



# HEARTSHARE

## HeartShare Cohort Consortium Governance Principles

Last updated July 20, 2023

*Note: This agreement was developed based on the NHLBI CHARGE Consortium principles and procedures dated 02/01/2008, and from the N3C Community Guiding Principles dated 08/06/2020.*

### Introduction

The HeartShare Cohort Consortium is an activity associated with the NHLBI HeartShare Study and is based on the model established by the NHLBI CHARGE and C4R Consortia. The HeartShare Cohort Consortium has developed policies for the Consortium, which are listed in the HeartShare Consortium Agreement (available on the study website: <https://www.heartsharestudy.org/>).

The purpose of the HeartShare Cohort Consortium is to use aggregated data on heart failure (HF) patients and comparators from epidemiology cohorts, registries, and completed clinical trials to allow discovery and validation of subtypes (endotypes) and novel therapeutic targets for HF with preserved ejection fraction (HFpEF). Combining previously collected clinical data, images, and omics will allow a more precise description of the subtypes of HFpEF and their associated molecular mechanisms and treatment targets.

### Organization and Responsibilities

#### The HeartShare Data Translation Center (DTC):

- Establishes policies and procedures for participation in the HeartShare Cohort Consortium.
- Forms committees and working groups to identify and prioritize datasets, prepare datasets for analysis, combine different data types, and develop and conduct analyses, and may form additional committees and working groups as needed.
- Collaborates with NHLBI BioData Catalyst (BDC) internal staff and the BDC Data Management Center to provide access to HeartShare Cohort Consortium data.
- Standardizes, oversees, and grants access and permissions to Cohort Consortium members and external collaborators to Cohort Consortium data in BDC.
- Aims for transparency, timely communication, effective coordination, and sharing of responsibilities, challenges, and opportunities among Cohort Consortium members and users.
- Encourages collaboration between Cohort Consortium members and users and non-consortium partners.
- Encourages ancillary study applications to accomplish new scientific aims.
- Offers educational and research opportunities to junior investigators and fellows through the HeartShare Research Skills Program.

### **The HeartShare Steering Committee:**

- Provides scientific leadership for the HeartShare Cohort Consortium and the HeartShare study in collaboration with the Foundation for the NIH Accelerating Medicines Partnership in Heart Failure (AMP-HF) Steering Committee.
- Is composed of members of the HeartShare DTC, HeartShare Co-Chairs, HeartShare Clinical Center Principal Investigators, NHLBI Program Officers, and AMP-HF partners.
- Meets regularly to review study progress and discuss issues or challenges.
- Reviews and approves policies and procedures drafted by HeartShare committees and working groups.
- Evaluates and may approve changes to the HeartShare study protocol (including policies and procedures regarding the Cohort Consortium data) proposed and agreed upon by the HeartShare Steering Committee, AMP-HF Steering Committee, and members of relevant committees and working groups.

### **HeartShare Committees and Working Groups:**

- Conduct the primary work of the HeartShare Cohort Consortium.
- Are composed of representatives of the HeartShare DTC, Clinical Centers, and AMP-HF partners.
- Are led by a chair or co-chairs, who may be appointed by the DTC or chosen by committee/working group members, who are responsible for running meetings and management of proposals, initiatives, timelines, and work products.
- May encourage ancillary study applications to accomplish new scientific aims.
- May draft policies and procedures related to the committee or working Group area of focus; committees or working groups are responsible for bringing draft policies and procedures to the HeartShare Steering Committee for approval.

## **Ethics Statement**

HeartShare Cohort Consortium community members are expected to follow all laws, regulations, and their organization's policies related to the responsible conduct of research. Further, members will respect and protect the privacy and other interests of participants included in the studies that compose the HeartShare Cohort Consortium by minimizing risks of harm and maximizing potential benefits to individuals or groups through inclusivity and equity in research design and outcome dissemination. It is expected that Cohort Consortium members and affiliated scientific investigators (including external collaborators) consider the effects that their research could have on vulnerable populations, communities, and society such that HeartShare Cohort Consortium resources will not be used for research that is discriminatory or stigmatizing of individuals or communities.

The HeartShare Cohort Consortium will uphold the highest standards of publication ethics and best practices, by appropriately attributing and citing works and contributions, and developing and disseminating original works that uphold scientific integrity, promote the rapid advancement of scientific findings, and bolster public trust in research.