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Letters

RESEARCH LETTER

Rewarding Site-Based Research

A Step Toward Improving the Ecosystem of Heart Failure Clinical Trials

The ecosystem of heart failure (HF) clinical research in the United States faces numerous challenges, contributing to modest HF clinical trial enrollment rates compared with other regions.[1] Site-based research teams, including study coordinators (SCs) and principal investigators (PIs), play a critical role in the recruitment of clinical trial participants and in the ultimate success of therapeutic development programs. However, although collaborative networks and other resources have emerged to assist the clinical trial process, the work of site-based research teams goes largely unrecognized.

Since 2019, the multidisciplinary HFC (Heart Failure Collaboratory) has partnered with the HFSA (Heart Failure Society of America) in a unique, national awards program that highlights the outstanding work of site-based research teams in HF clinical trials.

Award nominations are solicited via email to the HF community, social media (eg, Twitter), and the HFC and HFSA websites. Site PIs, SCs, and research sites are eligible for nomination. Members of the HFC working group evaluate and select awardees in conjunction with the HFSA awards committee based on total enrollment, enrollment of underrepresented populations, diverse study teams, data quality, participant retention, and trial involvement. Awardees receive a certificate, $500 toward the HFSA Annual Scientific Meeting (ASM), and recognition in the *Journal of Cardiac Failure* Editors' Page, on social media, HFC and HFSA websites, and at an awards session during the HFSA ASM.

Since the program's inception, this effort has recognized more than 100 individuals (PIs and SCs) and more than 20 research sites. We aimed to measure the impact of these awards to date. This analysis does not include participant identifiers or participant-level data and was exempt from ethics approval.

In November 2022, the HFC working group, with feedback from previous awardees and active SCs, developed a 4-question survey to better understand the impact of this awards program. The survey was sent to all past award recipients. The survey was delivered successfully to 56 of 57 site PIs and 35 of 53 SCs (66%) (19 emails received "email address not found" automated replies). Ten SCs and 24 PIs completed the survey, for an overall response rate of 37% (43% among PIs and 29% among SCs).

All respondents acknowledged that recognition with an award was at least "somewhat meaningful," with 27 awardees (79%) classifying the awards as "very meaningful" (**Figure 1**). No awardees received a raise or bonus as a direct result of their award. However, most respondents (88%, n = 30) have their research award listed on their curriculum vitae, and 5 SCs (50%) referenced their award in performance reviews or career advancement discussions. Eight SCs (80%) and 9 PIs (38%) received some form of additional recognition from their home institution related to this award, and more than one-third of respondents shared news of their award on social media.

Feedback on recognition type varied by individual responder with no clear consensus. "Recognition at the HFSA ASM and certificate" was the highest scoring response for both SCs and PIs—with "offered authorship on main or secondary paper" as a close second choice among PIs. Respondents had the opportunity to write open-ended suggestions for future recognition. One PI suggested sending certificates of recognition to HF clinical trial sponsors, and another suggested that PI awardees be placed on an "A-list" of PIs ready for Data Safety Monitoring Board experience or national trial leadership for sponsor reference. SCs and PIs may be motivated by different incentives, and whenever possible, leadership should consider using multiple forms of recognition to reward strong work.

Opportunities for site PIs to engage in authorship on main and secondary papers deserve strong consideration by trial leadership, as this may represent an important incentive to investigators and strengthen their commitment to clinical research. Methods of assigning authorship to all participating site investigators have been successfully implemented in large clinical trials.[2]

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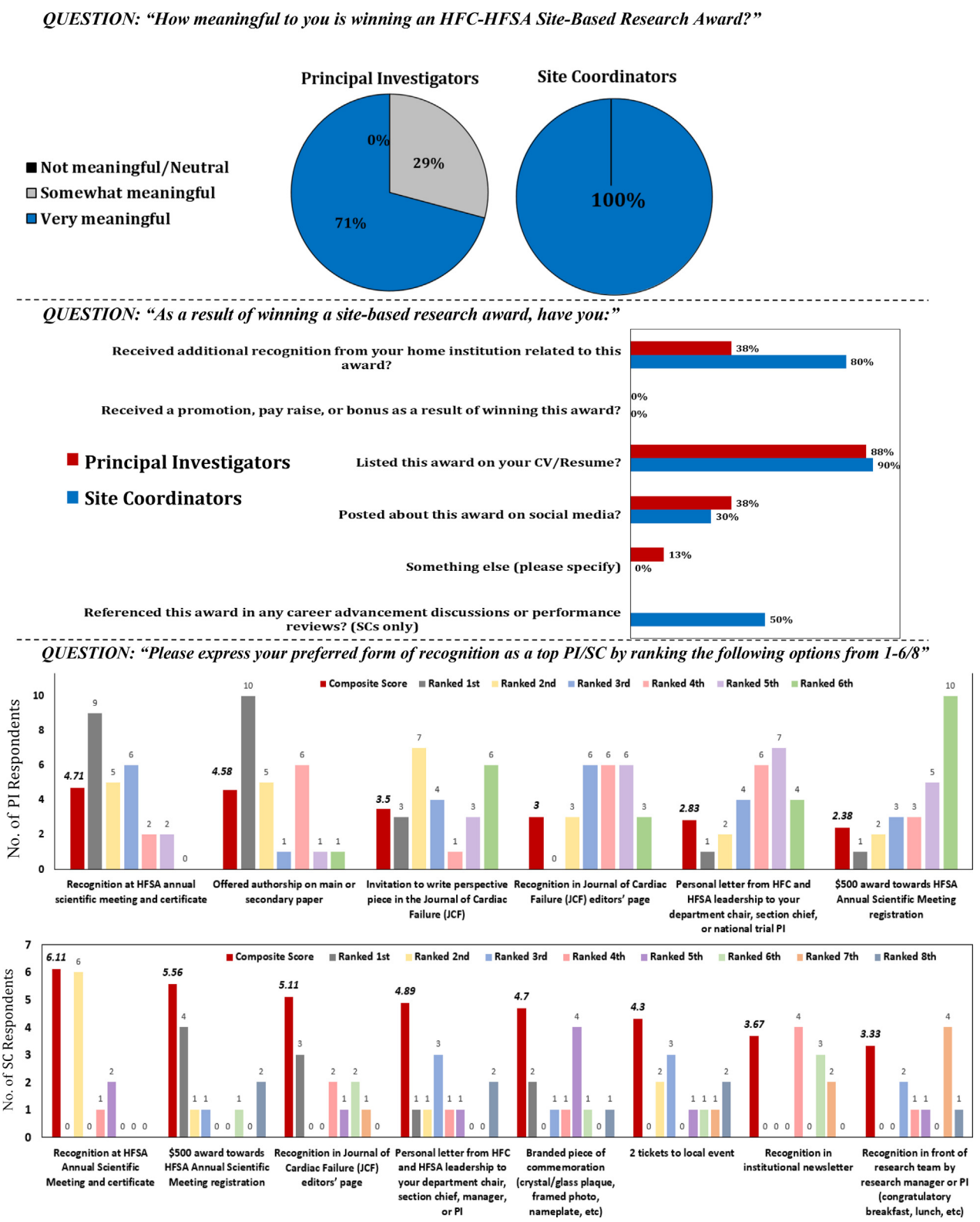
FIGURE 1 Aggregate Survey Responses From 34 Past HFC-HFSA Research Awardees, Including PIs and SCs



CV = curriculum vitae; HFC = Heart Failure Collaboratory; HFSA = Heart Failure Society of America; PI = principal investigator; SC = site coordinator.

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Our inability to contact many SCs highlights the high rate of turnover among these positions, which are often perceived as transient or steppingstone roles. Low response rate among SCs suggests that stronger incentives, among other interventions, may be needed to facilitate higher retention rates.

It is important to reiterate that low engagement from investigators is one of many barriers facing clinical trials. A 2019 report identified numerous other stressors to clinical trial operation, including insufficient budgets, contracting delays, finding subjects, lack of qualified coordinators, and institutional review board approval.[3] Resources targeted at other operational challenges, such as training and staffing programs for coordinators and regulatory personnel may also be effective measures to improve trial efficiency. However, our data indicate that recognizing outstanding work can play a role in promoting strong research culture.

Our survey response rate was higher than similar surveys conducted by national societies; however, it should be noted that there is potential for nonresponse bias in these survey data, as nonresponses could be interpreted as feeling that recognition was "not meaningful."[3,4] Therefore, these results should be interpreted with caution. The survey was received by only 66% of study coordinator awardees, likely because of high turnover in coordinator roles.

The short timeline of the program limits understanding potential long-term benefits of recognition, such as future study leadership opportunities. This survey did not ask about combatting feelings of "burnout," and future research should investigate this outcome. Finally, 2 slightly different surveys were used to poll SCs and PIs—each tailored to be more applicable to the respective roles.

Public recognition may be important and meaningful to members of research teams, including both PIs and SCs. Finding creative ways to encourage, recognize, and reward significant contributions to the research community could be one mechanism to increase engagement among research teams and improve clinical trial efficiency.

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Barry Greenberg, MD, served as Guest Editor in Chief for this paper.
Dr Mentz is a consultant to Abbott, Medtronic, Boston Scientific, and Zoll. Dr Lala is a Speakers Bureau member for Abiomed, Cytokinetics, Novartis, and Zoll; and performs contracted research for Merck. Dr Whellan is a consultant to Novo Nordisk. Dr Walsh has served as a consultant for Bayer and Verily; serves on an advisory board for Regeneron; serves on the steering committee for Cardionomic; and serves as a principal investigator for EBR Systems. Dr Costanzo has served as a Board of Directors member for Nuwellis; has received research grants from Bayer, Novartis, V-Wave to the Midwest Cardiovascular Institute; and is an associate editor for the *Journal of the American College of Cardiology*. Dr Yehya has received speaking honoraria from Merck; and has served on advisory boards for Merck and CareDx. Dr Malik is an employee and shareholder of Cytokinetics. Dr O'Connor has received grant or research support from Merck; and consulting fees from Merck, Bayer, and Abiomed. Dr Bristow has served as a director, officer, partner, advisor, consultant, or trustee for ARCA biopharma; has received research grants from the American Heart Association and National Institute of Allergy and Infectious Diseases; and reports personal payments from ARCA biopharma. All other authors have reported that they had no relationships relevant to the contents of this paper to disclose. The authors thank the Heart Failure Society of America (HFSA) for their partnership and support of the annual HFC-HFSA Site-Based Research Awards Program.
The authors attest they are in compliance with human studies committees and animal welfare regulations of the authors' institutions and Food and Drug Administration guidelines, including patient consent where appropriate. For more information, visit the Author Center.

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