute such lists to all HeartShare investigators on a regular basis.

- To support submission of Ancillary Studies that are aligned with HeartShare objectives for extramural funding

C. Administrative Structure of the PAS Committee

The PAS Committee oversees all HeartShare Program publication activities and ancillary studies, with final adjudication of decisions by the SC. The PAS Committee approves the proposal of publications, the submission of abstracts, as well as completed manuscripts before they are submitted for publication and presentations before they are made in a public forum. The PAS Committee will deliberate on HeartShare ancillary studies. The PAS Committee submits its decisions to the SC for approval at the SC meeting. Appeals of the PAS Committee decisions may be made to the SC. However, the expectation is that only occasionally will decisions made by the PAS Committee be discussed at SC meetings in detail. Such occasions might be an appeal or another exceptional circumstance.

If more than one person submits the same or similar topic, the PAS Committee may decide who will assume the project lead. The PAS Committee also may re-assign first responsibility if reasonable progress on completing an abstract or manuscript has not occurred.

D. PAS Tracking and Reporting Activities

The PAS Committee will provide access to a listing of ancillary studies and publications via the HeartShare Program website. This report lists the Lead Author, Senior Author, working title, date of receipt, proposal status, and date of approval by the SC. For publications, the journal submission title and final reference will be included.

The following reports will be distributed at each SC meeting:

- Ancillary Study list
- Manuscript Status List - number, title, lead author, date received, status, date submitted, and date approved.
- Manuscript Publication List - full citations of all papers published to date.
- Abstract Presentation List - full citations including names of meetings and dates.

E. Membership of the PAS Committee

The PAS Committee will comprise of members from all the CCs, the DTC, NHLBI, and the SC Co-Chairs. The following individuals serve on the PAS Committee as of January 2022 with a term to be determined. Recommendations to replace member to be nominated by each CC, DTC, HF AMP partner, or NHLBI, if needed.

Name	**Institution**
Sadiya Khan (Co-Chair)	Northwestern CC
Renee Wong (Co-Chair)	NHLBI
Sanjiv Shah	Northwestern DTC
Denise Scholtens	Data Management Core
Lauren Balmert Bonner	Data Management Core
Peggy Doyle	Biospecimen Core

David Kass/Kavita Sharma?	Johns Hopkins CC
Bret Goodpaster	Muscle/Adipose Core
Barry Borlaug	Mayo CC
Maggie Redfield	Mayo CC
Akshay Desai	MGH/BWH CC
Michael Givertz	MGH/BWH CC
Imo Ebong	UC Davis CC
Javier Lopez	UC Davis CC
Nipavan Chiamvimonvat	UC Davis CC
Julio Chirinos	Penn CC
Alain Bertoni	Wake Forest CC
Nicole CyrilleSuperville	Wake Forest CC
Lothar Roessig	Bayer
Mark Perelis	Ionis
Dieter Kubli	Ionis
Maria Hughes	Novartis
Mike Mendelson	Novartis
Ashley Akerman	Ultromics
Ross Upton	Ultromics
Svati Shah	SC Co-Chair
Javed Butler	SC Co-Chair
Patrice Desvigne-Nickens	NHLBI
Jung Nam Joo	NHLBI
Vandana Sachdev	NHLBI
Emily Tinsley	NHLBI

2. Definitions

A. Main Papers and Presentations

Main papers and presentations are those reporting results dealing with the main objectives of HeartShare, as well as papers and presentations using the complete study data set. In general, main papers and presentations refer to use of study data from all sites.

B. Design Paper

A design paper reports the design of a study rather than analysis of study data. Benefits of a design paper include demonstrating innovations as well, as the ability for citation in future papers (e.g., main and ancillary results). HeartShare expects to publish a design paper written early in the study, and additional papers may report results, specialized processes, lessons learned, etc.

C. Abbreviated Communications

Abbreviated communications, typically in the form of a letter to the editor, may be appropriate from time to time for clarification of previously published work, response to critiques, or dissemination of important negative results that would not be publishable in a full paper.

D. Other Papers and Presentations

Other papers and presentations are those not encompassed by the above categories. Examples include those related to work done in ancillary studies, papers related to HeartShare operations, and manuscripts using datasets from non-HeartShare investigators and HeartShare data.

E. Content

1. HeartShare study design, screening, and baseline data may be used for preparation of abstracts and presentations prior to the planned end of the study.
2. Observational studies with complete data on an intermediate time point may be used for preparation of abstracts and presentations prior to the planned end of the study, either by agreement of the PAS Committee or for study aims that were pre-specified in the protocol.
3. With the exceptions listed in points 1 and 2 above, HeartShare data involving patients will not be analyzed for purposes of publication or presentation outside HeartShare until the planned end of the study.

F. HeartShare Investigator

A HeartShare investigator is staff (e.g., physician, coordinator, core lead) at the DTC, a CC or a core laboratory AMP HF industry partner, or NHLBI staff, who is involved in conducting the HeartShare study.

G. Investigator Datasets

HeartShare investigator datasets are similar to public use datasets, but are accessible only to HeartShare investigators and not fully de-identified. With approval from the SC and DTC?, HeartShare investigators may access these datasets for the purpose of preparing manuscripts using local (non-DTC) statisticians. Manuscripts prepared in this fashion are governed by all HeartShare publications procedures [e.g., formation of Writing Committee (WC), WC responsibilities, and PAS approval).

NHLBI has guidelines on de-identification. The HeartShare standard is generally to include a blinded CC ID in investigator and public use datasets. However, this will not be included for studies with only CC and/or relatively few participants per CC, or if there is a study-specific reason to not include a blinded CC ID.

H. Quorum

All materials and decisions for approval by the PAS Committee rather than just the PAS Chairs require a quorum of 9 PAS Committee members (1 vote per clinical center/core/industry partner/SC Chair/NHLBI). In all instances, the waiting period for PAS Committee member response is the stated deadline for the review/decision in question, even if 9 members reply before the deadline.

3. Proposal and Approval Process for Abstracts, Presentations, Publications, and Data Requests

A. Research Data Sharing

NIH believes that data sharing is essential for expedited translation of research results into knowledge, products, and procedures to improve human health. NIH endorses the sharing of final research data to serve these and other important scientific goals and expects and supports the timely release and sharing of final research data from NIH-supported studies for use by other researchers." 'Timely release and sharing' is defined as no later than the acceptance for publication of the main findings from the final data set. The main findings are defined as including the primary and important secondary endpoints.

As stated in the to the NIH Policy for Data Management and Sharing, NHLBI encourages submission of data into NHLBI BioData Catalyst (BDC), especially for data from studies that must comply with NHLBI's Accrual of Human Subjects (Milestones) Policy and for those projects supported by funding opportunity announcements that encourage data deposition into BDC. NHLBI also encourages the submission of data into BDC for NHLBI projects and ancillary studies to NHLBI parent studies subject to the NIH Genomic Data Sharing Policy. For data submitted to repositories other than BDC, an appropriate globally-unique, persistent identifier with sufficient metadata should be shared with NHLBI to promote FAIR principles and populate a master index for data generated from all NHLBI-supported research.

B. Data Analysis of Study Outcomes

The statistical analysis of HeartShare studies is performed by the DTC. The Final Study Report (FSR) of the study will be issued by the DTC following completion of the statistical analyses. The FSR is generally available within 2 to 3 months of locking the study dataset. The SC Chairs will monitor progress toward completion of the FSR.

C. Data Analysis Requests

Prior to submission of de-identified study datasets to BDC, HeartShare data analysis requests are only available to HeartShare investigators. Access is governed by the policies and procedures outlined below. Investigator datasets are for the use of HeartShare investigators only, as well as collaborations with HeartShare and AMP HF. Other collaborations would require a data use agreement. Data can only be used for publications, presentations, or other purposes with the approval of the SC and PAS Committee (if required). Publications and presentations must follow standard HeartShare procedures, including prioritization by the SC, co-author sign-up, and approvals through the DTC, and approval for submission by the PAS Committee.

Types of Data Available

Data available through HeartShare are those collected in the course of preparing, implementing, and conducting clinical studies.

Stipulations for Data Analysis Requests

1. A request for data analysis should be made using the HeartShare Data Analysis Request and Writing Topic Proposal Form (*Appendix 1*).
2. Data are analyzed at the DTC, and the raw data are not shared with other investigators.
4. Any publication, public presentation, or electronic posting of HeartShare data must

receive HeartShare review and approval prior to release.

5. HeartShare investigators must acknowledge NHLBI/NIH HeartShare and FNIH AMP HF support in the manuscript, and the submission of the final printed manuscript is managed by the HeartShare DTC.

D. Data Request Types

Request for Center-Specific Data

Center-specific data are available only to the center itself and are intended for the investigator's exclusive internal use.

Request for Patient-Specific Data

Patient-specific data are not made available unless the request is made by an agency or individual with legal authority or is accompanied by an appropriate, signed informed release executed by the patient, the patient's legal guardian, or patient's heirs.

Request for Permission-To-Publish Data

Permission-To-Publish data requests are made by individuals for the purpose of preparing review articles or similar presentations, including requests to reproduce previously published figures or graphs.

Proper acknowledgement to HeartShare and AMP HF is required for any material publicly published, presented, or posted and will require the same acknowledgements as delineated below.

E. General Abstract and Manuscript Policy

The SC, in collaboration with the DTC, will develop a list of potential manuscripts, target journals, and Writing Committee (WC) membership. The PAS Committee will approve the potential manuscripts and WCs, as well as prioritize the efforts.

Although the SC will generate most proposals for abstract and manuscript topics, any HeartShare investigator can propose a writing topic to the SC and PAS Committees.

An overview of the steps in this process is below.

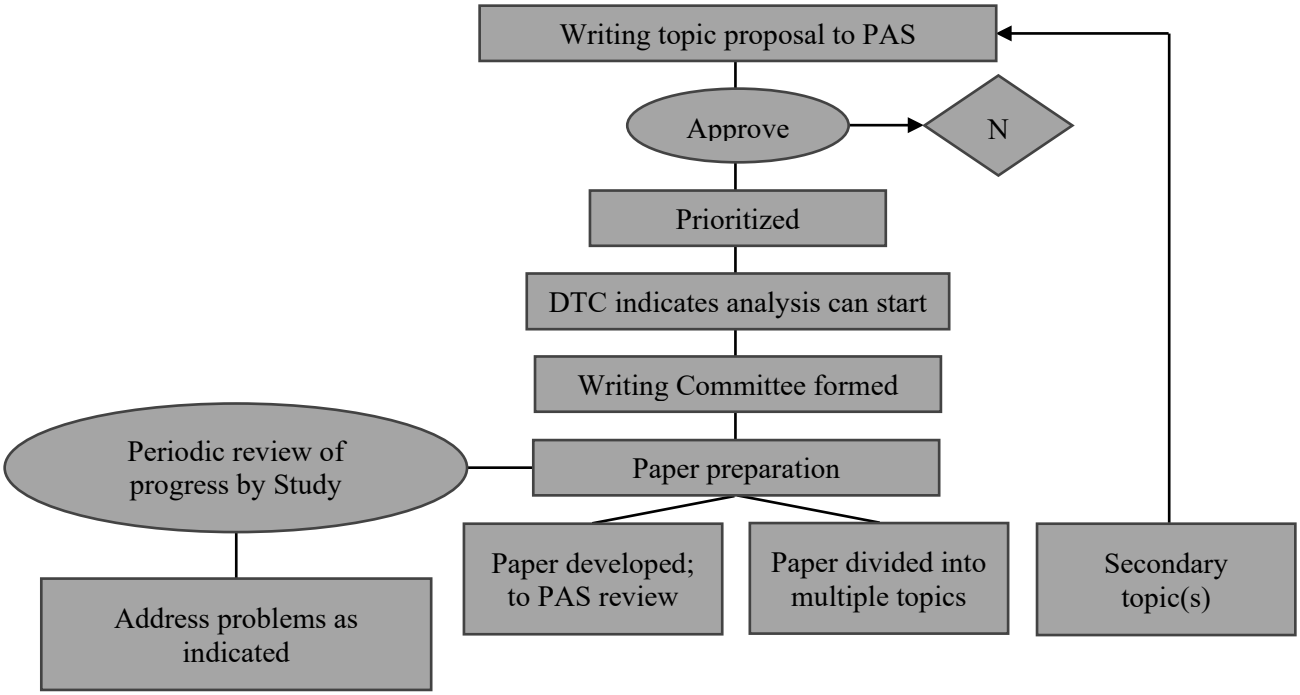

Figure 1. Manuscript Preparation Steps

The PAS Committee is charged with evaluating and prioritizing all proposals for abstracts, presentations, and manuscripts related to the main study. All publications from HeartShare will require approval from the PAS Committee. Any manuscripts utilizing HeartShare data, including those arising from approved ancillary studies, will require approval from the PAS Committee. Single- or multi-site projects that are focused on topics relevant to the HeartShare Program or make extensive use of HeartShare-generated meta-data or procedures/protocols must adhere to the publication approval process outlined below. Multi-site projects should have data and resources available to be analyzed and a draft of the manuscript within approximately one year from Data Analysis Request and Writing Topic Proposal Form submission.

F. Manuscript Selection and Prioritization

A primary manuscript reporting the results of HeartShare or a HeartShare position paper will be prepared in a timely manner upon completion of the study. No HeartShare primary study results will be released, presented, or published prior to the conclusion of the study and release of the final dataset by the SC.

G. Proposal Submission and Approval Process for Manuscripts

1. Prior to writing a manuscript utilizing HeartShare data, a Data Analysis Request and Writing Topic Proposal Form must be submitted in writing to the PAS Committee.
2. This process may be initiated by the SC, individual investigators with or without affiliation with HeartShare sites, or the DTC. Each Data Analysis Request and Writing Topic Proposal Form should include at least one HeartShare Investigator sponsor. The Lead (first) Author submits a completed Data Analysis Request and Writing Topic Proposal Form (*Appendix 1*), which is reviewed by the PAS before starting data analysis, forming a Writing Committee (WC), and preparing the manuscript.
3. Writing Topic Proposals should include the following information: submission date,

requesters, working title, objectives/rationale, research hypothesis, abstract, HeartShare data needed [main and/or ancillary study data], brief analysis plan and statistical support needed, references, potential journals, and overlap with exciting proposals.

4. Writing Topic Proposals should be written with the understanding that only one paper will be prepared if the proposal is approved.
5. The PAS Committee will review the proposal within the context of other proposed and approved writing topics. If approved, the topic will be prioritized for development. If approved with modifications, the Writing Topic Proposal must be revised before it is sent out for WC member nominations.
6. If during the course of developing a paper, the WC determines that the original topic is best addressed in multiple papers, the WC must choose the specific paper they will write and provide the PAS Committee Chairs with a brief explanation. The PAS Committee Chairs will determine the suitability and priority of the chosen subtopic, and has the discretion to involve the PAS Committee as a whole in this assessment. Writing Topic Proposals will then need to be developed for topics not included in the chosen paper and these must be submitted, approved, and prioritized following the procedures herein. A WC(s) will be constituted for the approved topic(s) per the procedures in *Section H "Selection of Writing Committee (WC) Chair and Members for Papers and Abstracts."*
7. In general, an individual should not be Chair of more than one actively working WC at a time. A WC is considered to be "actively working" from formation until a manuscript is submitted to a journal. With appropriate justification, the PAS Committee Chairs will approve exceptions to this rule.
8. The DTC will inform the PAS Committee when data analysis for an approved writing topic can begin and will assign a statistician to the topic. In the case of manuscripts using investigator datasets and non-DTC statisticians, the WC Chair will inform the DTC of the assigned statistician and the proposed start date of the analysis.
9. From time to time it may become apparent, before a WC is convened, that there are negative or other minor results from a HeartShare or ancillary study that merit reporting (e.g., form of a letter to the editor). In this circumstance, the lead investigator—either the HeartShare investigator or the ancillary study PI—should notify the PAS Committee Chairs of the intent to submit an abbreviated communication, along with the proposed author list. The PAS Committee Chairs have the discretion to decide whether or not additional HeartShare authors need be identified.

H. Selection of Writing Committee (WC) Chair and Members for Papers and Abstracts

1. In most cases, the proposer of a Writing Topic will chair the WC and be the Lead Author. The PAS Committee Chairs and WC Chair will determine the membership of the WC. All WCs for main papers, abstracts, and presentations will have DTC representation. Any disagreements about the membership of a WC will be addressed first by the PAS Committee. If resolution is not possible, the matter will be referred to the SC.
2. A WC will be constituted when the DTC indicates that data analysis for a topic can begin within two months, or when a HeartShare Investigator has indicated that a manuscript using an investigator dataset is ready to begin analysis. On behalf of the PAS Committee Chairs, the DTC will invite nominations from HeartShare Investigators. The WC Chair must provide the rationale for each nominee (such as level of participation in the development or implementation of the study protocol, or the nominee's specialty area of expertise). Nominations received by the stated deadline will be forwarded to the PAS

Committee Chairs and copied to the NHLBI.

3. Most WCs will have one representative from each HeartShare site. However, in some instances, it may be appropriate for a site to nominate more than one representative, and in others none, depending on the topic. A HeartShare investigator can propose more than one nominee, under exceptional circumstances, with appropriate justification. Examples of reasons for additional nominees include a mentor-mentee relationship and, for manuscripts using investigator datasets, local (non-DTC) statisticians.
4. It is the intent that selection of WC members is equitable and fair to all groups and individuals participating in this collaborative program, including encouragement of participation by younger professional colleagues and Study Coordinators, with due regard paid to exceptional efforts of groups or individuals.
5. The PAS Committee Chairs will send the list of approved WC members to the DTC. The DTC will then notify the members by email and send them the HeartShare Writing Committee Responsibilities. The DTC will post the writing topic and WC members, and the approved Writing Topic Proposal on the HeartShare website. The final analysis outline will be re-posted once the WC has met and finalized the plan.

I. Manuscript Preparation

The steps listed below should be followed in the preparation of HeartShare manuscripts.

1. WC Chair/Lead Author Responsibilities
   The WC Chair should first review the HeartShare Abstract, Presentation, Publication, and Data Request Policies and Procedures and then should:
   a. Contact the PAS Committee if a change in WC Chair/Lead Author is necessary (for instance, due to workload) and informs them of the request to transfer the lead to another individual.
   b. Keep the SC and PAS Committee informed of the manuscript's progress.
   c. Ensure that all authors meet ICJME requirements for authorship prior to submission.
   d. Submit the final version of a manuscript for approval by the PAS, which then sends recommendations to the SC . Authors must receive approval from SC prior to submitting the manuscript to a journal.
   e. Circulate a copy of the submitted manuscript to the writing group.
   f. Contact each WC member and review the specific charge to the WC and the timeline for developing the paper
   g. Communicate with the WC to develop a detailed manuscript outline, specify research hypotheses, and draft dummy tables. The Data Analysis Request and Writing Topic Proposal Form is to be modified by the WC Chair to document all WC decisions.
   h. Submit the finalized Data Analysis Request and Writing Topic Proposal Form and dummy tables to the DTC statistician and collaborate with the statistician to identify needed data and analyses. The WC was formed with the knowledge that the DTC is ready to perform needed analyses, but all should be aware that the DTC will process all requests for data analysis according to the overall priorities of HeartShare as determined by the SC. Analysis requests will be triaged by the DTC PI according to this principle and where necessary, if there are competing priorities across HeartShare studies, the SC will provide guidance.
   i. In the case of manuscripts utilizing investigator datasets and non-DTC statisticians, the WC Chair is responsible for identifying a statistician, communicating requests with them, and ensuring timely progress.
   j. Assume a leadership role in writing the paper (Lead Author). Obtain input from

every WC member and make every effort to accommodate the expression of differing interpretations and alternate analyses within the body of the manuscript, so that all points of view are represented to the satisfaction of every member. The WC Chair is responsible for tracking and documenting the contributions of the WC member with regard to input provided on all draft documents.

k. Monitor the progress of development of the paper.
l. Communicate with the PAS Committee Chairs if the WC decides that the original writing proposal is too broad and should be divided into two or more papers rather than the one paper originally approved (*Section 3, parts G4-6*).
m. Monitor the participation of the WC members. Members of each WC should participate actively in the writing and review of the paper assigned to that group. The following process will be used for addressing non-performing WC members:
    1. The WC Chair will first contact the individual directly and indicate concern over lack of participation. Defining this will be at the discretion of the WC Chair, but in general, would include failure to attend WC meetings or conference calls, failure to read and respond substantively to working drafts, and/or repeated failure to meet response deadlines.
    2. If there is still no or inadequate response from the individual, the WC Chair will notify the DTC and PAS Committee Chairs and copy the respective CC PI (in the event that the non-performing individual is a CC PI, the WC Chair will then instead copy the NHLBI Project Scientist). The CC PI (or PAS Committee Chair) will then speak directly with the individual.
    3. If reasonable participation is still not forthcoming, as determined by the WC Chair in consultation with the DTC and PAS Committee Chairs, the individual will be removed from the WC and excluded from co-authorship. Whether the CC PI can appoint a substitute will be considered on a case by case basis in consultation with the WC Chair and the PAS Committee Chairs.
n. Draft a brief (3-5 sentences) summary of the manuscript for the HeartShare public website that addresses the following: background/reason for undertaking the study, overview of method, key findings, and implications.

2. WC Member Responsibilities

Inclusion on a WC carries responsibilities that must be met in order to be included as an author for the paper or abstract (*Section 3, part J*). Each WC member is expected to:

a. Participate in all WC conference calls. If unable to attend a call, the member is expected to notify the WC Chair and the DTC and provide input to the Chair before the call.
b. Review the analysis summary before the call.
c. Review all drafts within the stated time frame (typically two weeks) and to provide commentary and/or edits to the WC Chair. If the topic of a conference call is to discuss a draft manuscript, members are expected to have read the manuscript before the call.
d. Review the final draft before its submission to the PAS Committee and submit the approval signoff to the DTC.
e. Voluntarily withdraw from a WC if unable to participate fully in the WC process. This will not preclude future participation in other WCs.

J. Authorship

PIs will ensure that all members at their site, who have contributed to the proposed effort

outlined in the manuscript proposal, will be proposed to the WC Chair for authorship. Once the manuscript proposal has been approved by the PAS Committee, it is then the responsibility of the WC Chair to communicate with all co-authors.

1. For main papers and presentations, the names of members of the WC shall be listed as authors in the masthead, followed by the phrase "for the HeartShare and AMP HF Investigators." The WC Chair, with the concurrence of WC members, should determine the order of authorship. The Chair may choose to add HeartShare investigators to the authorship who are not initially in the WC, with prior approval from the PAS Committee Chairs. A major criterion for order of authorship shall be the effort and contribution made by each member of the writing committee in preparation of the manuscript. Membership in a WC without substantive contribution to the manuscript does not justify authorship..
2. The list of authors may not be exactly the same on the abstract and corresponding paper.
3. The phrase "for the HeartShare and AMP HF Investigators" added after the names of the authors in the masthead is optional in papers reporting local data, or ancillary studies using local data.
4. Regardless of source of funding, papers produced from ancillary studies must acknowledge the use of HeartShare subjects in the Methods or Support section of the paper.
5. Acknowledgement of support from the NHLBI and FNIH must be included in all HeartShare papers and presentations with the following text (*Appendix 2*):
   "This work was supported by the NHLBI HeartShare Program through the following grants: U54 HL160273 (Northwestern University Data Translation Center); U01 HL160279 (Northwestern University); U01 HL160277 (University of Pennsylvania); U01 HL160274 (University of California at Davis); U01 HL160226 (Mayo Clinic); U01 HL160272 (Wake Forest); U01 HL160278 (Massachusetts General Hospital) and by the FNIH Accelerating Medicines Partnership Heart Failure (AMP HF) Program [including RFP 2023-1345-001 (Johns Hopkins University).
6. Disclosures of significant financial interest must be reported by all authors as required by the journal.
7. A credit roster of all major committees, core laboratories, the DTC, and HeartShare centers with their members (generally no more than ten persons from each center) is to appear at the end of each main paper (printed as an appendix). Each site PI, the DTC PI, and the NHLBI Project Scientist will be responsible for designating investigators from his/her center who are to be listed in this appendix. It is the responsibility of the DTC to solicit, obtain and prepare the final list for inclusion in each HeartShare study.
8. If an NHLBI staff member is listed as an author on a HeartShare manuscript, the following disclaimer (*Appendix 2*) must be included in the manuscript, and approval of the manuscript must be obtained by the NHLBI. To expedite approval, it is recommended that the article be submitted simultaneously to the PAS Committee and the NHLBI.
   "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; the National Institutes of Health; or the U.S. Department of Health and Human Services."
9. If a co-author of a HeartShare manuscript has a change in institutional affiliation between the time the research was performed and the time of publication, the affiliation of the co-author will be listed as the institution where the research was performed,

regardless of whether the new affiliation is a HeartShare site. If the first author has a change, then the author's current institutional affiliation and address will be listed separately from the research affiliation section of the title page, for correspondence purposes.

Authorship and Dispute Resolution
The PI of the proposed ancillary study or the WC Chair of each writing project, with the concurrence of other members of the group, determines the order of authorship. A major criterion for this determination is the effort and contribution made by the WC members in preparation of the manuscript. Criteria for authorship will follow the recommendations of the International Committee of Medical Journal Editors (ICMJE). ICMJE recommends that authorship be based on the following four criteria:

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting the work or revising it critically for important intellectual content; AND
- Final approval of the version to be published; AND
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

The primary requirement for authorship of any HeartShare publication is a substantive contribution to the research effort. This may include but is not limited to: hypothesis generation, concept development, protocol development, study implementation, subject enrollment, data collection, data analysis, and manuscript preparation and completion. While contributions by authors may occur in several areas, all are expected to contribute to manuscript preparation and completion.

All HeartShare Investigators (*Section 2, Part F*) are eligible for authorship on the final primary manuscript from the study. While eligibility for authorship does not guarantee authorship, eligible authors must still make substantive contributions.

Establishing Author Order
The person with the primary responsibility for writing the first draft manuscript will be the WC Chair/Lead Author. The ordering of authors depends on the intellectual input in study design and analysis and successful patient accrual and follow-up. The ordering of authors will be reviewed and approved by the PAS Committee.

K. Manuscript Review, Clearance, and Submission

Manuscript Review and Clearance
The purpose of manuscript review is to evaluate scientific merit, writing clarity, and consistency with other HeartShare Program findings.

If there is a NHLBI co-author, final versions of the manuscript must be submitted to the NHLBI program team for review and approval.

A copy of the manuscript is submitted to the PAS Committee, who will review and submit recommendation to the SC and NHLBI program team for review.

1. Submission to the PAS Committee should be treated as if the manuscript is absolutely ready to be submitted to a journal, so drafts should be clean, with figures labeled appropriately, and references in proper format.
2. Journal requirements for length and other formatting should be followed.
3. PAS Committee members will prepare comments on the manuscript and a recommendation for approval, modification, or disapproval of the manuscript on the electronic form provided. These forms should be submitted to the DTC and to the WC Chair simultaneously by the deadline. If the WC Chair is simultaneously a member of the PAS Committee, he/she will be recused from participation in PAS Committee decision-making related to that manuscript (other members of the WC who are also on the PAS Committee should still participate).
4. PAS Committee members should recuse themselves from review if they are engaged in any professional activity that might represent real or perceived conflict of interest and raise a question of bias. If in doubt about whether there is a potential conflict, please contact the PAS Committees or NHLBI.
5. The DTC will forward all comments received by the deadline to the PAS Committee Chairs. The PAS Committee Chairs will prepare a summary letter indicating approval or disapproval, proposing a resolution to any conflicts among reviewers' recommendations, and indicating whether PAS Committee review of the revised manuscript is required. This letter will be sent electronically to the DTC.
6. The DCC will then send the summary letter and copies of the comments from individual PAS Committee members electronically to the WC Chair and members.
7. If only minimal revisions (as indicated by the PAS Committee Chairs in the summary letter) are requested, the manuscript may be submitted for publication without additional PAS review. A copy of the submitted manuscript should be sent electronically to the DTC and to all co-authors by the WC Chair.
8. If substantial revisions (as indicated by the PAS Committee Chairs in the summary letter) are required, the revised manuscript will require formal re-approval by the co-authors, and then will be submitted to the DTC for distribution to the PAS Committee for review and approval before submission to the journal.
9. Upon PAS Committee approval of the final manuscript, the SC discusses the review and manuscript during conference call or by e-mail within two weeks. If no comments are received within this time period, the manuscript is considered approved.

Manuscript Submission

1. The final manuscript draft and a brief lay summary of the study findings for the HeartShare public website should be submitted to the DTC. The DTC will distribute this to each co-author for review with a form for final electronic sign-off. After this has been accomplished, the DTC will submit the manuscript and lay summary for the HeartShare public website to the PAS Committee for review, with a specified deadline.
2. If revisions to a manuscript are requested by a journal, the manuscript will be revised with input from all co-authors, at the discretion of WC chair, depending on the extent of the revisions and need for certain expertise among the WC members. All co-authors will confirm that they agree with the revisions. The revised manuscript and the letter to the editor will be sent to the DTC and forwarded to the PAS Committee Chairs for approval before resubmission to the original journal or to a new journal. If major revisions (with 'major' determined by the PAS Chairs) were requested by the journal, the PAS Committee will review the manuscript again.

3. If responses to published commentary are requested by a journal editor, the WC Chair will prepare and distribute the document to coauthors and PAS Committee Chairs for review with cc: to the DTC. The WC Chair will determine authorship of the commentary based on contributions, journal requirements/limitations, subject matter, and time frame. Distribution and documentation of published commentary will follow step HeartShare procedures.
4. Since all circumstances that might cause disagreement among HeartShare investigators on the content and conclusions of a given paper cannot be foreseen, these disagreements will be resolved by the PAS Committee. If resolution is not possible within the PAS Committee, the matter will be referred to the SC.

Manuscript PubMed Submission

1. When a manuscript is accepted for publication, it must be submitted to the National Library of Medicine's Pub Med Central as required by the NIH Public Access Policy.
2. The WC Chair/Lead Author is responsible for submission of any manuscript arising from a project with direct funds from NIH to the National Library of Medicine's PubMed Central. Assistance from the DTC with the submission process is available; however, the final responsibility for submission remains with the WC Chair/Lead Author.
3. Prior to submitting a manuscript to a journal, the WC Chair/Lead Author must ensure that all agreements with the journal publisher permit: 1) submission of the accepted manuscript to Pub Med Central; and 2) archiving the manuscript in the HeartShare central repository.
4. When a manuscript has been accepted for publication, the WC Chair/Lead Author must submit the manuscript to PubMed Central using the NIH Manuscript Submission System (NIHMS). A final manuscript includes manuscript revisions resulting from the peer review but not necessarily copyediting changes from the publisher. This submission fulfills the requirement to submit a copy of a publication with a grant progress report.
5. The WC Chair/Lead Author should indicate when the manuscript should be made public, i.e., from publication date to 12 months later.
6. If the manuscript is accepted by a journal that submits all NIH-funded final published articles to PubMed Central, then no further action is required by the WC Chair/Lead Author.
7. The WC Chair/Lead Author should send the initial NIHMS ID and then the PubMed Central reference number (PMCID) to the DTC. When preparing an application, proposal, or progress report, papers that resulted from NIH funding must be cited by including the PMCID at the end of the citation. When a PMCID is not yet available, then include the NIH Manuscript Submission System reference number (NIHMS ID) and state "PMC journal -- in process." Note: PubMed (PM ID) and PMC (PMC ID) numbers are different numbers

4. Policies for Abstracts and Presentations

A. Abstract Submission for Meetings

1. Abstracts will require review by the PAS Committee. They must comply with the policies and procedures set forth for single- and multi-site projects. HeartShare should be in the title of all abstracts.
2. The abstract must be circulated to the appropriate sites for approval and request for

authorship. The abstract must be reviewed by the author list associated with that approved project and all associated authors should be notified of an abstract submission.

3. All abstract citations should be sent to the PAS Committee before presentation at least 4 weeks prior to the meeting so that the HeartShare Program bibliography can be updated accordingly. If there is a NHLBI co-author, final versions of the abstract or presentation must be submitted to the NHLBI for review and approval.
4. With rare exception, abstracts must be based on a manuscript already under development in a previously convened WC, and will be prepared by that WC. The PAS Committee will give priority to abstracts based on manuscripts that are near completion. If an abstract proposal does require the formation of a new WC, then the steps for Study Committee approval and WC nomination outlined in *Sections G-J* should be followed.
5. In the rare event that a proposed abstract requires formation of a new WC, the proposal must be submitted to the PAS Committee and then to the DTC at least 4 months prior to the meeting abstract deadline to guarantee the availability of completed data analyses, the opportunity for WC discussion and interpretation of initial findings, and completion of requests for any secondary analyses. The initial analyses will be provided to the WC Chair of the abstract at least 7 weeks prior to the abstract deadline.
6. All WC members should have the opportunity to have input into the abstract and must approve the final draft before its submission to the PAS Committee. WC members will be listed as co-authors only if they have reviewed the abstract and accepted authorship prior to the abstract submission deadline.
7. The final abstract must be approved by the PAS Committee before it can be submitted to the meeting organizers for consideration. Completed abstracts and certification of co-author review must be submitted to the PAS Committee at least 10 days prior to the abstract deadline in order to guarantee review and allow time for revision if required by the PAS Committee. Supporting data in the form of tables and graphs should be included if these data are not contained in the abstract.
8. WCs are encouraged to have a first draft of the manuscript available for review by the entire Committee within 12 weeks of presentation of the abstract.
9. Abstracts from ancillary studies must also be approved by the PAS Committee prior to submission to meeting organizers. For an ancillary study using only local data, as determined by the PAS Committee, permission of the PAS Committee must be obtained before submission of results for presentation or publication if this occurs before publication of the main HeartShare study results. For all other single-center and multi-center ancillary studies, the PAS Committee Chairs will determine the level of PAS Committee review and approval required. If an abstract is submitted without prior PAS Committee approval, and the PAS Committee then disapproves, the author(s) will be required to withdraw that abstract immediately.

B. Presentations

1. New presentations will require review by the PAS Committee. HeartShare should be in the title of all abstracts. Use the HeartShare slide template for presentations
2. When an abstract is selected by the organizers for presentation at the meeting, the presentation itself—e.g. PowerPoint slides, poster, or other format—must also be reviewed and approved in advance by the PAS Committee. Submission of the presentation for PAS Committee review should occur no later than 10 days prior to the meeting date.
3. Slides or posters which either a) have been reviewed and approved previously and used

again for a different presentation or b) have been prepared using only published HeartShare data do not need to reviewed again by the PAS Committee. Copies of the slides or poster along with a description of the presentation (meeting name, purpose, date) should be sent to the DTC to include in the HeartShare bibliography. Presentations that include a few slides with published HeartShare data but do not focus on HeartShare studies do not have to be reported to the DTC.

5. Policies for Design Papers and Abbreviated Communications

A. Design Paper Preparation and Submission

Preparation and submission of design papers should, in general, follow the process outlined above. However, prioritization and a Writing Topic Proposal may not be required. In lieu of a WC, the Lead Authors may submit an abstract/paragraph to the DTC for distribution to the PAS Committee Chairs. Additionally, when only a small group has been leading the design, there may not be a need to have every site represented on the WC. The PAS Committee Chairs should be consulted for questions of authorship in such instances. Once the PAS Committee Chairs approve the proposed authorship, site PIs will be contacted to seek their concurrence with the proposed author from their site. There will not be a general call to all sites for proposed authors in this case.

B. Abbreviated Communication Preparation and Submission

Preparation and submission of letters to the editor and other abbreviated communications should, in general, follow the process outlined for abstracts and manuscripts. The PAS Committee Chairs may review these administratively or instead decide to refer them for full PAS Committee review. The PAS Committee Chairs should be consulted for questions of authorship on such communications.

6. Publication Process Documentation

1. For each publication, a Checklist will be maintained by the DTC so that adherence to the publication process is documented for each publication.
2. The DTC will document publication status on the HeartShare website for all HeartShare publications. The author list and analysis outline for each paper will be posted on the HeartShare website.
3. For the SC and PAS Committee calls, a summary table of manuscripts under preparation will be provided on a monthly basis.

7. Administrative Items: Acknowledgment Statements (*Appendix 2*), Reprints, and Publication Costs

1. Acknowledge all co-authors, HeartShare, and AMP HF.
2. Include relevant financial disclosures.
3. Acknowledge support from the NHLBI and FNIH must be included in all HeartShare papers and presentations with the following text (*Appendix 2*):
   "This work was supported by the NHLBI HeartShare Program through the following grants: U54 HL160273 (Northwestern University Data Translation Center); U01 HL160279

(Northwestern University); U01 HL160277 (University of Pennsylvania); U01 HL160274 (University of California at Davis); U01 HL160226 (Mayo Clinic); U01 HL160272 (Wake Forest); U01 HL160278 (Massachusetts General Hospital) and by the FNIH Accelerating Medicines Partnership Heart Failure (AMP HF) Program [including RFP 2023-1345-001 (Johns Hopkins University).

4. Include the following disclaimer (*Appendix 2*) if an NHLBI staff member is listed as an author on any HeartShare materials:
   "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; the National Institutes of Health; or the U.S. Department of Health and Human Services."
5. All requests for reprints of final and HeartShare Program network-wide papers are directed to the HeartShare site associated with the corresponding author of the paper. The costs of slides for specific presentations, publication of specific manuscripts, and reprints are the responsibility of the Lead Author. After manuscripts have been published, requests for non-individual level network-wide summary statistics can be released by the authors of the publication.

8. External Collaborations

The HeartShare Program is receptive to external collaborators that request to collaborate with the program and publish on scientifically relevant research topics. External collaborators are individuals that request to utilize HeartShare Program data. The Data Analysis Request and Writing Topic Proposal Form (*Appendix 1*) will follow the above guidelines with the addition of the following requirements:

- The external collaborator will not require a HeartShare Program member or investigator (site) to sponsor the introduction of the Data Analysis Request and Writing Topic Proposal Form to the PAS Committee. Upon approval of a Data Analysis Request and Writing Topic Proposal Form, the DTC or PAS committee will assign a HeartShare sponsor site or investigator, if one has not already been engaged.
- The HeartShare Program member sponsor (site) is responsible for executing the appropriate agreement with the external collaborator (e.g., research agreement; data transfer agreement) for performance of the study as applicable and assuring appropriate terms for data transfer, and compliance with HeartShare Program policies.
- HeartShare Program members can sponsor an external Data Analysis Request and Writing Topic Proposal Form.

9. Industry Collaborations

The HeartShare Program is composed of members and sites with specific expertise that is valuable for a multitude of projects that are of increasing interest to AMP industry sponsors. The DTC will act as the facilitator to connect HeartShare Program members with industry opportunities where the industry collaborator wants access to the sites and their expertise, however, does not want or need to utilize HeartShare data or work products.

The DTC will work with the industry collaborator to complete the Industry Collaboration Opportunity Form (Appendix XX TBD). The Industry Collaboration Opportunity form will be submitted for review and approval by the Steering Committee.

After circulation of the Industry Collaboration Opportunity form, the sites are responsible for contacting the industry collaborator if they are interested in participating. Contracts and data use agreements will be negotiated between individual sites and the collaborator. Network data will not be shared centrally as part of these industry collaborations.

The overall premise of AMP HF is to work together in a pre-competitive manner to speed and advance research observations. Rapid sharing of data and analytical tools will be enabled through a central data platform (such as the BioData Catalyst Platform). All users are subject to the platform's policies. Data generated through NIH awards are also subject to NIH policies and Federal laws and regulations. Any data provided for the AMP HF project must not include any personally identifiable information or any deidentified information that could be reidentified using reasonable efforts, technologies, or resources.

AMP HF researchers are encouraged to publish novel scientific findings that result from their research using AMP HF data in an open-access journal or in a hybrid open access journal as a fully open access article, and/or posted to an open-access repository under the Creative Commons Attribution 4.0 Generic License (CC BY 4.0) or an equivalent license. BioRxiv ("Bio-Archive"; http://www.biorxiv.org/) is the preferred repository for AMP HF publications.

Both NIH- and FNIH-funded AMP HF grant awardees are expected to engage in broad sharing of biological data, analytical methodology, and disease models before publication. NIH-funded AMP HF grantees will be required to comply with the NIH Public Access Policy. This policy is an open access mandate requiring that research papers describing research funded by the NIH must be available to the public free through PubMed Central within twelve (12) months of publication. With respect to AMP HF NIH grant awards (HeartShare and others), in the event of a conflict between NIH policies or federal laws and regulations and any AMP HF policies, including these Principles, the NIH policies and Federal laws and regulations shall control.

10. Ancillary Study Principal Study Investigators Responsibilities

1. Costs: The investigator applying for an ancillary study must supply all additional funds required to conduct the study. The PAS and SC will be concerned with both the obvious and the hidden costs to HeartShare entailed by an ancillary study (such as costs to the DTC for coordinating the additional data collection, costs to recruitment sites for administering informed consent, clinical examinations, imaging and laboratory tests at the site, data and sample collection and processing, and notification of alert values, costs to laboratory for retrieving samples, etc.). It is critically important for ancillary studies that involve clinical tasks at the sites to include approval of the study procedures and budget in advance by all participating site PIs and ensure adequate funding in the grant application to cover the local site costs. In the event of a significant budget cut to an application, the DTC will facilitate development of an acceptable solution between the participating sites and the ancillary study PI.

It is important to note that HeartShare DTC nearly always incurs expenses on behalf of ancillary studies by providing support in data collection, data management, quality control, data analysis, study coordination and communications, events ascertainment, and other functions. These services can be of critical value to an ancillary study. PIs who plan to propose an ancillary study with the intention of seeking grant funding should first consult with the HeartShare DTC to determine what level of involvement will be required of the DTC and the associated costs. In general, this will result in a subcontract proposal from the DTC to be included in the PI's grant application.

2. Confidentiality and identification of HeartShare participants: Confidentiality of individually identifiable data about HeartShare participants must be assured. As a general rule, no personal identification of participants will be provided to ancillary study staff. There are no assurances that participants will be able to be identified and contacted in the future for the purposes of an ancillary study, particularly after HeartShare ends.

3. Clinical implications of findings: The proposing investigator must clearly delineate any findings of clinical significance that may result from the study, including genetic findings, and propose how these will be handled, including reporting to participants and their physicians and providing recommendations for follow up. This includes incidental findings, such as pathology identified from an imaging study that is not the focus of the study.

4. Genetic studies: Genetics studies may include only participants who provided appropriate informed consent. Investigators should consult the online HeartShare metadata catalog to estimate the number of participant samples eligible for analysis based on responses from the appropriate informed consent. Medical and other (ethical, legal, and social) implications of the findings and reporting of results must be addressed in the proposal.

5. Ancillary studies to existing HeartShare ancillary studies: A new ancillary study that involves participants, staff, or biological samples of an existing HeartShare ancillary study but not those of the main HeartShare study is also considered an ancillary study to the parent (existing) ancillary study. Such proposals are to be submitted to the parent ancillary study PI for review and approval prior to the PAS and SC approval.

6. Inclusion of sponsoring HeartShare investigator(s): Investigators not affiliated with HeartShare are welcome to propose ancillary studies. These investigators need to work with a HeartShare- affiliated investigator who must be included as a co-investigator on an ancillary study. This individual is responsible for approving the ancillary study proposal before it is submitted to the PAS Committee, monitoring the study to assure continuing compatibility with HeartShare, and serving as a liaison to the HeartShare SC. In addition, each manuscript and abstract is generally expected to include a HeartShare investigator. A list of potential HeartShare investigators will be provided.

7. Early communication with HeartShare CCs: The proposing investigator and/or their liaison should consult with PIs of CCs, laboratories, and the DTC, depending on the anticipated involvement of recruitment site staff and oversight, biospecimen analysis, and data management, analysis, and coordination. Such discussions should focus on scope, feasibility, and provision of necessary resources and do not constitute formal approval of

the study.

8. Timeline: All proposed ancillary studies must be submitted to the HeartShare PAS for subsequent circulation and review. Reviews are performed in two stages. Study proposals must be submitted 8 weeks prior to the application deadline. Studies submitted after these deadlines may not receive timely approval. In addition, studies that involve a subcontract to the DTC must have their final budget negotiated and approved no later than 4 weeks prior to the application deadline.

9. Final application or proposal: The HeartShare PAS will request a copy of the final proposal as submitted for funding.

10. Industry participation: TBD pending AMP finalization

11. Status reports: The ancillary study PI must keep the HeartShare DTC apprised of major developments in the status of the application or proposal, including success of funding, start date, changes in protocol, and any resulting publications or presentations. The HeartShare DTC will query PIs annually or as needed for a status update on their ancillary studies, the results of which will be included in SC and Observational Safety Monitoring Board reports.

12. Revising or resubmitting proposals; unfunded proposals: Once approved by the PAS, ancillary studies have 3 years to become active (with or without funding), after which they will be marked as "withdrawn" and are considered inactive. After 3 years, if the original investigator wants to continue to pursue the project, a new proposal must be submitted to the PAS for review, with an explanation about reactivation of the project. If the initial submission to a funding agency is unsuccessful and the PI submits the proposal as a revision application or for a subsequent funding opportunity, they must communicate this to the HeartShare DTC. Substantial changes to the science or scope of an approved ancillary study, either before or after becoming active, require re- review by the HeartShare PAS, DTC, and SC.

13. Review of publications and presentations: All manuscript proposals (based on the main HeartShare components or ancillary study data) require approval of the HeartShare PAS committee. Publications, presentations, and abstracts from an ancillary study must also be reviewed and approved by the HeartShare PAS through the Manuscript proposal process, in accordance with the general rules for publications and presentations, in addition to ancillary study approval.

14. Incorporation of ancillary study data into HeartShare database: Ancillary studies will generally collect data using the HeartShare infrastructure. These data will be integrated into the main database at the DTC, after which the ancillary study investigators will receive the integrated file(s) containing necessary data from the main study. The ancillary study PI will be given the exclusive opportunity to analyze, present, and publish data collected under the auspices of the ancillary study. After a reasonable time (in general, 24 months after data collection and cleaning are complete) the ancillary study data will be made available for additional (noncompeting) uses by other HeartShare investigators in collaboration with the ancillary study investigators. Data from ancillary

studies not evidencing progress toward completed analyses within 36 months of completion will be made available for competing uses. It is the responsibility of the ancillary study PI to state in writing to the PAS any special circumstances that would militate against these guidelines for data sharing.

APPENDIX 1: HeartShare Data Analysis Request and Writing Topic Proposal Form

HEARTSHARE

Data Analysis Request and Writing Topic Proposal Form

This form must be completed by anyone who wishes to request data analysis and/or propose a new manuscript topic. The data analysis request/manuscript topic must be approved by the HeartShare Publication and Ancillary Studies (PAS) Committee after which writing group members will be solicited. Forward the completed form to XXX at email address for review by the PAS Committee and the HeartShare DTC.

Date:

Proposal from: *(Include all requesters and contact information of lead requester; at least one HeartShare investigator is required to be a Sponsor)*

Working Title:

Objectives/Rationale:

Research Hypothesis:

Abstract:

HeartShare Data Needed: *(main and/or ancillary study data)*

Brief Analysis Plan and Statistical Support Needed:

References: *(limit to 15)*

Potential Journals:

APPENDIX 2: Acknowledgement Text

(To be included on all abstracts and manuscripts submitted for presentation or publication in addition to "HeartShare" in title)

HeartShare Program

The HeartShare Program was supported through the following NHLBI grants: U54 HL160273 (Northwestern University Data Translation Center); U01 HL160279 (Northwestern University); U01 HL160277 (University of Pennsylvania); U01 HL160274 (University of California at Davis); U01 HL160226 (Mayo Clinic); U01 HL160272 (Wake Forest); U01 HL160278 (Massachusetts General Hospital) and through the FNIH Accelerating Medicines Partnership Heart Failure (AMP HF) Program [including RFP 2023-1345-001 (Johns Hopkins University)].

NHLBI Disclaimer (include if an NHLBI staff member is listed as an author on any HeartShare materials)

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; the National Institutes of Health; or the U.S. Department of Health and Human Services.

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BDC Use

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