NHLBI HeartShare Program
Ancillary Studies Policies & Procedures

Contents

Updated 9/21/2023

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 ancillary studies 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 of the NIH (FNIH) has named a seventh CC through the Heart Failure Accelerated Medicine Partnership.
- **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 and is made up of a representative at each HeartShare Study site, the DTC, NHLBI, and Co-Chairs.
- **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, NHLBI, and 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 publications activities and ancillary studies, with final adjudication of decisions by the Steering Committee. 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 Steering Committee for approval at the Steering Committee meeting. Appeals of the PAS Committee decisions may be made to the Steering Committee. However, the expectation is that only occasionally will decisions made by the PAS Committee be discussed at Steering Committee 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 Steering Committee. For publications, the journal submission title and final reference will be included.

The following reports will be distributed at each Steering Committee 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, the NHLBI and the 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, or NHLBI, if needed.

Name	**Institution**
Sadiya Khan (Co-Chair)	Northwestern CC
Renee Wong (Co-Chair as of June 2023)	NHLBI
Sanjiv Shah	Northwestern DTC
Denise Scholtens	Data Management Core
Lauren Balmert Bonner	Data Management Core
Peggy Doyle	Biospecimen Core

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
Jason Duran	Ionis
Dieter Kubli	Ionis
Maria Hughes	Novartis
Mike Mendelson	Novartis
Ashley Akerman	Ultromics
Ross Upton	Ultromics
Svati Shah	Steering Committee Co-Chair
Javed Butler	Steering Committee Co-Chair
Patrice Desvigne-Nickens	NHLBI
Vandana Sachdev (former Co-Chair)	NHLBI
Emily Tinsley	NHLBI

2. Proposal Submission and Approval Process for Ancillary Studies

A. Definition of an ancillary study

An ancillary study is one that is proposing any of the following above and beyond the core HeartShare study and goals:

- Involves the collection of new data, either directly from participants or from previously collected samples, images, or other sources (e.g., electronic health records), regardless of the method of funding, OR
- Any study that provides external funding for the DTC or one or more CCs is an ancillary study

Ancillary studies may be single-center or multi-center. The relationship between ancillary studies and the HeartShare Program must be recognized in any resulting presentations or publications. Ancillary studies are subject to all HeartShare Program analysis, authorship, and publication policies.

B. When an ancillary study proposal form is not needed

If an investigator is seeking to use an existing HeartShare dataset, and the project does not involve new data collection (with participant contact), new analyses of stored biospecimens, or preparation of a unique dataset by the DTC, then an ancillary study application is not needed, but one or more manuscript proposals must be submitted for approval prior to initiation of analysis. This will allow HeartShare to ensure tracking of all ancillary and manuscript proposals.

C. Process for ancillary study proposal submission, review, and approval

Investigators wishing to conduct an ancillary study are required to submit a HeartShare Ancillary Study Proposal form (**Appendix 1:** https://redcap.nubic.northwestern.edu/redcap/surveys/?s=MNY8JA9TFHA7HPFL)

Investigators who are not yet affiliated with HeartShare are encouraged to propose ancillary studies. If these investigators are not affiliated with a HeartShare investigator, the PAS or DTC can provide suggestions to identify a sponsoring HeartShare investigator. See section 5 for additional details pertaining to external collaborators.

HeartShare Ancillary Study Review Procedures

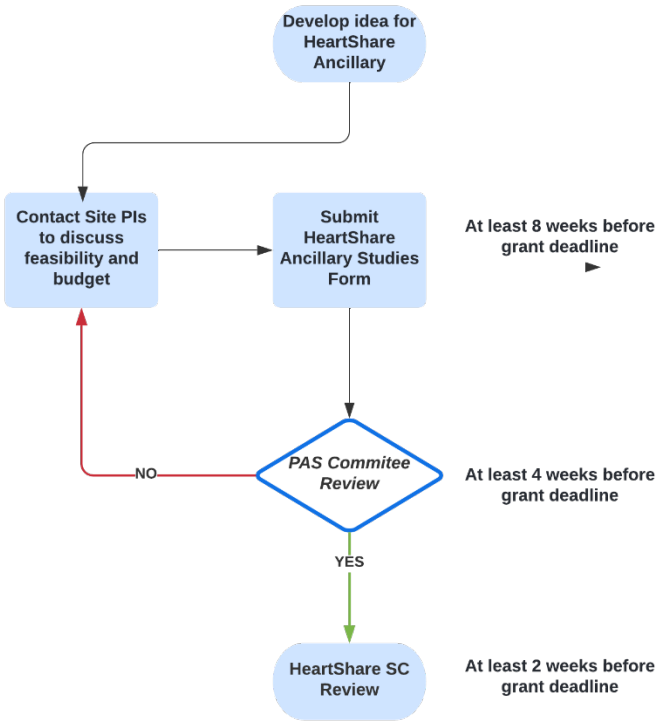
1. External investigators wishing to propose Ancillary Studies that pose participant, recruitment site, laboratory, or DTC burden should discuss their studies with a sponsoring investigator for HeartShare.
2. The Principal Investigator submits an ancillary study proposal using the REDCap form provided for this purpose and linked from the HeartShare website.
3. All members of the HeartShare PAS will be invited to review the proposal (including biostatistical expertise) with at least one member from each site providing feedback for administrative compliance (assures that all relevant questions have been answered), to adjudicate overlap with existing planned studies, and to assess participant/biospecimen burden and involvement of HeartShare recruitment sites, laboratory, and DTC. If a member of the HeartShare PAS is a part of the investigative team for an ancillary proposal, they will be recused from review/voting. If the proposal is not complete, the investigator will be contacted by email to invite a revision of the proposal.
4. The HeartShare PAS will discuss the proposal reviews during their monthly standing call, may also invite the PI (and/or the PI's HeartShare sponsor) to present the proposal and answer questions if needed, and issue a decision to approve, approve with revisions (needing Chair re-review), revisions required (needing PAS re-review), or reject the proposal (1 vote per clinical center/core/industry partner/SC Chair/NHLBI). The ancillary study Principal Investigator will be notified of the decision by email within 2 working days of the call by the HeartShare PAS coordinator. The PAS will provide the decision to the SC/DTC who will provide the final approval and a letter of support.
5. Proposals will be discussed by the SC, generally during their regular monthly conference calls. In some cases, the SC may also invite the PI (and/or the PI's HeartShare sponsor) to present the proposal and answer questions and absent themselves during discussion and voting if additional information is required to allow a decision to be reached.
6. The HeartShare Observational Safety Monitoring Board reviews the final proposal,

any relevant review materials, and the additional information regarding participant burden.

D. Submission Deadlines for Ancillary Studies (Proposed Figure)

Ancillary studies require proposal submission 8-10 weeks prior to grant deadline depending on the requested budget (see deadline tables for specifics). Note earlier deadlines for applications requesting >$500K direct costs in any year due to the NHLBI 500K Process.

Ancillary studies involving a subcontract must have their final budget negotiated and approved for review with the DTC and each CC no later than 5 weeks prior to a funding application.



HeartShare Ancillary Pre-Submission Deadlines

Deadlines	New R01 applications requesting <$500K direct costs (DC) in any year		
	Cycle I: October Council	Cycle II: January Council	Cycle III: May Council
DTC Statistician, Core Lab, Biorepository Review* (10 weeks prior to R01 deadline)	November 27	March 27	July 27
Ancillary Study Proposal Receipt Date to PAS (8 weeks prior to R01 deadline)	December 11	April 10	August 10
PAS Review** (4 weeks prior to R01 deadline)	January 8	May 8	September 7
PI Contacts DTC for Letter of Support (2 weeks prior to R01 deadline)	January 22	May 22	September 21
R01 Application Receipt Date to NHLBI	February 5	June 5	October 5

* Required only if proposals include these components; if N/A, follow ancillary study proposal receipt date to PAS
** Approved proposals requiring major changes must be re-reviewed by PAS; if minor changes, revised proposals reviewed by PAS Chairs
Abbreviations: DTC = Data Translation Center; PAS = Publication and Ancillary Studies Committee

HeartShare Ancillary and NHLBI 500K Process Pre-Submission Deadlines

Deadlines	New R01 applications requesting ≥$500K, <$1.515M DC in any year		
	Cycle I: October Council	Cycle II: January Council	Cycle III: May Council
DTC Statistician, Core Lab, Biorepository Review* (10 weeks prior to R01 deadline)	September 16	January 14	May 16
Ancillary Study Proposal Receipt Date to PAS (8 weeks prior to consultation)	September 30	January 28	May 30
PAS Review** (4 weeks prior to consultation)	October 28	February 25	June 27
PI Contacts DTC for Letter of Support (2 weeks prior to consultation)	November 11	March 11	July 11
NHLBI Staff Consultation Completed*** **(earlier contact recommended)**	November 25	March 25	July 25
NHLBI Letter of Request Deadline	December 14	April 13	August 14
NHLBI Decision to Accept Proposal (Letter of Acceptance Receipt)	December 28 – January 25	April 27 – May 25	August 28 – September 25
R01 Application Receipt Date to NHLBI	February 5	June 5	October 5

* Required only if proposals include these components; if N/A, follow ancillary study proposal receipt date to PAS
** Approved proposals requiring major changes must be re-reviewed by PAS; if minor changes, revised proposals reviewed by PAS Chairs
*** Required consult is the first step to request NHLBI approval to submit an application ≥$500K, <$1.515M DC in any year

E. Ancillary Study Review Criteria

Ancillary study review criteria will be assessed for the following:

1. Do not interfere or overlap with the main HeartShare objectives or previously approved ancillary studies
2. Have the highest scientific merit
3. Produce the smallest burden on HeartShare participants and the least demand on HeartShare resources, such as blood samples
4. Require the unique characteristics of the HeartShare cohort or be relevant to the core mission of HeartShare
5. Include HeartShare Investigators, HeartShare CC Site PIs, and appropriate statistical expertise

In addition, priority for studies requesting biological samples will be highest if they:

1. Do not make use of samples from those participants with the fewest samples;
2. Use previously thawed samples whenever possible;
3. Involve assays that may be done on more than one sample type to allow selection of the most abundant type available (e.g., serum or EDTA plasma);
4. Use the smallest sample volume possible; evidence of attempts to minimize volumes
5. Can be integrated with other studies to conserve sample or limit freeze-thaw cycles

F. Responsibilities of Ancillary Principal Study Investigators (**Appendix 3**)

APPENDIX 1: HeartShare Ancillary Study Proposal Form

A. Template Description of the Proposed Ancillary Study Form

Accessible at: https://redcap.nubic.northwestern.edu/redcap/surveys/?s=MNY8JA9TFHA7HPFL

*Please provide a **brief (maximum 4 pages not including citations)** description of the proposed study. Include the following:*

1. Abstract

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

2. Background and Rationale

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

3. Specific Aims

Detail the research questions or hypotheses to be addressed by the ancillary study

4. Methods

- Study Population: Describe the sample of interest (the prospective, retrospective HeartShare cohort or certain subgroups). Include the anticipated time frame of participant involvement (if any).
- Data Collection: Describe information to be collected and any methods or equipment to be used. Include detailed explanations and protocols for each method in the ancillary study. Explain how the information from the method or equipment will address the question(s) of the study. Attach copies of any study instruments (questionnaires and forms) that HeartShare participants or administrators will be expected to complete. Include an estimate of the time necessary to complete them. Describe the data needed from the HeartShare main study (including outcomes/events).
- Statistical Analysis: Explain how each study hypothesis (from section 3 - Specific Aims) will be analyzed. Include any current hypotheses or information that might influence the approach to the analysis or the question itself.

5. Sample Size Calculations

6. Literature References

B. Basic Study Information and Projected Impact on HeartShare

1. Draft / Modification Date:

2. Title of Study:

3. Initiating Investigator(s) (name, address, phone and fax numbers, e-mail address):

4. HeartShare Sponsor:

5. All other Co-investigators:

6. Please confirm that you have reviewed any potential areas of overlap by checking the current list of approved ancillary studies at *:**

7. Collaboration approval: Does this ancillary study use data from or rely upon the use of data from another approved ancillary study? **:** Yes ☐ No ☐ If Yes, please provide the Ancillary Study name and number, as well as documentation of approval of this collaboration from the Ancillary Study PI.

8. Keywords:

9. Funding

1) Source:
2) If NIH, funding mechanism:
3) Grant due date:
4) Proposed grant start date:
5) Proposed grant end date:
6) Grant title (if different from study title):
7) Does this study involve the support or collaboration of a for-profit entity?
8) Estimated direct costs per year (please provide an estimate even if a final figure is not available):

FY01	FY02	FY03	FY04	FY05	
$	$	$	$	$	

Note: You must have pre-approval from NIH to submit an application with estimated direct costs ≥ $500K in any year.

10. Sample Size: Explicitly state the size and any special characteristics of the participant sample.

11. Participant Involvement: Will participants be contacted, interviewed, or examined (even if only to report results from this study)?

If yes, please describe participant involvement and estimate the time required of each participant.

Radiation exposure level (if applicable):

12. Biological Specimens: Do you propose to use stored specimens?

i. Date of Repository Impact Report included with this submission:

ii. Specimens:

a. DNA :

Specify amount of DNA:

b. Blood or urine (specify):

1) Study year(s) for which blood or urine samples are to be used:

2) Sample type (e.g., serum, EDTA, citrate):

3) Sample volumes:

4) Requirement for frozen vs. previously thawed samples (if the latter, please indicate whether there are any limitations on the number of freeze-thaw cycles):

5) Efforts to integrate sample needs with those of other studies to conserve sample and/or limit freeze-thaw cycles:

iii. Labwork Location and personnel:

1. Projected timeline for:
   - pulling samples and shipping:
   - sample analysis:
   - return of samples to Lab:

13. HeartShare Cores: Yes ☐ No ☐ If yes,

Describe materials (including scans, tapes, digital images, tracings, …) from a HeartShare Core Center to be used.(These source materials may include chest CT, abdominal CT, ECG, cardiac MRI, carotid MRI, carotid ultrasound, brachial endothelial function, spirometry, and retinal photography. Data already derived from readings are available without the involvement of a Core Center.)

14. HeartShare Clinical Centers: Yes ☐ No ☐ If yes,

Indicate which Clinical Centers have agreed to participate, and describe the effort and estimated time required of HeartShare staff at each participating Clinical Center.

15. HeartShare DTC Involvement: Yes ☐ No ☐ If yes,

Describe the effort and estimated time required of HeartShare DTC staff. Specifically:

i. Will the following work be done at the DTC? (please check all that apply)
   ☐ Sample selection
   ☐ Data set preparation *(ie, preparation of a unique dataset not available online)*
   ☐ Consultation
   ☐ Statistical analysis

ii. How many manuscripts do you estimate will be written from the ancillary study?

iii. Will the DTC be involved in data collection or preparation of forms or software?

iv. If a Core is involved, will data be sent directly from the Core to the DTC for processing?

16. HeartShare Data: State the data from the HeartShare main study (demographics, risk factors, events, etc.) and analyses needed for the ancillary study:

17. Genetic information (defined as any data from a participant's DNA):

a. Does your proposal contain the use of genetic data? (please check one)
   ☐ No (go to question 17) ☐ Yes (continue with questions 16 b-e)

b. Name the gene(s) to be investigated:

c. Is genetic information used to address a primary aim or secondary aim of the HeartShare? (please check one or both)
   ☐ Primary aim (HFpEF)
   ☐ Secondary aim (other health conditions)

d. Should genetic results be reported to patients' physicians? Base your response on your knowledge of existing literature and current practice regarding increased risk and availability of treatment for adverse outcomes associated with the gene mutations to be studied. Describe the plan for addressing any relevant clinical or other (ethical, legal, or social) implications of the findings.

e. If your proposal requires genetic informed consent, state the estimated number of participants who have the appropriate consent.

18. Clinical Implications: Will the findings have clinical implications? If so, describe the plan for reporting results to participants and providing recommendations for follow-up.

19. Patent Intent: Do you intend to use the data to patent any process, aspect or outcome of the analysis?

20. Rationale, Impact, and Overlap: What is the advantage and value added of conducting the study within the HeartShare cohort? What is the overlap between the study and HeartShare (i.e., protocols, data collection, etc.)?

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 initiated and funded by the NHLBI 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)

APPENDIX 3: Responsibilities of Ancillary Study Investigators

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, 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.