

## **Report**

### **Stakeholder Engagement In-Person Meeting**

### **December 3, 2019**

**Date: March 31, 2020**

This report is a compilation of work beginning with input from the NIA IMPACT Collaboratory's Stakeholder Advisory Committee and then finalized after additional Stakeholder Engagement Team discussion during and following the NIA IMPACT Collaboratory in-person meeting January 28 & 29, 2020.

The IMPACT Collaboratory's Stakeholder Engagement Team (SET) conducted a one-day in-person meeting on December 3, 2019 including members of the Stakeholder Advisory Committee (SAC) and additional participants relevant to the IMPACT Collaboratory's efforts regarding stakeholder engagement.

The **Objectives** for the December 3<sup>rd</sup> in-person meeting of the SET and SAC were to:

- 1) Review the role of the SAC;
- 2) Provide advice for the IMPACT Collaboratory to address stakeholder engagement;
- 3) Strategize ways to assist investigators with pilot studies of embedded Pragmatic Clinical Trials (ePCTs); and,
- 4) Discuss priority topics to address in guidance materials.

The **Meeting Agenda** included:

- Welcome and Overview of NIA IMPACT Collaboratory
- Introductions
- Defining Stakeholder Engagement
- Informing the Collaboratory: Pilot Studies
- Informing the Collaboratory: Lived Experience Panel
- Informing the Collaboratory: Engaging Health Care Systems
- Summary advice from SE team members to the NIA IMPACT Collaboratory

#### **Welcome and Overview of the NIA IMPACT Collaboratory**

The meeting began with a welcome from Gary Epstein-Lubow and Katie Maslow before an overview presentation of the IMPACT Collaboratory from Susan Mitchell and Vince Mor. This was followed by personal messages about the importance of research to address aspects of the lived experience of dementia; presented by a person living with dementia, Louise Phillips, and a family caregiver and dementia care clinician, Katie Brandt.

## Introductions

All meeting participants shared their professional background which led to discussion and questions about definitions of stakeholder engagement (SE) as related to the work of the IMPACT Collaboratory.

## Defining and Evaluating Stakeholder Engagement

Lori Frank presented definitions of SE as prepared by the Patient-Centered Outcomes Research Institute (PCORI). PCORI has examples of logic models from the PCORI evaluation framework, with one focused specifically on engagement, and this could be instructive for an evaluation plan for the IMPACT Collaboratory. The model identifies elements of engagement that are potential predictors of intermediate and long-term outcomes. Intermediate outcomes include process variables hypothesized to be influenced by engagement, such as recruitment and retention rates, and long-term outcomes including uptake and use of information generated from studies with research engagement.

The IMPACT Collaboratory could consider work on stakeholder engagement in AD/ADRD research as opportunities to 1) further refine definitions and models of SE, 2) add to the evidence base about engaged research models, and 3) evaluate the impact of engagement on projects. To begin acting on these opportunities, the IMPACT Collaboratory could seek to better describe engagement and track the impact of engagement by adopting and/or refining the PCORI-created evaluation framework. Additionally, questions about SE could be asked of all awardees and of engaged research partners as a means of capturing varying perspectives of engagement and tracking its impact. Other work with the potential to inform IMPACT Collaboratory engagement efforts includes the engagement research reports completed as part of the PCORI Dementia Methods Pre-Summit in advance of the 2017 Dementia Care and Services Research Summit.

Ellen Tambor presented SE work from the original NIH Healthcare Systems Research Collaboratory. This section explained commonly used definition of “stakeholders” in the context of clinical research and a definition of “engagement” that emphasizes the bi-directional relationship between stakeholders and researchers. The rationale for stakeholder engagement in research includes both moral/ethical arguments related to the rights of individuals to have a say in what and how research is conducted, and pragmatic arguments related to improving the quality, relevance, and usefulness of clinical research. Patients, broadly defined to include individuals having lived experience with a particular condition, as well as, family members, caregivers, providers, payers, and patient advocates, should always be considered as key stakeholders. In addition, a range of clinician stakeholders may be important to include. For pragmatic trials, “front-line” providers of all types are particularly important stakeholders.

The Stakeholder Engagement Core for the NIH Collaboratory focused on learning from the experiences of the first cohort of demonstration pragmatic clinical trials (PCTs) and convening a multi-stakeholder advisory committee to discuss challenges that were common across PCTs. Clinician engagement emerged as a key challenge, highlighting the need to move beyond buy-in at the health system leadership level to directly engage with front-line clinicians in conducting pragmatic trials. The SE Core applied this and other lessons learned from the demonstration PCTs to the chapter on stakeholder engagement in the *Living Text Book of Pragmatic Clinical Trials*. The IMPACT Collaboratory can build on this work by agreeing on principles of how stakeholder engagement should occur at a central as well as individual pilot project level.

Katie Maslow presented information about SE specific to dementia care research in the U.S. Until the past few years, people living with dementia (PLWD) and their family caregivers were included as subjects (research participants) in many care-related research studies in the U.S., but they were rarely included as team members (research partners) or stakeholder informants to team members in such studies.

In 2017, PCORI sponsored a 2-day Dementia Methods Pre-Summit to convene researchers, care providers, clinicians, people living with dementia, family caregivers, and policy analysts to discuss general concepts about stakeholder engagement in research and how those concepts apply to research on dementia care. Summit participants discussed the potential roles of people living with dementia, family caregivers, and other stakeholders as research partners and recommendations for next steps. Reports were produced from this meeting, and findings and recommendations were presented at the first National Research Summit on Care, Services and Supports for Persons with Dementia and their Caregivers in 2017.

Six stakeholder groups were convened to inform the 2017 National Research Summit on Care, Services and Supports for Persons with Dementia and their Caregivers in 2017. These stakeholder groups were tasked to develop research recommendations for Summit leadership. Drawn from these stakeholder groups, 6 people living with dementia and 4 family caregivers spoke at the summit, presenting research recommendations from their respective group. This involvement of people living with dementia and family caregivers was very well received, and similar procedures were used in planning for the second National Research Summit in 2020. Publications from the 2017 Summit and those that may become available in 2020 regarding all stakeholder groups are instructive for the IMPACT Collaboratory.

PCORI has funded two new dementia-related projects. One project is now developing training for researchers and other stakeholders about how to engage people living with dementia and their caregivers as research partners. The second project is a comparative effectiveness study of two models of dementia care coordination. This study is making extensive use of a national stakeholder committee and local stakeholder committees in each of the study sites. These projects will provide valuable information to support increased and improved stakeholder engagement in dementia care research.

Important issues and questions that arise in the process of engaging people living with dementia as research partners include the following:

- Representativeness: many different characteristics affect willingness and capability of individuals to be involved in research and their perspectives on research needs and research processes; how can we reduce bias?
- Progression of cognitive impairment: rates of progression differ, and loss of specific cognitive functions may make involvement in research very difficult; how can we evaluate progression? How can we maintain engagement for as long as possible?
- Engagement of people living with dementia who can no longer speak for themselves. Can family members and other caregivers speak from the perspective of the person with dementia? What other options should be tried?

Investigators who are designing and implementing dementia care research supported by the IMPACT Collaboratory will benefit from information and coaching to develop appropriate stakeholder engagement practices.

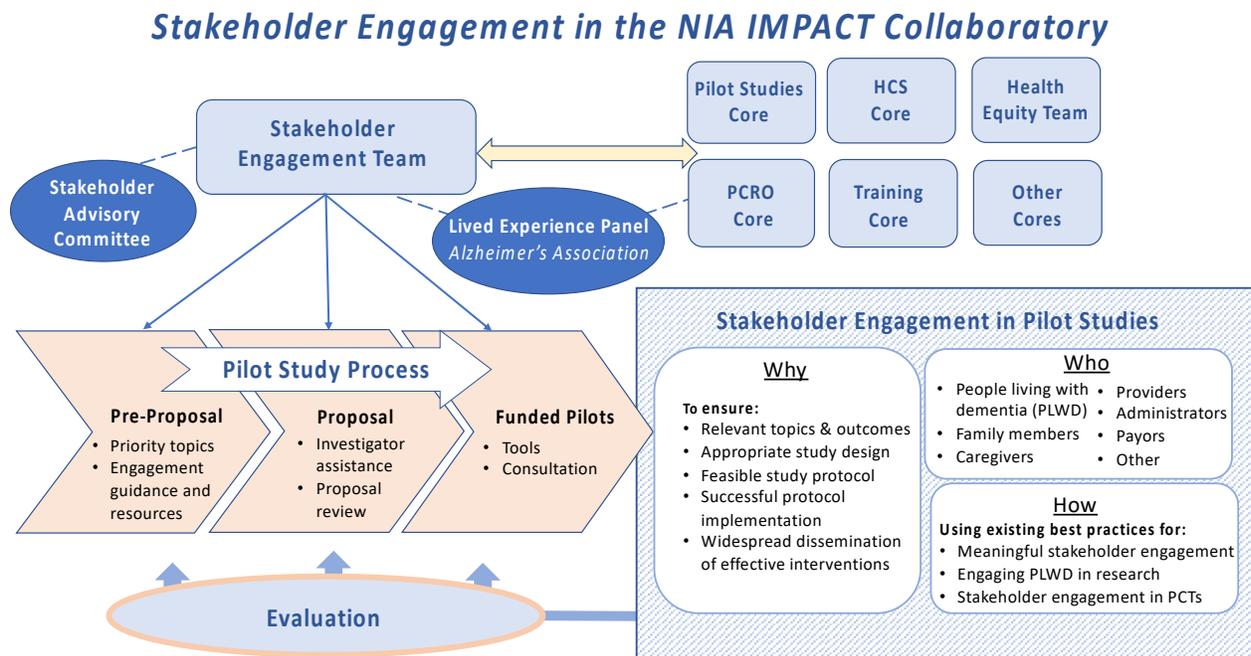
### **Informing the Collaboratory: Pilot Studies**

The IMPACT Collaboratory's process for supporting pilot ePCTs was reviewed by Laurie Herndon followed by suggestions from Jill Harrison as to how stakeholders can be integrated into the pilot study processes. The discussion of engaging stakeholders in the pilot process began with a review of the size and complexity of the social network configuration of the IMPACT Collaboratory. The intention of this review was to emphasize the collective power the SAC has in facilitating interconnectivity among individual members and in broadcasting the signal of IMPACT to larger networks of stakeholder groups outside of the IMPACT Collaboratory. SAC members were asked to consider how far and wide they want the reach of the IMPACT Collaboratory to be, taking into consideration a multitude of factors, including the composition of our network, the range in subject matter expertise across IMPACT Cores and Teams, and the pressing fact that research is not keeping pace with the rate at which people are developing dementia. A brief reflection on earlier comments from Louise Phillips, a person living with dementia, and Katie Brandt, a family caregiver, further emphasized the urgency for "real world" interventions to improve dementia care. The discussion was also anchored in a brief review of statistics from the Alzheimer's Association, highlighting a common statistic that one person in America develops Alzheimer's disease every 65 seconds.

Participants explored the typical pathway for pragmatic trials in which an intervention originates from a researcher rather than emerging as a direct result of asking stakeholders to define the problem or even prioritize the problems they need addressed by research. This potential risk for lack of relevancy and/or alliance between the interventions selected by researchers and stakeholders' everyday lives has been described as one reason why some interventions are never adopted into care delivery, despite their success during trial. Because

pragmatic trials have been defined as an essential approach in the national strategy for AD/ABRD to rapidly and dramatically improve dementia care, it is essential that trials are aligned with what matters most to PLWD, their caregivers, frontline staff, and the health care systems that care for them if we want them to be adopted as part of the standard delivery of care.

A logic model regarding the roles of the SET was drafted following the in-person meeting. An infographic will accompany suggestions for best practices pilot study investigators can use when planning stakeholder engagement components of their ePCTs. In addition, a logic model with infographic(s) will also support the SET in communicating procedures within the IMPACT Collaboratory. The initial draft of this logic model is below.



This infographic shows the SET as maintaining continuous interactions with the IMPACT Health Equity Team and IMPACT Collaboratory Cores. With the PCRO Core and the Alzheimer's Association, the SET will collaborate on development of a Lived Experience Panel. The SET will also maintain the Stakeholder Advisory Committee which will continue to provide input to all aspects of the IMPACT Collaboratory. Specifically, regarding the pilot study process, members of the SET and SAC will be available to assist investigators from pre-proposal through to implementation of SE aspects of funded studies. The Why, Who and How of SE is noted along with the importance of continually evaluating how SE is occurring in and affecting pilot studies.

An additional infographic is planned to communicate suggestions for engaging stakeholders in the pilot process; these suggestions may include:

- 1) requiring evidence of engagement with stakeholders early in the submission process by specifying requirements in future RFAs;
- 2) requiring evidence of relevancy of the proposed intervention to the health care sites where the trials are embedded;
- 3) including stakeholder engagement in the application preparation process (and in the review process, including informing applicants of scoring criteria to be used by stakeholders as formal reviewers;
- 4) requiring consumer-friendly summaries from applicants of proposed projects;
- 5) using consumer-friendly summaries to facilitate rank ordering of importance/relevancy by PLWD, caregivers, direct care staff, and health care systems; and,
- 6) conducting listening sessions/focus groups with multi-stakeholder groups by different setting type (i.e. nursing homes, hospice, hospitals, etc) to define most pressing needs from their perspective.

As a component of the additional infographic, or in a separate format, there will be suggestions for activities the IMPACT Collaboratory can do to promote SE in ePCTs, including:

- 1) creating a national registry to connect consumers with researchers;
- 2) conducting virtual listening sessions/focus groups with consumers interested in IMPACT;
- 3) facilitating interprofessional work teams with the Health Care Systems Core, Health Care Systems Leaders Council, Dissemination & Implementation Core, and the SAC to promote integration of stakeholders in pilot projects; and,
- 4) refreshing and revising the composition of the SAC based on target populations of interventions proposed by pilots (i.e. PLWD, direct care staff, family caregivers).

### **Informing the Collaboratory: Lived Experience Panel**

In the afternoon sessions, expectations of pilot studies were further explored as they relate to the involvement of people with lived experiences of dementia as well as diverse inclusion of clinicians, service providers, health care system leaders, payers and other stakeholders.

Antonia Bennett of the IMPACT Collaboratory's Patient and Caregiver Reported Outcomes (PCRO) Core provided an overview of the objectives of the PCRO Core, and then began a discussion about the domains which could be assessed in AD/ADRD ePCTs that are relevant to

the experience of PLWD and their caregivers. Attendees provided feedback on an initial draft of a measurement framework composed of seven domains: 1) detection and diagnosis, 2) assessment and care planning, 3) medical management, 4) symptoms and ADLs, 5) information and support, 6) transition and coordination, and 7) caregiver specific. Each domain is composed of subdomains, for example, the domain "medical management" includes three subdomains: a) physical symptoms, b) co-morbidities, and c) medication issues. Attendee feedback noted additional subdomains which could be included in the framework. This discussion during the SAC in-person meeting will be continued via a Lived Experience Panel, described below. A final draft of the measurement framework will be used to define the organizing structure and scope of the library of clinical outcome assessments that will be developed by the PCRO Core.

Monica Moreno of the Alzheimer's Association (AA) described the development of a "Lived Experience Panel." This Panel is proposed to be modelled similarly to successful work the AA has completed with their Early Stage Advisory Group (ESAG) regarding contributing input to AA initiatives regarding policy, research, and community-based services. The AA previously partnered with the leadership of the 2017 and 2020 National Research Summit on Dementia Care regarding the Stakeholder Group of Persons Living with Dementia. For the IMPACT Collaboratory, the AA proposes that the Lived Experience Panel be comprised of 12 individuals (4 persons living with dementia, 4 family caregivers, and 4 representatives of persons living with moderate-to-severe dementia) who will undergo a recruitment process similar to how ESAG members are identified and invited to participate. There will be a defined rotating schedule such that the membership is not entirely reconstituted at each time of transition. After a person living with dementia completes her/his work with the Lived Experience Panel, that person's family caregiver can apply for consideration to participate.

The PCRO Core, the AA, and the SET will work together with the Health Equity Team to define the recruitment procedures, roles/responsibilities, agendas, and products of the Lived Experience Panel. Other IMPACT Collaboratory Cores will be informed of the work of the Lived Experience Panel, including possible opportunities for members of the Panel to inform and assist work of other Cores.

### **Informing the Collaboratory: Engaging Health Care Systems**

The discussion on engaging health systems leaders was led by Alice Bonner and included Lee Jennings, David Gifford, Eric Larson and other contributors. The conversation addressed examples of strategies for principal investigators to use when engaging health care system leaders and clinicians during development and implementation of ePCTs. There was a discussion of how to individualize strategies by health care system stakeholder type, including which strategies may be best suited for engaging clinicians, healthcare system staff, administrative leaders, community health team members and others. There was also discussion of how a pathway might be developed to facilitate match making between health care system leaders and investigators regarding exploration and initiation of pilot studies and/or preliminary activities leading to the development of ePCTs.

## Summary advice from SE team members to the NIA IMPACT Collaboratory

The final session was an overview of selected advice growing from discussion of the meeting's content. It was agreed that objectives of the in-person meeting had been achieved, with outcomes including: 1) successful orientation of SAC members; 2) preliminary plans for clarifying definitions and processes regarding SE within the Collaboratory; 3) review of SE activities related to pilot study investigators; and 4) discussion of future SE activities including development of a Lived Experiences Panel, guidance documents for investigators, a logic model for SE activities within the IMPACT Collaboratory, and methods for evaluation of SE activities.

Subsequent to the in-person meeting, the SET has defined future activities, as listed below:

Interaction with other IMPACT Collaboratory Cores and Teams about Stakeholder Engagement: this process is undergoing active development with the Health Equity Team and the PCRO Core; contact with individual Core leaders has occurred in addition to routine all-leadership discussions.

Defining of a process model for the roles of the SE Team and the SAC within the IMPACT Collaboratory: The initial infographic and description are included in this report. Additional infographic(s) are being considered. Membership of the SAC may be addressed in future years by considering additional participants, including persons representing "front-line" clinicians, healthcare system leaders, payors and/or family caregivers; a process for identifying additional participants may be defined in collaboration with the IMPACT Health Equity Team.

Coaching of investigators on inclusion of stakeholders: The SE team will provide guidance language on the roles and responsibilities of stakeholders in pilot studies and full ePCTs. This may include specifically asking awardees to provide a rationale for the engagement they plan, and if it is not comprehensive – at all stages of the project – they should provide a rationale for why not. Ideally the IMPACT Collaboratory will teach and empower awardees to answer this question.

Collaboration on a Lived Experience Panel for work with PCRO Core: This is under development with the Alzheimer's Association, as described in this report.

Contribution to identification of stakeholders' priority research areas: The SET is considering how it may work with other Core and Team leaders to help determine "what matters most" to PLWD, caregivers and clinicians. Significant work has been completed in this area as preparation for the 2017 and 2020 Dementia Care Research Summits; this has been summarized by Katie Maslow. There may be consensus on the importance of addressing health-related quality of life and value; such a focus could lead the IMPACT Collaboratory to address controversies about measurement of healthcare value with regard to dementia care. Beyond quality of life and value in healthcare, a dialogue about the list of potential topics is important. PCORI, the Lind Alliance, and the Alzheimer's Disease Patient and Caregiver

Engagement (AD PACE) Initiative have done important work in this area. There is caution against prioritizing that which can be easily measured without considering whether it matters.

Linking methods for stakeholder engagement developed by PCORI and others: As the SE process model develops along with creation of guidance materials, there will be determination of metrics for evaluation of SE in pilot studies. These materials will be linked to SE methods from developed by PCORI and others.

Evaluation of stakeholder roles and responsibilities in pilot studies: Metrics of success need to be identified at the individual program level and for the IMPACT Collaboratory more broadly. Ensuring that questions about the contribution of engagement to specific programs will also be important. Projects can build this information collection into the work and the IMPACT Collaboratory can include questions about engagement in awardee reporting.

Collaborating with health care system leaders to address issues of workforce: The in-person meeting included discussion of different settings of care to consider as intervention targets, including ensuring there's active attention to the links between health care settings and other places important to people living with dementia. It is essential that interventions not add workflow burden, and de-implementation will be appropriate in some cases. A challenge is addressing workforce limitations – building toward an ideal while maintaining realism about staffing possibilities. The SAC may be helpful in terms of providing a holistic view of intervention contexts.

Actively attending to nomenclature and terminology: Reaching a current consensus on person-centered language about people living with cognitive symptoms is important for internal Collaboratory communication and should be emphasized in all public communications with similar language recommended at the local level of ePCT implementation.

Support of dissemination and implementation: There is potential for stakeholder activities to support the dissemination and implementation work of the IMPACT Collaboratory. The SAC can be useful in terms of representing priorities of a range of stakeholders in dissemination and implementation.

Addressing the importance of “local implementation”: Methods for SE within particular communities and systems will need to be addressed regarding which procedures are universal and which have to be uniquely adapted to the specific environment.

Considering establishment of a consumer registry: The IMPACT Collaboratory receives inquiries from people interested in contributing. Tracking these inquiries is already occurring. There could be invitation into a registry, with potential matching of volunteers to investigators or other activities.

Stakeholders involved in merit review: There should be a clear model for how a range of stakeholder views will be incorporated into pilot study review, and as noted above, this should be communicated to applicants. Some choices:

- 1) Non-research stakeholders review LOIs only for feasibility and patient-importance. To be determined: will this be the charge of a standing panel? Will SAC members be asked to contribute based on expertise?
- 2) Non-research stakeholders review full applications using all merit review criteria but they do so in a session separate from that of the researcher reviewers. They may be asked for online input without a discussion, for example. There are definite pros and cons of this strategy (and I don't recommend it).
- 3) Non-research stakeholders are included in merit review fully but their input is only used from a subset of merit review criteria.
- 4) Non-research stakeholders join researchers in merit review, with their scoring on all merit review criteria incorporated into review decisions.

Instructions to the non-researcher reviewers need to be well thought out. PCORI invested in training for patients and other stakeholders involved in merit review.

### **Future meeting schedule of the NIA IMPACT Collaboratory Stakeholder Engagement Team and Stakeholder Advisory Committee**

The Stakeholder Engagement Team will meet monthly by conference call. Members of the SET will participate in work with other IMPACT Collaboratory members and provide updates regarding this work during the monthly SET meetings.

The Stakeholder Advisory Committee will meet annually. In Year 2, the meeting will take place by videoconference to review pilot study activities and progress of the IMPACT Collaboratory in advancing ePCTs. In Years 3-5, the meeting will be in person at the NIA IMPACT Collaboratory Scientific Meeting. Members of the SAC will contribute to support of pilot study investigators and to activities of the IMPACT Collaboratory; during the SAC annual meetings, SAC members will report on these activities.

This report was prepared by the Stakeholder Engagement Team, including:

<i>Team Leader:</i>	Gary Epstein-Lubow, MD
<i>Associate Team Leader:</i>	Katie Maslow, MSW
<i>Executive Committee Members:</i>	Ellen Tambor, MA, Louise Phillips, MD
<i>Administrative Core Liaisons:</i>	Susan Mitchell, MD, MPH – MPI Jill Harrison, PhD – Executive Director Laurie Herndon – Project Director

## The December 3, 2019 Meeting Participants included:

Individual	Organizations	SAC Member
Gary Epstein-Lubow, MD	Brown University; Butler Hospital	x
Katie Maslow, MSW	Gerontological Society of America	x
Brenda Nicholson, MD	Retired physician, Person Living with Dementia	x
Louise Phillips, MD	Retired physician, Person Living with Dementia	x
Ellen Tambor, MA	Center for Medical Technology Policy	x
Lori Frank, PhD, MA	RAND Corporation	x
Monica Moreno, BS	Alzheimer's Association	
Grace Whiting, MIM	National Alliance for Caregiving	x
Ian Kremer, JD	LEAD Coalition	x
Susan Dickinson, MS	Association for Frontotemporal Degeneration	x
Angela Taylor, BA	Lewy Body Dementia Association	x
Robyn Stone, PhD	Leading Age	x
Sarah Lock, PhD	AARP	x
Barbara Resnick, PhD, RN, CRNP	AMDA: The Society for Post-Acute and Long-Term Care Medicine	x
Cari Levy, MD, PhD	AMDA: The Society for Post-Acute and Long-Term Care Medicine	x
Lee Jennings, MD, MSHS	American Geriatrics Society	x
Dave Gifford, MD, MPH	American Healthcare Association	x
Shari Ling, MD	Centers for Medicare & Medicaid Services	x
Amy Kilbourne, PhD, MPH	Veterans Administration	x
Alice Bonner, PhD, RN	Institute for Healthcare Improvement Johns Hopkins University School of Nursing	x
Katie Brandt, MIM	Family Caregiver, Massachusetts General Hospital	
Susan Mitchell, MD, MPH	Principal Investigator, Hebrew SeniorLife	
Vince Mor, PhD	Principal Investigator, Brown University	
Ellen McCarthy, PhD, MPH	Executive Director, Hebrew SeniorLife	
Jill Harrison, PhD	Executive Director, Brown University	
Laurie Herndon, MSN	Project Director, Hebrew SeniorLife	
Kathryn Wessel, MPH	PCRO Core, University of North Carolina	
Antonia Bennett, PhD	PCRO Core, University of North Carolina	