

# SUMMARY OF PROMIS WAVE 2 PROTOCOLS

## Congestive Heart Failure (CHF) Protocol Summary Information

<b>Organization's Unique Protocol ID:</b>	07-03
<b>Brief Title:</b>	Validating PROMIS Instruments in Congestive Heart Failure Patients Receiving a Heart Transplant
<b>Official Title:</b>	Validating PROMIS Instruments in Congestive Heart Failure Patients Receiving A Heart Transplant
<b>Study Type:</b>	Observational
<b>Human Subjects Review:</b>	Submitted, approved
<b>Board approval number:</b>	10/02/2008
<b>Board Name:</b>	The Duke University Health System Institutional Review Board for Clinical Investigations (DUHS IRB)
<b>Board Affiliation:</b>	Duke University Health System
<b>Board Contact:</b>	John Harrelson, M.D. (919) 684-5304 <a href="mailto:harre004@mc.duke.edu">harre004@mc.duke.edu</a> Box 3023 Med Ctr Durham, NC 27710
<b>Oversight Authorities:</b>	United States: Institutional Review Board
<b>Sponsor:</b>	National Institutes of Health
<b>Collaborators:</b>	Stanford University and the University of Pittsburgh
<b>Brief Summary:</b>	The purpose of this research study is to learn about the experience and impact of having Congestive Heart Failure (CHF). In particular, we hope to develop better questionnaires that can measure heart failure patients' quality-of-life.
<b>Detailed Description (if desired):</b>	This project will assess the validity (including responsiveness) of selected Patient Reported Outcome Measurement Information System (PROMIS) instruments in patients with severe chronic heart failure (CHF) who receive heart transplants. The following is a list of goals for this project: <ul style="list-style-type: none"><li>• To estimate the responsiveness of PROMIS domain scores by comparing scores in patients with severe heart failure before and after a clinically significant event (heart</li></ul>

transplant). The specific PROMIS domains assessed are physical functioning, fatigue, satisfaction with discretionary social activities, depression, and global health.

- To estimate the responsiveness of a disease-specific PRO measure, the Kansas City Cardiomyopathy Questionnaire (KCCQ) and the Medical Outcomes Study Short Form-36 Vitality subscale (SF-36v2) and the Patient Health Questionnaire (PHQ-2).
- To collect cross-sectional and longitudinal data on traditional clinical measures of heart failure outcome (6 minute walk test and NYHA class) that can inform the definition of a minimally important difference (MID) for the PROMIS domains of physical functioning, fatigue, satisfaction with discretionary social activities, depression, and global health.

<b>Overall Recruitment Status:</b>	Not yet recruiting
<b>Study Start Date:</b>	Anticipated December 2008
<b>Study Design: (Observational Study Model)</b>	Cohort
<b>Time Perspective:</b>	Prospective
<b>Enrollment:</b>	Target: 150
<b>Number of Groups/Cohorts:</b>	1
<b>Group/Cohort Label:</b>	Heart transplant recipients
<b>Group/Cohort Description:</b>	To be eligible, heart failure had to represent the greatest medical limitation on daily function for the patient in the judgment of the attending cardiologist.
<b>Intervention Type:</b>	Other; this is an observational study only. No treatment will be assigned to these patients through this protocol. The intervention decision (heart transplant surgery) will be made solely by patients and their physicians and reported to us. Usual clinical care for patients in this study will not be altered.
<b>Conditions or Focus of Study:</b>	Congestive Heart Failure
<b>Study Population Description:</b>	Participants will be recruited through heart transplant program registries and in consultation with practicing cardiologists at Duke University, Stanford University and the University of Pittsburgh.

**Sampling Method:** Non-Probability Sample

**Eligibility Criteria:** Inclusion criteria: To be eligible, heart failure had to represent the greatest medical limitation on daily function for the patient in the judgment of the attending cardiologist.

1. Must be 18 years old or older
2. Ability to read, write, and speak in English
3. Ability to understand and provide informed consent
4. No current diagnosis of psychosis or dementia
5. Placement on heart transplant registry (awaiting heart transplant surgery)

**Gender:** Both

**Age Limits:** Minimum age of participants: 18 years  
Maximum age: N/A

**Facility:** Duke University Medical Center  
Durham, NC USA

Stanford University  
Palo Alto, CA  
USA

University of Pittsburgh Medical Center  
Pittsburgh, PA  
USA

**Recruitment Status:** Not yet recruiting

**Facility Contact:** Felicia L. Graham, MBA  
919-668-8670  
[Felicia.graham@duke.edu](mailto:Felicia.graham@duke.edu)

**Investigators:** Kevin P. Weinfurt, Ph.D.  
Role: Site Principal Investigator

**Central Contact:** Felicia L. Graham, MBA  
919-668-8670  
[Felicia.graham@duke.edu](mailto:Felicia.graham@duke.edu)