Taking Care of Us© Protocol (IRB Approval 9/25/2020)

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V. Research Summary:

A. Introduction and Background:

Heart failure is the number one reason older adults are hospitalized in the United States. The proposed pilot study will evaluate a novel patient-care partner intervention (Taking Care of Us) that promotes 1) shared appraisal (i.e. similarity between how patients and their spouse care partners appraise the patient's symptoms), 2) communication between the patient and their care partner about their heart failure and related concerns, 3) collaboration between the patient and their spouse care partner to manage the heart failure together and 4) confidence of the patient and their spouse care partner to manage the heart failure as a means to improve the outcomes of both the heart failure patient and their spouse care partner. Facilitating and promoting shared appraisal, communication, collaboration and confidence are hypothesized to improve the physical and emotional health of both the patient and the spouse care partner. Specific aims and hypotheses are:

Aim 1 (primary): To determine the preliminary efficacy of the *Taking Care of Us* intervention on dyadic health.
Hypothesis: HF care dyads in the Taking Care of Us group will have better dyadic (i.e., better health (primary outcome), lower depressive symptoms and anxiety, better dyadic health and less healthcare utilization) and individual health (i.e., lower care-related strain and better HF-specific QOL) compared with HF dyads in the control group.

Aim 2: To determine the preliminary efficacy of the *Taking Care of Us* intervention on dyadic appraisal & dyadic management.
Hypothesis: HF dyads in the Taking Care of Us group will have more similar appraisal of patient symptoms (i.e., dyspnea, pain, fatigue), greater collaboration in HF management behaviors, greater shared activities and greater communication and dyadic confidence compared with HF dyads in the control group.

Aim 3: To determine the feasibility and acceptability of the *Taking Care of Us* intervention.
We will determine feasibility and acceptability of the program to inform future studies.

2. Provide the scientific or scholarly reason for this study and background on the topic

Heart Failure is a Major Public Health Problem: HF is the fastest growing cardiovascular disorder in the U.S., and most common reason for both hospitalization and rehospitalization among older adults. There are more than 1 million hospital admissions and 3 million emergency visits for HF in the U.S. annually. HF patients experience severe symptom burden, significant functional limitations, and poor QOL, with only 50% surviving five years post-diagnosis. Although family care partners make substantial contributions to the management of HF, experience poor health and significant care strain, they are rarely the focus of HF interventions. Thus, there is great need for novel dyadic interventions (i.e., interventions that target patient and care partner simultaneously) to reduce the family burden of HF.

Most non-pharmacologic HF interventions involve patient education and behavioral counseling, with limited success. Potential reasons for lack of efficacy include individual-based interventions, a focus on adherence only, and failure to acknowledge relational aspects of illness. Similarly, 50% of the small number of HF interventions (e.g. educational) targeting care partners only did not improve outcomes. Family-based interventions are more successful than individual interventions in chronic illness. In HF, involving care partners increases patient adherence; but, the majority of family-based HF interventions are focused on education and

specific aspects of adherence with little-to-no attention to care partner outcomes, HF management more broadly, dyadic management or the dyadic relationship. Moreover, prior studies have been inconsistent in efficacy. Indeed, current clinical guidelines (e.g. American Heart Association) call for greater family participation in HF management. Importantly, there also are calls from NIH for family self-management programs. Hence, theoretically- and empirically-driven dyadic interventions that are tailored to go beyond education are vital to address factors that impede dyads from collaborative HF management and optimize the health of both members.

There is strong evidence of the interdependence of health within dyads across chronic illnesses. The life- and QOL-limiting context of HF, unpredictable nature of the illness, and continual need for symptoms to be managed place considerable demands on HF patients and their care partners resulting in poor physical and mental health for both. Although dyadic research in HF is an emerging area, early evidence has confirmed the interdependence between patient and care partner health. Indeed, meta-analytic evidence shows that care partner health is associated significantly with HF patient health and clinical outcomes. Thus, there is strong scientific rationale for a dyadic approach to HF intervention research to optimize the outcomes of both members of the HF dyad.

The theoretical framework for the proposed study is our new Theory of Dyadic Illness Management. A product of extensive empirical evidence, our Theory of Dyadic Illness Management focuses on the care dyad as an interdependent team, with the goal to optimize dyadic health. How dyads communicate and collaborate to appraise and manage conditions like HF has great bearing on the health of the dyad as well as the health of each member of the dyad. Greater *shared appraisal* of patient symptoms and greater *collaboration*, *communication* and *confidence* around management of HF are purported to lead to optimal health of both members of the dyad.

B. Specific Aims/Study Objectives:
The proposed dyadic intervention will be one of the first to target the outcomes of both the HF patient and their spouse care partner simultaneously through a team-based intervention centered on shared appraisal, collaboration, communication and confidence to promote optimal dyadic health. The proposed study is, therefore, significant in addressing an important gap. Our study will determine the feasibility, acceptability and clinical meaningfulness of the *Taking Care of Us* program.

Aim 1 (primary): To determine the efficacy of the *Taking Care of Us* intervention on dyadic health.
Hypothesis: HF care dyads in the Taking Care of Us group will have better dyadic (i.e., better health (primary outcome), lower depressive symptoms and anxiety, better dyadic health and less healthcare utilization) and individual health (i.e., lower care-related strain and better HF-specific QOL) compared with HF dyads in the control group.

Aim 2: To determine the efficacy of the *Taking Care of Us* intervention on dyadic appraisal & dyadic management.
Hypothesis: HF dyads in the Taking Care of Us group will have more similar appraisal of patient symptoms (i.e., dyspnea, pain, fatigue), greater collaboration in HF management behaviors and shared activities, and greater communication and dyadic confidence compared with HF dyads in the control group.

Aim 3: To determine the feasibility and acceptability of the *Taking Care of Us* intervention.
We will determine feasibility and acceptability of the program to inform future studies.

C. Materials, Methods and Analysis
The proposed study is a two-group randomized controlled trial with separate assessments of patients and spouse care partners at 0, two months and five months. A community-based sample of patient-spouse care partner dyads will be recruited and randomly assigned by block (patient gender) to either the *Taking Care of Us* intervention or to an educational attention-control. All sessions will be delivered via Zoom (or phone) - there will be no in-person contact with participants throughout the study. *The term spouse refers to spouse or*

unmarried partner. All participants will be assessed three times baseline, two months and five months. We believe 7 biweekly sessions over two months, with the first follow-up interview taking place immediately at two months is realistic and appropriate. Our second follow-up will take place at five months to explore sustained effects. The attention-control group will receive three educational sessions over two months (at approximately 0-, 4- and 8 weeks). The sampling frame for the proposed research is community-dwelling adults with NYHA class II-III HF and their spouse/partner. The target sample is 72 couples with HF (36 couples per arm) with equal gender representation.

Eligible and consented dyads will be randomly assigned to one of two groups. Block randomization stratifying by patient gender will be done using an online research randomizer (www.randomizer.org). We will stratify by patient gender to ensure equal distribution between the two conditions. Participants will be provided with separate e-mail-specific links to the patient and spouse web-based survey using our REDCap platform; baseline surveys will take approximately 45 minutes to complete. Participants will be instructed to complete the survey separately without discussing the questions with their spouse/anyone else (this procedure has been successfully used in all dyadic work by this team and is the standard procedure in couple research). Participants who do not want to or cannot complete the survey electronically will be offered the option to complete the survey with a trained interviewer (blinded with respect to treatment assignment) via Zoom, phone or to complete a mail survey. Patients and their spouses will be interviewed separately and privately as in our other dyadic research. For the few participants who request a mail survey, they will receive individual packets and consent forms and return the survey and signed consent form in the stamped, addressed envelope provided. These procedures are identical to those successfully used by this team in other couple studies.

All Taking Care of US© (TCU) and educational sessions will be conducted via Zoom (or phone). Relevant materials for the sessions will be mailed to dyads ahead of the first session. For dyads in the TCU group, the project coordinator will inform the interventionist to schedule the first session with the dyad. The interventionist will communicate the treatment assignment to the dyad. Following completion of the 7 sessions of TCU, the interventionist will inform the project coordinator, who will schedule the immediate post-treatment interviews. For the control group, the trained educator (not involved in data collection) will contact the dyad to communicate their assignment to the attention-control condition and schedule a time for their first education session. Two additional education sessions will be done at 4 and 8 weeks. Following completion of the final education session, the trained educator will inform the project coordinator, who will schedule the immediate post-treatment interviews (approximately two months).

Follow-up web-based surveys will be done using our REDCap platform at two months and five months and will take approximately 30 minutes to complete (alternative modes of completion will be offered when necessary, e.g., by Zoom, phone or mail). The project director will make follow-up contact with each participant to confirm ongoing willingness to participate and ensure no change in e-mail address and to confirm preferred mode of completion. Participants will then be sent a follow-up e-mail with a link to the survey. At no time will RAs involved in collecting any data be aware of a dyad s treatment condition.

Taking Care of Us Intervention
Taking Care of Us is a theoretically and empirically informed intervention that is communication-based and relationship-focused, building on the strengths of the dyad while fostering new skills. Briefly, the Theory of Dyadic Illness Management focuses on the care dyad as an interdependent unit. The theory proposes that dyads who have shared illness appraisals, and collaborate and communicate to manage the illness have better health outcomes at the dyadic and individual level. The proposed intervention is directly informed by this theory by a) targeting the dyad as the focus of the intervention rather than the individual patient or care partner, b) integrating the needs of both members of the dyad to move towards shared goals of care, and c) targeting the main concepts of the theory dyadic appraisal, dyadic collaboration and communication to manage illness - as the processes that optimize dyadic and individual health. Measures of both dyadic and individual health are included.

Control Group: Dyads randomly assigned to the attention-control group (SUPPORT) will receive three educational sessions **at 0, 4 and 8 weeks** guided by the Heart Failure Society of America (HFSA) education

modules (*https://hfsa.org/heart-failureeducational- modules*). The first session will be identical to session 1 in the TCU program regarding a general overview of the importance of HF symptom management per the HFSA modules. The two subsequent sessions for the control condition will focus on healthy eating and physical activity.

Survey data will be gathered from both patients and their spouse care partners for the explicit purpose of research. Patient and spouse surveys will include demographic and background questions and measures of patient and care partner quality of life, depressive symptoms, anxiety, healthcare utilization, engagement in HF management behaviors, confidence to manage HF, communication, perceptions of relationship quality, social support and the impact of Coronavirus on several aspects of their life. In addition, both patients and care partners will be asked to appraise the patient's dyspnea, pain interference and fatigue. Finally, patients will be asked to rate their HF-related QOL and spouses will be asked to rate their care-related strain. Patients and care partners will be asked to respond to questions about the strengths and weaknesses of the program they participated in at both **two months** and **five months** assessment (see attachment).

Measures Relevant to Aim 1 (Dyadic & Individual Health)

General health: The 10-item PROMIS Global Health short form will be used as a general measure of QOL for patients and care partners. The measure includes specific ratings of physical, mental and overall QOL. Depressive symptoms: The Center for Epidemiological Studies-Depression (CES-D) scale is a widely used measure of depressive symptoms. Participants respond to 20 statements (based on feelings during the past week) using the response categories 1=rarely or none, 2=some or a little, 3=occasionally or moderate, and 4=most or all. The potential range of scores is 0-60, with higher scores indicating greater depressive symptomatology. The CES-D scale has been widely used with older adults, demonstrating good internal consistency with Cronbach's alpha in the .86 to .92 range in samples of FMs and cancer PTs. Sensitivity, specificity and validity of the scale have also been supported. Anxiety: Patient and care partner anxiety will be measured using the 4-item PROMIS Anxiety short form.
Healthcare Utilization: The Stanford Patient Education Research Center (PERC) Healthcare Utilization assessment will be used at 0 and 28 weeks to collect physician, mental health, emergency room visits and hospitalizations for both patients and care partners. Care-related strain: The Multidimensional Caregiver Strain Index (MCSI) will be used to capture physical, social and interpersonal strain, time constraints and demands. HF-Specific QOL: The Kansas City Cardiomyopathy Questionnaire (KCCQ), a 12-item Likert scale will be used to measure patient HF-specific quality-of-life. Scores range from 0-100 with higher scores reflecting better QOL.Cronbach s alpha on these subscales range from 0.75-0.85.

Measures Relevant to Aim 2 (Dyadic Symptom Appraisal & Dyadic Management)

Patient and care partner appraisal of the patient's symptoms will be measured at all waves using measures from our previous HF and dyadic appraisal research. Dyspnea will be measured with the 6-item dyspnea subscale of the Heart Failure Somatic Perception Scale (HFSPS Dyspnea). The HFSPS asks about how much the patient was bothered by dyspnea during the last week on a 0 (not at all) to 5 (extremely bothersome) scale. The measure has demonstrated strong reliability and validity. Pain Interference will be measured using the psychometrically sound 6-item PROMIS pain interference scale. Fatigue will be measured using the 8-item PROMIS fatigue scale. HF Management Behaviors: Patient and care partner engagement in HF management will be measured using the management scores of the Self-Care of HF Index v6.2 (SCHFI). The SCHFI has 6 items that capture HF management. Response options range from 1 (not likely) to 4 (very likely). Scores are standardized to 0-100 with higher scores indicating greater engagement. The scale has demonstrated good reliability and validity across HF populations and care partners (CC-SCHFI), including our recent studies. In addition, patients and care partners will be asked to rate how much they collaborate regarding HF management behaviors using modified versions of the measure. Dyadic Heart Failure Management: Collaborative management around heart failure will be measured using the revised Stanford Chronic Disease Self-Management measure. Patients and spouses are asked to rate their level of collaboration around six aspects of the patient's heart failure (e.g., fatigue, emotional distress) on a 0 (never) to 10 (always) scale. A summary score is created by calculating the mean collaboration level across the six items. Self-Efficacy to

Manage HF: Patients and care partners will be asked to rate their self-efficacy to manage heart failure using the Stanford Chronic Disease Self-Management measure. Patients and spouses are asked to rate their self-efficacy to manage six aspects of the patient's heart failure (e.g., fatigue, emotional distress) on a 0 (no confidence) to 10 (totally confident) scale. A summary score is created by calculating the mean self-efficacy level across the six items. Finally, the 5-item common/joint dyadic coping subscale from the Dyadic Coping Inventory will be used to measure how much couples engage in collaborative coping. Patients and spouses respond to each item (e.g., joint problem-solving, communication) on a 1 (very rarely) to 5 (very often) scale. The scale has demonstrated strong reliability and validity across contexts and cultures. Dyadic Communication: Two aspects of Dyadic Communication/Coping will be measured. The Dyadic Coping measure consists of two subscales (active engagement and protective buffering). Active engagement assesses the extent to which the patient and spouse view their partner's active involvement and support. Participants respond to five items using a Likert scale from 1 (never) to 5 (very often). Higher scores indicate higher levels of perceived active engagement. The scale has exhibited high Cronbach's alpha values (.77 to .97) in studies of couples with cancer. Protective buffering assesses the extent to which the patient and spouse view their partner's use of hiding concerns and denying worries. Participants respond to six items using a Likert scale from 1 (never) to 5 (very often). Higher scores indicate higher levels of perceived protective buffering. The scale has exhibited high Cronbach's alpha values (.75 to .87) in studies of couples with cancer. We will also ask one global appraisal measure of how well they think they are communicating. Shared activities at each time point will be measured using 2 items developed by this team and used in our previous research on couples with illness. Patients and spouses are asked to rate engagement in a) fun activities together and b) physical activity together on a 0-4 scale.

Measures Relevant to Aim 3 (Feasibility & Acceptability)
There will be several indicators of feasibility and acceptability including refusal rate, number of sessions attended, and amount of time spent in each session. Dyads who receive at least 5 of the 7 sessions will be considered completers. Measures will also assess satisfaction with the program (amount of relevant information provided, interpersonal qualities of the interventionist) and advantages and drawbacks (e.g., I learned a lot during these sessions, the program took more time than I wanted to spend). These measures will only be administered to the treatment group (see attachment). Additionally, in a series of closed and open ended questions TCU participants will be asked about length of sessions, time between sessions, # of sessions and preferred delivery modality and two open-ended questions regarding benefits and drawbacks of the program.

Study data will be collected using REDCap (housed at Boston College). Standard descriptive statistics of frequency, central tendency, and dispersion will be used to describe the sample. All analyses will be performed using SPSS v26 (Chicago, IL) and HLM v7 (Skokie, IL). Our analytical approach to our previous dyadic research has used multilevel modeling (MLM) to control for interdependencies of the dyadic data. MLM provides a powerful and flexible framework for analyzing change. MLM, used with clustered data (e.g., couple data), extends multiple regression to the case where the responses of the members of the dyad are viewed as units nested within dyad. An important feature of MLM is that it allows for differences in both the number and spacing of the waves of data collection across dyad and controls for the autocorrelation among repeated assessment and nonindependent dyadic data. The dyadic model can be parameterized in two ways: 1) to examine a matched pairs model that explicitly allows for examination of actor, partner and within-dyad effects (i.e. APIM models) and 2) to examine dyadic appraisal or incongruence (gap between patient and care partner). Although these models are mathematically similar, the difference in parameterization allows for complementary information about the dyad to be modeled. These models have been described and used extensively by this team, including samples similar in size to the proposed study. Missing Data: We will examine attrition and patterns of missing data. In the case of data missing MCAR or MAR, model-based full maximum likelihood estimation will allow unbiased parameter estimation using all available data. Covariate Selection: Covariates will be identified for inclusion based on correlations with each outcome.

Aim 1:To determine the efficacy of the *Taking Care of Us* intervention on dyadic and individual health. *Hypothesis: HF care dyads in the Taking Care of Us group will have better dyadic (i.e., better health (primary outcome), lower depressive symptoms and anxiety, better dyadic health and less healthcare utilization) and*

individual health (i.e., lower care-related strain and better HF-specific QOL) compared with HF dyads in the control group. Aim 2: To determine the efficacy of the *Taking Care of Us* intervention on dyadic appraisal & dyadic management. *Hypothesis: HF dyads in the Taking Care of Us group will have more similar appraisal of patient symptoms (i.e., dyspnea, pain, fatigue), greater collaboration in HF management behaviors and shared activities, and greater communication and dyadic confidence compared with HF dyads in the control group.* For Aims 1 & 2 we will have the following procedures. First, we will run a series of longitudinal APIM (matched pairs) models to simultaneously examine patient and care partner trajectories in health, depressive symptoms, anxiety, perceived dyadic health and healthcare utilization (Aim 1), engagement in heart failure behaviors, shared activities, communication and confidence (Aim 2) over time (controlling for interdependent data). Each HLM Level 1 model has four coefficients representing intercepts (baseline assessments) and slopes (rates of change) for patients and care partners that become outcome variables in an unconditional Level 2 model. Conditional Level 2 models will examine the effect of GROUP on patient and care partner dyadic health and dyadic management variables (controlling for covariates). A significant coefficient for GROUP on the slope parameter and a significantly better fitting model (as evidenced by the deviance statistic) will indicate the rate of change across time is statistically dependent on treatment condition. Second, to examine dyadic symptom appraisal, a longitudinal incongruence model will be used to directly examine patient-care partner dyadic appraisal over time where the slope represents the pattern of change in incongruence (gap in appraisal between the two members of the dyad). Three separate models will be estimated for each outcome (patient dyspnea, pain, & fatigue). We will know how large the gap is, the type of gap (e.g., care partner rating lower than patient), how the gap changes over time (e.g., increases, decreases, remains stable), and how much variability there is around the average pattern of change. The effect of TCU on dyadic appraisal will be tested directly by examining the role of GROUP. Third, for individual level variables (i.e., care strain and HF-QOL) individual MLM will be used to examine the role of GROUP.

Aim 3: To determine the feasibility and acceptability of the Taking Care of Us intervention. *We will determine feasibility and acceptability of the program to inform future studies.* Concurrent quantitative and two open-ended questions assessing satisfaction and advantages and drawbacks of the TCU program will be used to determine the acceptability of the program and any needed changes. Additionally, data regarding refusal rate, retention, and # sessions attended will be used to determine the feasibility of the program. Qualitative responses will be descriptively examined for value-added information to refine the program and understand quantitative responses. All data will be examined at the patient, care partner and dyad level to understand the strengths and limitations of the program within and across dyads.

Research Population & Recruitment Methods:

The sampling frame for the proposed research is community-dwelling adult women and men with HF and their spouse care partner.

Formal inclusion and exclusion criteria for patient participants are:
Inclusion criteria:
Willing and able to provide written informed consent
Age greater than or equal to 18 years
Diagnosis of HF
Current HF symptoms (i.e. NYHA Class II-III; AHA/ACC Stage C HF)
Reachable by telephone/email/texting
Access to device with camera (e.g., computer, tablet) to participate in Zoom sessions or phone
Have a co-residing spouse/unmarried partner willing to participate
Exclusion criteria:
Major and uncorrected hearing impairment
Significant cognitive impairment
Heart transplantation/mechanical circulatory support prior to enrollment
Concomitant terminal illness that would impede participation in a longitudinal study
Active psychosis or severe substance abuse that would impair the ability to complete the study
Inability to complete the requirements of the study, including enrolment in an additional intervention trial

Formal inclusion criteria for spouse care partner participants are:
Age greater than or equal to 18 years
Co-residing with the patient at the time of recruitment
Have lived with the patient for a minimum of one year similar to other couple studies
Be willing and able to provide written informed consent

Inclusion Criteria Justification: An approximately equal number of women and men with heart failure will be enrolled. No potential participant will be excluded based on gender, race or ethnicity.

With 72 couples (144 participants total), and allowing for a 17% missing data rate, i.e. 60 dyads), we have 80% power to detect a 6.6 point difference in dyadic PROMIS global health scores between intervention and control groups (score mean=50, SD=10), which is greater than a minimally clinically important difference (estimate of ½ SD (5) due to no additional estimates available). These preliminary data are required to determine the sample size needed for a larger trial.

HF patients are generally older, though it can occur at any age. Those younger than 18 will not be approached for enrollment as the underlying heart failure pathology (e.g. congenital heart defects) is dissimilar to those with coronary artery disease, hypertensive heart failure and other forms of cardiomyopathy and our focus on couples renders the study not relevant to children. Based on epidemiologic data, we anticipate an age range of 18 to 90 with an average of approximately 60-70 years. Our previous HF patient samples have had means of approximately 57 years of age. We anticipate that spouses/unmarried partners will have a similar age distribution. HF occurs in both genders and in persons of all races and ethnicities. No potential participant will be excluded based on gender, race, ethnicity, or sexuality. As an equal number of men and women comprise the HF patient population, approximately equal numbers of men and women will be enrolled in the proposed study (along with their spouse/partner). Specifically, we plan to stratify our randomization by patient gender to ensure equal representation of patient gender across our intervention and attention-control conditions. As with our previous HF research, if enrollment in the total sample becomes imbalanced, every effort will be made to increase the enrollment of the underrepresented gender.

Robust enrollment and retention of persons from minority populations is absolutely desired in the proposed study to achieve our goal of a representative sample of patients with HF (and their care partners). Planned enrollment is based on the distribution of race in Massachusetts where the sample will be drawn. Most recent data shows 80.8% of people in Massachusetts are Caucasian (71.4% Caucasian non-Hispanic or Latino), 8.9% are African American, 7.1%% are Asian, 0.5% are American Indian/Alaska Native, 0.1% are Native Hawaiian/Other Pacific Islander, 2.5% report two or more races and 12.3% are Hispanic or Latino. *https://www.census.gov/quickfacts/MA* We, therefore, believe we can attain a diverse and representative sample in recruiting at least 7 African American dyads (10%), 7 Asian dyads (10%), and 1 Native American Indian and Alaska Native dyads (0.1%). We also hope to recruit approximately 10 dyads (13%) who identify as Hispanic or Latino. We are firmly committed to a representative sample. We will actively target and oversample, where possible, potential minority participants. If our strategies to recruit persons from minority populations are not effective, we will consult with colleagues who specialize in HF research among specific minority groups for alternative strategies. We believe we can attain a sample where 25% of participants identify with a racial minority.

The targeted sample is 72 community-dwelling couples with heart failure (72 HF patients & 72 spouse care partners) with equal patient gender representation (36 couples per condition) to maximize ability to generalize. We will recruit approximately 6 dyads per month during 12 active months of recruitment for a total of 72 couples through the community and social media and referrals from Tufts Medical Center, Atrius Health and other cardiology professionals within our network.

We will use standard recruitment procedures that have been successful in our prior couple studies. Recruitment flyers will be shared in the community and through social media to advertise the study. Flyers will

provide interested heart failure patients with information about the study and contact information for the Boston College research team. Those dyads who are interested in the study and contact the research team will be screened by study staff not directly involved with patient care. Study staff will speak with both members of the interested HF dyad and determine eligibility. If both members of the HF dyad are interested and eligible, the project coordinator will ask participants to carefully read and provide written informed consent using an online consent/HIPAA authorization form via our Research Electronic Data Capture (REDCap) platform. (In rare circumstances where participants cannot or do not want to complete this process electronically we will mail a consent form and stamped, addressed return envelope). Regardless of mode, we will describe the study in detail, make sure participants have all of their questions about the study addressed and obtain written informed consent from all participants. Heart failure patients are often older in age, so as in our past studies, the option for reading the consent form detailing the requirements of participation will be offered to both patients and their care partners. In fact, reading aloud the entire consent form to potential participants has become the standard default in our current research. A copy of the consent form will be provided/sent to each participant (both members of the heart failure dyad). Participants can ask questions regarding the study on an ongoing basis. Waiver of elements of informed consent or HIPAA authorization will not be sought. We will not use parental consent, assent procedures, or any other form of proxy consent in this study.

Tools that will be used to recruit Recruitment flyers distributed in the community and through social media.

Research Incentives and Payments: Dyads will also be compensated with a $100 gift card for their participation.

Informed Consent Procedure:
All team members will attend virtual training hosted by the study MPIs. The training will include didactic presentations, roleplaying, feedback and problem solving about performance as well as study procedures and potential issues that may arise during sessions. The program will include information specific to HF and the components of the intervention/education programs as well as training for the RAs. Ongoing training will include review of completed forms to provide feedback on standardized protocol. To ensure independence of observations, interviewer, interventionist and control group educator training will be conducted separately. MPIs will closely monitor the interventionist and control group educator throughout the study to ensure fidelity of implementation by holding bi-weekly meetings. Treatment fidelity will be maximized by developing a standardized intervention manual in the first phase of the study.

The project coordinator and study staff will screen and obtain verbal consent and then direct eligible and interested dyads to complete written informed consent using an online consent/HIPAA authorization form via our Research Electronic Data Capture (REDCap) platform. All study staff will undergo training by the MPIs of the study as well as completing all necessary human subject education training.

After the consent form has been read to the participants we will ask them to summarize their understanding of the study and their participation. Participants will be strongly encouraged to ask questions about procedures and questions at all stages of the process.

Study staff will speak with both members of the interested HF dyad and determine eligibility. If both members of the HF dyad are interested and eligible, they will be asked to provide verbal consent to participate in the study. Once verbal consent has taken place, the project coordinator will first ask participants to carefully read and provide written informed consent using an online consent/HIPAA authorization form via our Research Electronic Data Capture (REDCap) platform.

Regardless of mode, we will describe the study in detail, make sure participants have all of their questions about the study addressed and obtain written informed consent from all participants. Heart failure patients are often older in age, so as in our past studies, the option for reading the consent form detailing the requirements of participation will be offered to both patients and their care partners. In fact, reading aloud the entire consent form to potential participants has become the standard default in our current research. A copy of the consent form will be provided/sent to each participant (both members of the heart failure dyad). Participants can ask

questions regarding the study on an ongoing basis. Waiver of elements of informed consent or HIPAA authorization will not be sought. We will not use parental consent, assent procedures, or any other form of proxy consent in this study.

Confidentiality:
Data will be collected via REDCap and stored electronically as de-identified in encrypted, password protected files on the BC server. A separate and protected computer file that contains identifiable data that is necessary to contact participants for follow-up (medical record number, phone numbers, e-mail addresses, and U.S. mailing addresses) will also be kept in an encrypted, password-protected file on the BC server accessible to only the study MPIs and project coordinator. This file will be the only file that can link participant identifying information to the study unique codes.

All participating couples will be assigned a code number and all identifying information will be removed from all data sources (hard copies and electronic copies) so that only code numbers will be used. Codes will not contain any part of the 18 HIPAA identifiers (initials, DOB, MRN). Based on guidance from the Boston College IRB, we will keep one separate and protected computer file that contains identifiable data that is necessary to contact participants for follow-up (medical record number, phone numbers, e-mail addresses, and U.S. mailing addresses). This file will be the only file that can link participant identifying information to the study unique codes. All other data will be de-identified and labeled with unique study codes. All study meetings where protected information will be discussed will be closed and study meeting notes will be completed without reference to identifiable participant information. Although there are options for encryption of email, this team has decided to avoid emailing any identifiable patient information over email due to concerns over breaches of confidentiality. Procedures for maintaining confidentiality will be reviewed at all study meetings to assure compliance.

All participating couples will be assigned a code number and all identifying information will be removed from all data sources (hard copies and electronic copies) so that only code numbers will be used. These unique study codes will not be based on any individual identifying data (e.g., age, DOB). As part of the study protocol, no one except the MPIs and project coordinator will have access to an electronic master list containing names and numbers and other protected health information. This electronic file will be maintained for effective participant tracking and follow-up. The file will be encrypted and password protected and located in a secure, password-protected network folder on the BC server. Consent forms will be similarly stored electronically

Statement of potential research risks to subjects Physical and psychological risks associated with this study are considered no more than minimal. There are three potential risks to participants in the proposed study. First, participants may experience distress or become emotionally upset during the sessions or completion of the questionnaires due to the personal and sometimes sensitive nature of some of the questions/topics. Second, participants, particularly patients may experience fatigue completing questionnaires or sessions. Fatigue has not been a factor in our previous HF research that has included a larger number of measures and, in some cases, blood draws and physical function testing, but if fatigue becomes an issue in either interviews or intervention/control sessions, we will divide sessions up, take breaks and allow participants to delay or discontinue until they are ready to resume. We have, purposely, selected brief measures and contained the number of measures to minimize response burden and fatigue. Third, there is a risk that confidentiality about the patient s heart failure may be compromised by participating in the study. Such a breach of confidentiality has never happened in previous research by this team. We estimate the risk to be minimal in the proposed study and safeguards to protect participants are outlined below. There are no financial or legal risks foreseen related to participating in this study. Participation in the proposed study is completely voluntary and separate from medical care.
Participants will be informed verbally and in writing that they may withdraw from the study at any time.

All risks associated with this study are considered no more than minimal.

How will you minimize the risks?

Protection of all participants will be ensured. Each eligible participant will be given a consent form as described above and will have the study explained to them so they can make an informed decision to participate. The MPIs are experienced in conducting interviews with participants experiencing high levels of distress, health problems and recent bereavement. They will ensure that all project staff are appropriately trained. Throughout the study participants who are distressed will be treated in a sensitive and respectful manner. Participants will be advised of their right to leave any question unanswered and to withdraw from the study at any time. Our previous experience, however, suggests that couples who agree to participate in studies regarding chronic illness are very willing to answer difficult questions and share their experiences, and feel a sense of validation in being asked. All sensitive questions in the proposed study are worded respectfully and have been used in previous studies with no adverse consequences. As with all previous and current study protocols by this team, our measure of depressive symptoms (CESD) will be scored within 24 hours of administration. If we become aware of undocumented elevated depressive symptomatology (i.e., score of 30 or greater) one of the MPIs will contact the participant with a referral to speak with their own care provider.

During sessions and interviews, we will pay close attention to the fatigue and distress levels of all participants. As with our previous and current research, participants will be regularly reminded that they may take breaks during completion of an interview or session, reschedule, or refuse to complete any or all of the interview/session.

To minimize the risk of breach of confidentiality, the following steps will be taken: All investigators and staff involved in the study will sign confidentiality statements. All participating couples will be assigned a code number and all identifying information will be removed from all data sources (hard copies and electronic copies) so that only code numbers will be used. Codes will not contain any part of the 18 HIPAA identifiers (initials, DOB, MRN). As part of the study protocol, the key will be kept secure on a restricted network drive in a limited access folder which requires ID/password authentication. Only the study Principal Investigators and Project Coordinator will have access to these protected health information as they are necessary for the conduct of the study. All other data will be de-identified and labeled with unique study codes. Consent forms, which contain participants names, will be secured in a separate locked filing cabinet that does not contain any raw participant data or any link to the unique identifier of each participant. Participants will be informed of the steps taken to maintain confidentiality.

Statement of potential research benefits to subjects
Potential benefits to participants randomized to the TCU program include greater shared appraisal regarding the patient s symptoms, greater communication and confidence, more collaborative management of heart failure and improved health. Couples randomized to the attention-control condition may experience some benefits from the attention and education counseling sessions they receive. Overall, participants may feel satisfaction from knowing that their information will help other persons with similar health issues. Knowledge and findings from the proposed pilot intervention will lead directly to the refinement of the protocol and larger trials to increase generalizability of demonstrated effects.

Consider the likelihood of the benefits. Will all or some participants benefit?
Benefits are more likely to occur in the TCU group. The purpose of the study is to directly examine and understand who benefits more than others.