Correspondence: Approval of an Amendment to an Approved PI/SC Project Application, VA Central IRB Study Number 16-12

Date: 6/15/2017

From: VA Central Institutional Review Board

To:

Principal Investigator:	Bevanne Bean-Mayberry	Bevanne.Bean-Mayberry@va
Co-Principal Investigator:	Melissa Farmer Coste	Melissa.FarmerCoste@va.gov
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Facility Name: VA Greater Los Angeles Health Care System

Subject: Approval of an Amendment to the Approved PI/SC Project Application

Protocol Title: Facilitating Cardiovascular Risk Screening and Risk Reduction in Women Veterans

1. The VA Central IRB reviewed the following request of an amendment to the project listed above under expedited procedures.

   Amendment #: 01

   Determination Date: 6/9/2017 12:15:33 PM

   Amendment Summary: The amendment request involved 1) Adding Component B to the study protocol which involves Veteran surveys and interviews; and 2) Adding the Provider Mid-Implementation and Post Implementation Guides and Email Invitations for Component A to the study.

2. The VA Central IRB made the following determination regarding the above amendment to the PI/SC application:

   APPROVED: All IRB approval criteria have been met. The modifications for this amendment do not pose an increased risk to participants.

3. This approval does not change the date the project is due for continuing review. All documents associated with this approved amendment have been made available on the VA Central IRB SharePoint site and an approval notice has been forwarded to you, the local site investigators, and the local site liaison. If local policy requires R&D Committee review and approval amendments, please forward a copy of their review to our office upon completion of review.

4. Any questions concerning the review of this project or for any other administrative issue pertaining to this study and the functions and responsibilities of the VA Central IRB can be addressed to the VA Central IRB Manager for this project, Kendra Clarke, at 202-443-5766 or e-mail, Kendra.Clarke2@va.gov.

Documents posted to the VA Central IRB Share Point website:

01. Form 116_03/30/17
02. Form 112b_03/03/17
03. Form 10-0493_05/22/17
04. Form 103_03/30/17
05. Protocol tracked version_05/18/17
06. Patient Information Sheet_05/22/17
07. Patient Baseline Survey_03/30/17
08. Patient Invite Follow-Up_05/23/17
09. Patient Follow-Up Survey_03/20/17
10. Patient Invitation_05/18/17
11. Patient Baseline Interview Guide_
12. Patient Follow-Up Interview Guide_03/30/17
13. Provider Mid-Implemation Invite_03/30/17
14. Provider Post-Implementation Invite_03/30/17
15. Provider Mid-Implementation Interview Guide_03/30/17
16. Provider Post-Implementation Interview Guide_03/30/17
17. Baseline Survey_05/18/17

Copy To:

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FACILITATING CARDIOVASCULAR RISK SCREENING AND RISK REDUCTION IN WOMEN VETERANS

Project 1 of EMPOWER QUERI

Protocol Component A combined with Component B

Component B additions are in red in the track change version

Funding Agency: **QUE 15-272**

Principal Investigator/Study Chair: Bevanne Bean-Mayberry, MD

March 30, 2017

Abstract

Project Background: Cardiovascular disease (CVD) is the number one cause of death in American women. While the American Heart Association has documented that public awareness of CVD increased from 1997 to 2009 (from 30% to 54%), women still demonstrate limited understanding of imminent CVD-associated morbidity and mortality risks. Moreover, women's control of CVD risk factors, such as lipids, blood pressure and diabetes, is worse than men's, while women also have higher obesity and inactivity rates nationally. Given persistent VA gender disparities in CVD risks, we conducted a partnered project with VA Women's Health Services to identify barriers and facilitators to CVD screening and management in women Veterans. Findings informed development of the proposed multi-component cardiovascular (CV) risk reduction toolkit.

Project Objectives: The objective of this project is to implement and evaluate a (CV) risk reduction toolkit (CV toolkit) designed to increase identification of CV risk among Women Veterans, enhance patient/provider communication about their risk, and increase Women Veterans' engagement and retention in relevant health services including referrals to key health programs (e.g., MOVE!, dieticians, health coaches, and CV specialists as needed).

Project Methods: The CV toolkit will be implemented at four women's health clinics over two years. The CV toolkit includes four components: (1) Patient education/activation tools, such as informational posters and fliers about women's CV risk (2) a CV risk assessment computerized template, which systematically captures CVD risk factor history and data from patients' medical records, and provides open fields for the provider to enter any relevant information from the patient's CV worksheet (worksheet captures CVD risk of patient and family history), (3) provider information and education programs as well as referral tools to internal services (e.g., women's MOVE! Program, smoking cessation clinics, dieticians, health coaches, pharmacists and CV or mental health specialists as needed), and (4) the Gateway to Healthy Living program tailored to Women Veterans, a facilitated group meeting that occurs in a structured format with personalized goal setting and identification of key services available at the local site to assist with lifestyle changes necessary for patient-targeted CV risk reduction. We will conduct baseline and post-implementation surveys and/or interviews with 260 patients (65 per site) as well as pre-, mid-, and post-implementation non-human subjects research interviews with 60 staff (15/site).

Results: The project is currently in the pre-implementation phase at the first site (GLA) which includes the activities from Component A (non-human subjects research interviews with staff). We have also recruited the second site and will begin pre-implementation work once the site application (LSI) is approved.

Anticipated Impacts on Veterans' Healthcare: The proposed toolkit is designed to promote patient-centered decision-making and effective clinical action around CV risk reduction among women Veterans and their VA primary care providers. Toolkit implementation and spread should ultimately reduce persistent gender disparities in quality and outcomes of VA care.

List of Abbreviations Used in this Protocol

1. CV……Cardiovascular
2. CVD……Cardiovascular Disease
3. AHA……..American Heart Association
4. WH……Women's Health
5. WHS……Women's Health Services
6. GLA……..Greater Los Angeles
7. NCP……..National Center for Disease Prevention and Health Promotion
8. BPE……...Blueprint for Excellence
9. CPRS……Computerized Patient Record System
10. EMR……..Electronic Medical Record
11. REP……..Replicating Effective Programs
12. TECH……Tool for Evaluating Research Implementation Challenges
13. WHRN……..Women's Health Research Network
14. PBRN……Practice-Based Research Network
15. PACT……Patient Aligned Care Team
16. DART……Data Access Request Tracker
17. MORE……Measuring Organizational Readiness for patient Engagement
18. MOVE……A VA National Weight Management Program
19. GLM……...Generalized Linear Model
20. EMPOWER……..…Enhancing Mental and Physical health of Women through Engagement and Retention
21. PCP……Primary Care Physician
22. LVN……Licensed Vocation Nurse
23. MSA……Medical Support Assistant

Contents

The CV Risk protocol is divided into 2 components. Component A was approved on 08/09/2016 and focuses on providers and key stakeholders in this study (non-patient data collection and only pre-condition interviews). The current submission is a combination of Component A with Component B (in red in track changes version) and includes our protocol for implementation and summative interviews with providers and key stakeholders, protocol for patients in this study including patient data collection, and nonrandomized stepped wedge analysis.

1.0 Study Personnel

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2.0 Introduction

BACKGROUND

Cardiovascular disease (CVD) is the number one cause of death in American women, and all adult women are potentially at risk for CVD.[1,2] While the American Heart Association (AHA) has documented that awareness of CVD increased from 30% in 1997 to 54% in 2009, women still demonstrate limited understanding of the imminent risks of CVD-associated morbidity and mortality. Recent updates summarizing the public health impact of CVD in women identify the following topics as important issues: (a) greater need for prevention of incident cases of CVD, (b) need for increased awareness of CV risk among women, and (c) need for larger representation of women in prevention trials.[3,4] The recently released CV guidelines for Cholesterol, CV Risk Assessment, Obesity and Lifestyle support directed lipid treatment and more personalized evaluations by providers, in addition to a strong push for educating patients about their risks and strongly recommending lifestyle changes (i.e., physical activity, diet, and behavioral counseling).[2,5-7] There are clear gender differences in the control of CV risk factors such as lipids, blood pressure, and intermediate diabetes outcomes nationally and within the VA,[8,9] with women Veterans often at higher CV risk than their male counterparts.[3,10-15] The combination of disparities and gender-specific CV risk factors suggest an urgent need for CV risk factor management in women Veterans.

The goals of this project are to implement and evaluate a CV risk reduction toolkit (CV toolkit) designed to increase identification of CV risk among Women Veterans, enhance patient/provider communication about their risk, and increase Women Veterans' engagement and retention in relevant health services including referrals to key health programs (e.g., MOVE!, dieticians, health coaches, and CV specialists as needed). This multi-component toolkit is based on findings from our recently completed work for VA Women's Health Services (WHS), in partnership with VA GLA WH leadership, where we identified organizational barriers and facilitators to CV risk assessment and management in women Veterans. The CV toolkit incorporates the *Gateway to Healthy Living* program, a national program currently being implemented by the National Center for Disease Prevention and Health Promotion (NCP) that focuses on motivating and supporting VA patients with CV risks to engage in existing VA services in order to reduce their risk.

This CV toolkit aligns directly with both VA WHS's mission to provide comprehensive health care for women based on provider competencies and patient preferences (Hayes LoS), and NCP's disease prevention goals for all Veterans (Kinsinger LoS). Moreover, per the EMPOWER QUERI conceptual framework, the toolkit—a personalized, proactive-patient driven care model (BPE 6.2.a)—represents an innovation in women Veterans' health care (7.2.g) that will enrich organizational capacity to engage and retain women Veterans in appropriate care, thereby reducing their risk. This particular project is also responsive to the Blueprint for Excellence (BPE) Transformational Strategy 3.2.b in that we leverage information technology (CPRS templates, myHealtheVet tools) and models of healthcare delivery to optimize individual and population-based health outcomes.

RATIONALE

CV risk reduction is hampered by provider- and patient-level barriers that are addressable with evidence- based implementation strategies. Provider barriers to working with patients on appropriate CV risk reduction include lack of time, lack of awareness of the latest CVD prevention guidelines, difficulty interpreting the guidelines, difficulty accessing relevant electronic medical record (EMR) data at the point of care, low self- efficacy to counsel patients in behavioral change, habit or inertia, fragmentation of care, and perceptions of low patient interest or capacity to follow-through on recommendations.[16-19] These barriers may be decreased by provider education, training in the discussion and management of CV risk factors, centralization of relevant EMR information, patient activation support, and feedback to providers.[16,18] A meta-analysis of quality improvement (QI) efforts found that patient and provider education materials are effective at improving blood pressure control.[20] There is also evidence that clinical reminders are associated with better CV risk reduction practices in primary care populations.[21-24] In the VA, non-CVD clinical reminders have similarly been effective at increasing screening (e.g., fall risk screening, HIV testing).[25,26] While VA has multiple clinical reminders built into the VA electronic medical record (CPRS), this proposal merges existing data into a CV template and adds unique information for a more comprehensive screening and documentation process to facilitate the provider-patient discussion about each patient's CV risks. Moreover, the information will be easily accessible in one CPRS location.

Our team's formative "pre-conditions" local work on CV risk reduction among women Veterans guides our proposed CV toolkit implementation research. In our FY2013 WHS-funded operations project, we 1) performed a targeted literature search on CV educational and risk assessment tools; 2) identified barriers and facilitators to CV risk assessment and risk reduction in women Veterans; and 3) identified key areas to target educational programs or tools to address needs in CV risk management. We conducted three focus groups with 21 Patient-Aligned Care Team (PACT) team members and semi-structured interviews with 19 patients at the two VA GLA primary care women's clinics. Provider-identified barriers ranged from system difficulties in promoting prevention activities to communication challenges, limited time to dialog with patients, and limited patient knowledge. Provider-identified facilitators included strategies for effective patient engagement and motivation, tools and educational resources to aid CV risk discussions (especially in relation to co-morbidities), organized resources on CV health and available referrals, stronger integration of health coaches, and technology-based resources. Patient-identified barriers included poor motivation and competing demands, while facilitators included education about CV risks and complications in women, motivational and accountability support from others (including providers), and exercise programs that fit their lives and competing demands. Patients reported that various tools would be acceptable if their providers suggested using them, including paper tools, electronic tools, and in-person sources of support. Findings from this formative work indicate that evidence-based strategies need to be combined, tailored, and implemented at the local system level to facilitate provider-patient discussions, patient activation, and accountability to promote CVD risk reduction for women Veterans.

3.0 Objectives

SPECIFIC AIMS

The goals of this project are to implement and evaluate a CV toolkit designed to increase identification of CV risk among Women Veterans and enhance provider communication about their risk as well as increase Women Veterans' engagement and retention in relevant health services including referrals to key health programs (e.g., MOVE!, dieticians, health coaches, and CV specialists as needed). The CV toolkit incorporates the *Gateway to Healthy Living* program, a national program currently being implemented by NCP that focuses on motivating and supporting VA patients with CV risks to engage in existing VA services in order to reduce their risk by setting health behavior goals.

This project aims to 1) Refine the elements of the CV toolkit, including patient education/activation tools, a CV risk assessment computerized template in CPRS, provider information/education and referral tools, and NCP's Gateway to Health Living program specifically for Women Veterans; 2) Implement the CV toolkit in four VA facilities; 3) Evaluate CV toolkit implementation using a nonrandomized stepped wedge design and conduct an implementation-focused evaluation to further refine the CV toolkit to facilitate future spread.

4.0 Personnel

STAFF			PROJECT ROLE		STUDY ACTIVITIES				
Staff	Degree	Site	Role (Level)	Description	Access to PHI	Obtain Informed Consent	Recruit-ment	Conduct Interviews	Perform Data Analysis
SITE									
Bevanne Bean-Mayberry	MD	GLA	Site PI, Lead	PI responsible for implementation of the actual CV Toolkit Project.	x	x	X	x	x
Melissa Farmer Coste	PhD	GLA	Co-PI	Co-PI responsible for the evaluation of the implementation.	x	x	X	x	x
Alison Hamilton	PhD	GLA	Co-Investigator	Overall EMPOWER QUERI Director and Qualitative Expert.	x	x	X	x	x
Jessica Zuchowski	PhD	GLA	Co-Investigator	Will lead qualitative interviews and analysis.	x	x	X	x	x
Erin Finley	PhD	San Antonio	Co-Investigator	She is the Implementation Coordinator for the overall EMPOWER QUERI and will be the local site investigator for San Antonio.	x	x	X	x	x

Martin Lee	**PhD**	**GLA**	**Biostatistician**	**He is our senior statistician. He will provide consultation on all quantitative data analysis.**	**x**				**X**
Karen Chu	**MS**	**GLA**	**Statistical Analyst**	**She's the statistical analysist working on this project. She'll be obtaining data from CDW and PBM.**	**x**				**X**
Alissa Simon	**MA**	**GLA**	**IRB Specialist**	**She will be the consultant on all IRB issues.**					
Catherine Schweizer	**PhD**	**GLA**	**Fellow**	**She is a Psychologist/WH Fellow and will be working on all aspects of this project including measure development, interviews and analysis.**	**x**	**x**	**X**	**x**	**X**
Catherine Chanfreau	**PhD**	**GLA**	**Fellow**	**She is a Post-Doctoral Fellow and will be working on all aspects of this project including measure development, interviews and analysis.**	**x**	**x**	**X**	**X**	**X**
Julian Brunner	**MPH**	**GLA**	**Statistical Analyst**	**He is the statistical analyst working on this project. He'll be obtaining data from CDW and PBM. He will also assist with interviews and analysis.**	**x**				**X**
Alexis Huynh	**PhD**	**GLA**	**Co-Investigator**	**She is a statistical analyst with qualitative experience and will be working on both the qualitative and quantitative analysis.**	**x**	**x**	**X**	**X**	**X**
Cynthia Gammage	**BA**	**GLA**	**Administrative Support**	**She will be assisting with administrative support.**	**X**				
Hemen Saifu	**MPH**	**GLA**	**Project Manager**	**She will be managing the overall CV Toolkit Project.**	**x**	**x**	**X**	**X**	**X**

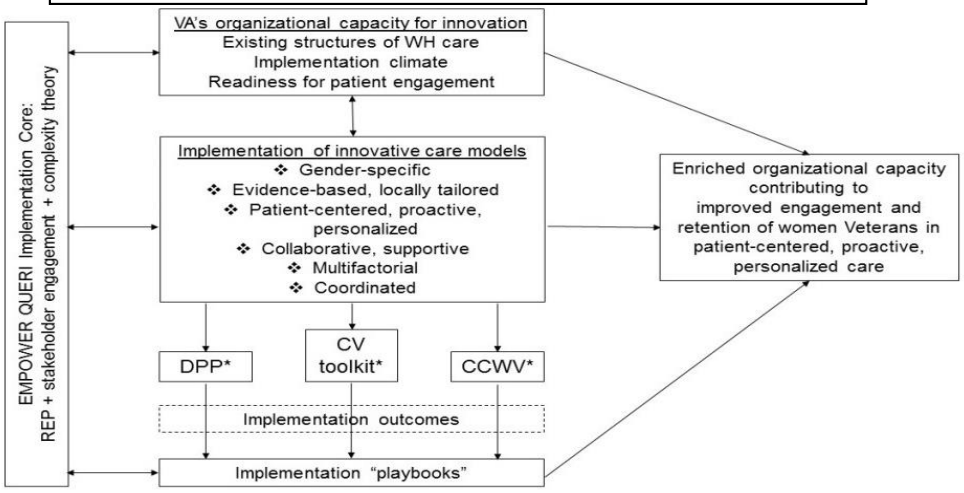
5.0 Study Procedures

The CV toolkit study is part of a large EMPOWER QUERI program focusing on innovation in care for women Veterans at the VA. Project stakeholders include patients as subjects as well as staff and leadership personnel as key informants. Products include development of an innovative approach for addressing implementation of care models that reduce CV risk for women Veterans.

5.1 Study Design

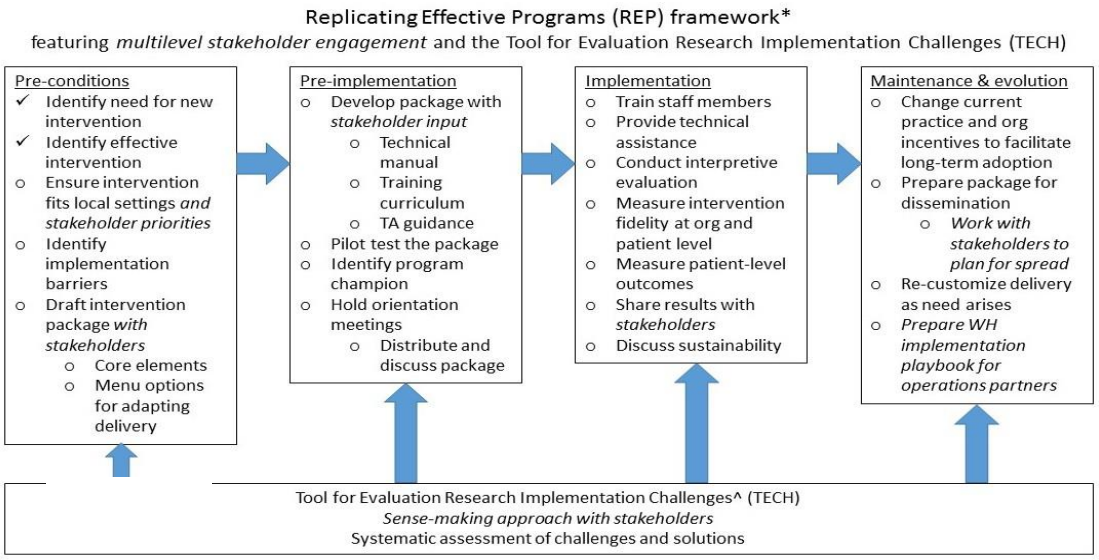
EMPOWER QUERI Conceptual Framework. EMPOWER QUERI focuses on strengthening WH organizational capacity for innovation in patient-centered care, using an Implementation Core and three projects as a collective platform for examining how particular characteristics of care models contribute to providers' ability to utilize the models and to patients' engagement and retention in the models. As depicted in our conceptual framework (Fig. 1), the Implementation Core forms the backbone of our program, and relies on an evidence-based implementation strategy, Replicating Effective Programs (REP) and emphasizes multilevel stakeholder engagement and complexity theory. The Core will examine organizational capacity for innovation in the context of local WH care arrangements, which we know to be quite diverse, as well as implementation constructs such as climate and leadership, and novel constructs. Knowledge of organizational capacity will inform implementation of innovative care models that address CV risk.[27] Together, these activities will contribute to our ultimate goal of enriching VHA's organizational capacity to engage and retain women Veterans in patient-centered, proactive, personalized evidence-based care.

EMPOWER QUERI Conceptual Framework Figure 1



*DPP=Diabetes Prevention Program; CV toolkit=Cardiovascular toolkit; CCWV=Collaborative Care for Women Veterans

Replicating Effective Programs (REP) framework Figure 2



EMPOWER QUERI Implementation Strategy: Replicating Effective Programs (REP). We will use REP[28] across all projects to maximize the implementation science knowledge that will be generated by a common approach. Grounded in theories of Diffusion of Innovation and Social Learning, REP was selected because of its strong evidence base and application in VHA health services research.[29] It also provides a phased *framework* for implementation, with different discrete implementation strategies being employed in different phases. REP's demonstrated effectiveness in promoting uptake of evidence-based practices allows us to focus on its application in varied settings and care models. Use across all projects will allow for further testing and expansion of the framework, particularly through our emphasis on multilevel stakeholder engagement and incorporation of complexity theory. The REP framework consists of four phases (Fig. 2): pre-conditions, pre-implementation, implementation, and maintenance/evolution. Careful attention is paid to intervention packaging during pre- conditions and pre- implementation; training, technical assistance, and fidelity assessment during implementation; and recustomizing during maintenance/evolution.

During each phase, local context is paramount, with varying deployment of the intervention depending on local priorities, needs, and resources. One of EMPOWER's implementation science goals will be to track the relative importance of each discrete strategy in each phase at each site and across sites, as well as in each project and across projects

Enhancing REP with Multilevel Stakeholder Engagement and Complexity Theory. REP was originally designed to guide dissemination of evidence-based practices in community-based organizations. Kilbourne and colleagues[29] note that "it was not designed to address multilevel barriers to implementation," so they enhanced REP with facilitation, using implementation experts as external facilitators to provide guidance for overcoming implementation barriers. Interestingly, outcomes were favorable for enhanced REP for their primary implementation outcome of uptake (i.e., completed contacts with Veterans with serious mental illness who had been lost to care), but not for increased utilization of services by patients who had dropped out of care.[30] This prompted us to consider alternate REP enhancements that are 1) more focused on participatory action[31] within complex adaptive systems[32] in VHA WH clinical settings,[33] and 2) potentially more effective in increasing patient engagement. Accordingly, we draw on complexity theory and multilevel stakeholder engagement. Complexity theory

postulates that outcomes in complex adaptive systems are nonlinear and unpredictable; it is a highly relational theory, examining how multiple agents involved in implementation interact in complex ways and "make sense" of implementation in different ways.[34] This emphasis on incorporating multiple perspectives and differing priorities is consistent with our VHA WH roadmap to delivering gender-sensitive comprehensive care for women Veterans,[35] which suggests that multilevel stakeholder engagement is key to improving women Veterans' health care.

We will operationalize complexity theory through use of the Tool for Evaluating Research Implementation Challenges (TECH),[36] which was designed to systematically assess impacts of implementation challenges and guide potential solutions. TECH, which has been used successfully in VHA and community studies, is codified into a series of interactive steps: identifying challenges (e.g., through observing day-to-day dynamics, listening to complaints, asking questions, etc.), interpreting the challenges in weekly meetings, generating and testing solution strategies, and, if necessary, addressing regulatory issues. Solution strategies are developed through open dialogue among the team members as well as others who might have perspectives on potential solutions. TECH will be our research team's internal way of tracking and documenting what's going on in the clinics. It's our way of understanding challenges and how to address it with people in clinic. We will ask the RAs at the sites to be involved in this process so they can give us a description of what's going on at their sites.

Multilevel Stakeholder Engagement in the EMPOWER QUERI. Our QUERI capitalizes on our seasoned team of implementation scientists, health services researchers, and clinicians, supported by a Strategic Advisory Group. Furthermore, we have the distinct advantage of being buttressed by the VHA HSR&D Women's Health Research Network (WHRN), which is comprised of the Women's Health Research Consortium and the Women's Health Practice-Based Research Network (PBRN), and a research aim on multilevel stakeholder engagement. Our entire team is associated with the WHRN (with EMPOWER QUERI PI Hamilton also being one of the WHRN PIs). In fact, this QUERI was developed with consistent input from the PBRN Site Leads (some of whom are on our team: Bean-Mayberry (PI), Mattocks, Sadler), and the projects will all be conducted at PBRN sites (Frayne LoS). Moreover, our QUERI proposal has been strengthened from its inception by invaluable input of women Veterans themselves. Specifically, a newly forming Women Veteran Patient Advisory Council has agreed to serve as an implementation partner for this QUERI Program (Gottke LoS); Dr. Hamilton will serve as an advisor to the Council and will use principles of patient engagement in research[37] to guide collaboration and involvement of the Council.

EMPOWER QUERI Methods

Setting: Women's Health Practice-Based Research Network (PBRN). The PBRN provides a research infrastructure for investigators seeking to increase inclusion of women in VHA research or conduct multi-site women's focused research in VHA. Comprised of 60 VAMCs that see one-third of women Veteran VHA users, the PBRN helps investigators overcome the challenges of multi-site studies through engagement of Site Leads with established working relationships with local clinicians and facility leadership. Site Leads have received implementation training, and have developed across-site relationships through regular national calls and technical support organized by the PBRN Coordinating Center in Palo Alto (Frayne LoS).

Site Selection, CV Toolkit, and REP Implementation Phases

The CV toolkit will be implemented at four VA facilities with moderately large panels of women Veterans. WH clinics are eligible if they have PC panels of women patients that total at least 2000+ women and they have at least 4-8 PCPs per site whose panels include at least 100 women Veterans and women comprise at least 10% of the provider's patient panel. Currently, two sites have been selected for implementation and two other sites will be added to our protocol at a future date. Our first site where we will launch the CV toolkit is GLA, where the PI (Bean-Mayberry) is the PBRN Site Lead. Our second site has now been recruited (West Haven) and their site application will be submitted to CIRB shortly. All site selection will be done in collaboration with Dr. Susan Frayne, Director of the VA WH-PBRN, and member of our Strategic Advisory Group (Frayne LoS).

The CV Toolkit includes four elements: (1) Patient education/activation tools, such as informational posters and fliers about women's CV risk, including information about MyHealth*e*Vet website resources. To activate patients to discuss CV risk with their providers, we developed a CV worksheet (Appendix 6) for patients to fill out at check-in to collect information about family history of CVD, pregnancy/gestational history, and smoking status, and to help patients formulate/document any questions regarding their CV risks that they would like to discuss during their visits. The goal is to help make CV risk discussion a priority for women before they enter the exam room. (2) A CV risk assessment computerized template systematically captures CVD risk factor history and data from the medical record, and provides open fields for the provider to enter any relevant information from the patient worksheet and the clinic visit (e.g., goals and decisions). The template also includes embedded links to locate CV guideline documents. Based on feedback from clinical teams at two GLA sites, the template includes data from the current visit as well as the last three entries in the medical record (automatically generated by the template) such as weight, blood pressure, and cholesterol lab results. This enables the provider to look at trends in risk factors without having to search the chart. The information is stored as a standard outpatient note in the patient's medical record (in CPRS) and is readily accessible (and searchable) at future visits so that CV risk status will be an ongoing discussion. Referral options are also included on the template, including referral to the *Gateway to Healthy Living* program, so the template will be a shared template available for other providers to access (e.g. health coach, dietician, specialist, etc.) to review when the patient comes for the referral.[40] (3) Provider information and education programs as well as referral tools to internal services (e.g., women's MOVE! program, smoking cessation clinics, dieticians, health coaches, pharmacists and CV or mental health specialists as needed). (4) The *Gateway to Healthy Living* program tailored to Women Veterans is a facilitated group meeting that occurs in a structured format with personalized goal setting and identification of key services available at the local site to assist with lifestyle changes necessary for patient-targeted CV risk reduction. In addition to the structured group, it includes at least two follow up phone calls from the facilitator (typically a health coach or health promotion disease prevention specialist) for support, reinforcement of lifestyle changes, brainstorming of barriers, and steps toward goal realization.

REP implementation phases: CV toolkit implementation will be guided by the REP framework consistent with all EMPOWER QUERI projects, and will feature multilevel stakeholder engagement to ensure that each phase is informed by women Veterans, providers, administrators, and operations partners. REP consists of four phases: 1) pre-conditions, 2)

pre-implementation, 3) implementation and 4) maintenance and evolution. The TECH will be used to guide assessment and documentation of implementation challenges during each REP phase.

Pre-conditions (Aim 1): In our prior work (funded by WHS), the need for the intervention was established and review of effective interventions completed. Building on work completed from partial restoration of our QUERI RRP funding for a smaller scale version of this project, we have completed the refinement, programming, functionality testing and loading of the CPRS-based template in the CV toolkit package. We are also culling VA and AHA information on CVD in women and testing online VA media for patient assessments in myHealtheVet. We have also been working with our partners at NCP and identified the *Gateway to Healthy Living* program for in-person, patient-directed goal setting. We will work closely with NCP to evaluate the results from the *Gateway to Healthy Living* pilot project (concluded FY15) to make program adjustments and further tailor the program for women Veterans. Specifically, some of these sessions will be offered as women only groups with women facilitators in addition to routine mixed gender group availability. Additionally, sex-specific handouts on cardiovascular risk factors in women will be available using approved information sheets from VA central office and the American Heart Association.

Furthermore, the pre-conditions phase has been completed locally at GLA, which will serve as an initial implementation site. For each additional PBRN site, we will revisit aspects of the pre-conditions phase to ensure that the toolkit, developed locally at GLA, is appropriate at the other sites. During site visits at the additional sites, the toolkit will be discussed with relevant key stakeholders (WH leaders, providers, women Veteran patient representatives), core elements will be explained, and, using the TECH the local team will discuss options for adapting delivery and anticipated barriers to implementation. For example, we will need to explore care options available at each site (e.g. health coaches, smoking cessation, MOVE!, etc.) and educational needs of the various WH teams at each site. Also during this phase, interviews and surveys will be conducted with all consenting key stakeholders with the exception of patients who will be interviewed and surveyed in the implementation phase (see below).

Pre-implementation (Aim 1 cont.): At each site, a local CV toolkit champion will be identified by the Site Lead when s/he signs onto the project. The toolkit package will be further developed and locally tailored, with attention to training and technical assistance needed for each site. Once prepared, the toolkit will be piloted locally to ensure that it works as intended with local systems and processes. Using the TECH, any challenges with pilot implementation will be discussed and addressed by the team. When the team determines that challenges have been sufficiently addressed, orientation meetings will be held with the broader clinic, where the toolkit will be distributed and discussed.

Implementation (Aim 2): The implementation phase will begin at the first PBRN site in the latter half of Year 2 and will last a total of 15 months to ensure adequate time for implementation evaluation and reach. The second site will begin the implementation phase at the start of year 3, and the toolkit will spread to two additional PBRN sites later in Year 3 through Year 4. For CV toolkit training, Dr. Bean-Mayberry (PI and primary care provider in the Sepulveda WH clinic) and Dr. Autumn Watson (Co-Investigator, VA Clinical Psychologist and GLA Health Behavior Coordinator, Supervisor of GLA Health Coach Program, with guidance from Dr. Ebrihimi,

cardiologist and consultant on project) will lead a series of provider education activities including facilitated discussions to educate the providers and office staff members on the importance of CV risk discussions for women within primary care as well as on how to use the toolkit in practice. At GLA, this training will be done in person, but the training programs will be tailored for virtual delivery (e.g. Lync meeting/cyberseminars) to the other sites. In addition, our partners at NCP will travel to sites to train the *Gateway to Healthy Living* facilitators or conduct virtual training with travel is not feasible. During implementation, we will assess any additional need for provider training and monitor the use of the template in the clinic by generating reports on template use. This information will be collected by the research staff, the data will be summarized (frequencies graphed over time), and then quarterly CV template reports will be presented to the WH clinical team. We will also take field notes during the trainings to document any issues that arise with the users (clinical team) and the CV toolkit within the context of each distinct clinic setting. These notes will be analyzed using ATLAS.ti, and will be examined in conjunction with other evaluation data as described below. During regular implementation meetings, TECH will be used to assess and address implementation challenges.

The CV toolkit is an innovative care model that is proactive, patient-centered and personalized to each woman that comes to an appointment. A patient begins using the CV toolkit at check-in for her appointment when she is given the CV worksheet to fill out while waiting to see her provider. Patient education materials specifically on women and CV risk will be in the waiting room and exam rooms. The CV worksheet will be used to initiate the provider-patient discussion of CV risk, and her provider or another staff member will use the information to fill out the CV template in CPRS during or after the appointment. Depending on the site needs and preferences, a research assistant and/or the Gateway facilitator may help populate the CV template with the screener information. The patient and provider will collaboratively determine the next steps (i.e. G*ateway to Healthy Living*, other referral, or waiting) and the provider will document the action plan in the template. All participants will be offered the *Gateway to Healthy Living* program by providers or other staff member as engagement and support for the patient action plan.

After the appointment, each woman will be asked if she is willing to participate in the project for monitoring CV risks and choices and if she consents, she will complete a patient survey and a possible interview with the RA (every 3rd consented patient will be asked to participate in both a survey and interview). At the sites where it is not feasible to consent a woman immediately after her appointment, the research staff will generate a patient list of all women seen in the clinic who had a CPRS template activated during her visit. Based on that list, a sample of the women will be mailed a consent and survey (and every 3rd consented patient will be asked to participate in the interview). Follow-up surveys and interviews will be administered to all women who completed the baseline survey six months after the baseline survey.

Those women who are referred to the *Gateway to Healthy Living* program will be contacted by the program facilitator immediately to arrange the group meeting. The women will be considered engaged in the *Gateway to Healthy Living* program when she attends the first group meeting. Information on goal setting, behavior change intentions and participation in other services will be collected by the facilitator at the group meeting and at the follow-up phone calls.

Maintenance and Evolution: The last phase in this framework allows us to take the feedback and make modifications to our implementation process to enhance adoption of the toolkit, fidelity to the implementation process, and dissemination at future sites. Sharing these details with stakeholders using TECH informs the current implementation process and sustainability for the future. The four REP phases allow us to account for each step of the guided implementation strategy. Finally, the interchange between these phases and the implementation process components provide a granular synergy for understanding whether the implementation of this CV toolkit requires further adaptation and customization prior to broader VA dissemination. During this phase, the research team will collaborate with the local implementation teams to develop points for future dissemination.

Study Design

We will use mixed methods to evaluate implementation. To assess our primary implementation outcomes, we will conduct pre-implementation, mid-implementation and post-implementation key stakeholder interviews (Component A) with providers and staff. For patients, we will conduct baseline and follow-up surveys as well as interviews with a subsample of those patients who completed surveys (interview approximately every 3rd consented patient with completed survey). We will use administrative data from the medical record (CPRS and CDW) to capture use of the CV toolkit (CPRS template) and referrals to preventive services. We will use a non-randomized stepped wedge design to evaluate the roll out of the intervention and the change in referrals over time across the sites.

Nonrandomized Stepped Wedge Study Design for Implementation Trials.

The CV Toolkit project will use a nonrandomized stepped wedge design, which rely on sequential roll-out to participating sites over time, while using other sites as controls until they begin implementation.[38] Consistent with our substantial prior experience using these designs in VHA and armed with complexity theory's recognition of nonlinearity of implementation,[39] we will use *nonrandomized* stepped wedges (rather than randomized) given their suitability for studying implementation. This design acknowledges that sites are heterogeneous, face multiple constraints, and, as a result, are ready to adopt interventions at different rates. The modified design explicitly considers the timing of implementation spread and addresses the statistical issues introduced by lack of randomization in implementation starts and processes. We will analytically compensate for the design by collecting patient-, provider-, and site-level data that may be associated with timing of the adoption of each intervention. We will include three levels in our hierarchical nonrandomized stepped wedge models: (1) patient, (2) time of intervention (i.e., when a provider starts using the intervention), and (3) site. Outcomes of interest (e.g. referrals to Gateway, other health promotion program and/or specialist) are measured for all patients at each site within the given intervention time period.

Nonrandomized stepped wedge designs make efficient use of all data available for within-site and between-site comparisons. For the within-site comparison, sites act as their own controls in an evaluation that compares sites pre- versus post-implementation. The comparison examines sites as they cross-over from control to intervention states. The between-site comparison evaluates the intervention period for a site vs. all other intervention and control periods for all sites. By having these two types of comparison, the design improves on the validity of the

evaluation of the intervention, by accounting for historical time trends that may occur outside of the intervention and for site contextual characteristics that may affect site performance.

Risk to Subjects

This study involves both Veteran (260 total across four sites) and VA Staff participants (60 total across four sites).

Veteran involvement and Characteristics

This 4-site research project aims to implement and evaluate the CV toolkit designed to increase identification of CV risk among women Veterans, enhance patient/provider communication about CV risk, and increase women Veterans engagement and retention in relevant health services including referrals to key health programs. We will recruit adult women Veterans who visit their women's health provider at one of the four study sites if a CPRS CV risk template was activated from their primary care visit or they attended the Gateway to Healthy Living program. As long as the woman Veteran patient is also able to give informed consent to complete our protocol, she is eligible to participate. We expect to approach up to 200 women Veterans per site over the study period in order to achieve a minimum of 65 women participants in the survey/interviews for CV toolkit at each site. Our goal is to have 260 women total (minimum 65 per site across 4 sites) engaged in the project over the course of the study. Participation includes a brief survey at baseline and six-month post-baseline, and for a subset of women, a brief qualitative interview (approximately every third consented woman with a completed survey will be approached for an interview for a minimum of 20 patient interviews at a site). Women will be consented at the time of the survey and interviews. The women will also be consented to link their responses to their medical records at the time of the survey.

We will also use medical record data (CPRS template data and CDW data) to evaluate the roll-out of the intervention and the referral rates at all sites. This data will be evaluated for all women patients seen by the providers in the study over the study period. The data will only be evaluated in the aggregate and will not be linked to the patient survey or interview data (unless medical record access consent is received at the time of the survey).

Provider / VA Staff Involvement and Characteristics

To obtain feedback from key participants and implementers of the CV toolkit, we intend to recruit approximately 15 staff per site. Staff members from each site will comprise of primary care providers, RN care managers, LVN provider or health technician, clinic clerk/MSA and other clinical staff members (e.g., dietitian, pharmacist, or mental health provider, etc.) and administrators (e.g., Women's Health Medical Director, Women Veteran Program Manager, Primary Care Chief). Given the diversity of VA staff, this sample will include women, men, and members of minority and ethnic groups. This scope of providers and administrative staff will provide broader perspective of the implementation process in the clinics.

Potential Risks

Risks are minimal and primarily related to loss of confidentiality.

For patients, study assessments will include potentially sensitive questions and information about mental and/or physical health symptoms. Thus, there is risk for embarrassment and negative effects on patient subjects if sensitive information was improperly disclosed and used in a discriminatory fashion against the individual. Additionally, individuals' social security numbers will be accessed in order to obtain data from VA databases and to collect information to contact them and link to medical records. If disclosed, this information could cause negative financial or legal consequences. Recruitment may also involve the risk of perceived coercion if the Veteran believes/assumes that refusal might threaten care or benefits.

For staff subjects, because this study asks questions about organizational issues at the clinic where they are employed, there is risk for embarrassment and negative effects on subjects if sensitive information was improperly disclosed and used in a discriminatory fashion against the individual. Risks could include psychological stress due to discussing uncomfortable topics or challenging situations at work involving patients or coworkers.

However, given the safeguards against improper disclosure and steps we are taking to ensure protection of sensitive information as detailed below, the likelihood of any disclosure is minimal.

Adequacy of Protection from Risk

Procedures to safeguard against adverse events. All data collection protocols will include procedures whereby research staff members report problems with the data collection, concerns about risk to subjects or others, or unusual occurrences during the collection. These allow project leaders an opportunity to quickly review and respond to any possible concerns or adverse effects.

Informed consent. Research subjects are advised of the voluntary nature of participation and research subjects are informed of their right to withdraw from the project at any time. Information obtained up to the time of participant withdrawal or termination may be used in the data analysis. Each participant receives a verbal and/or written description of the study. The Principal Investigator and delegated research team members are available at all points of the study to answer questions and to explain assessment procedures, uses to which the data will be put, and confidentiality of data. We will request a waiver for documentation of informed consent for interviews with staff members from each site.

Mandatory reporting safeguards. Procedures to prevent violation of confidentiality are limited by the mandatory nature of legal reporting requirements. Subjects are informed in the consent document that their responses to the surveys and interviews are confidential, except:

"1) If we need to protect you or others from harm. An example of this is if you want to hurt yourself or others. In that case, we will give information about you to others that is needed to protect you or others from harm.

2) If you tell us about the abuse of a child or of an elderly person, or if you tell us about being abused yourself. In that case, we must report this to a supervisor, who may report it to the authorities."

Staff training safeguards. As required, all research staff will be credentialed by their VA Healthcare System's research service, and will successfully complete all required trainings.

Research staff will meet with their local study supervisor (the Site Lead or the Project Director) on a weekly basis for supervision, ongoing monitoring of interactions with subjects, and problem solving. Research and clinical staff are trained to identify events that would fall under mandatory reporting guidelines, such as harm to self or others. The PI will be available at all times by cell phone. When the PI is not available, the PI will delegate this responsibility to another qualified, credentialed staff member.

Data safeguards. Before analysis of the data, all identifying information will be removed from the data. No information that could identify study subjects will be published or presented. Data will be reported only in the aggregate. Identifiable data will be stored separately from coded data sets. Access to identifiable study data will be restricted to research team on a need-to-know basis.

Discomfort with assessment, intervention procedures or disclosure safeguards. During the course of participation in the study, a subject could feel uncomfortable answering the survey or interview questions. All interviewers will be trained in the assessments and with sensitivity to the issues to be discussed. All subjects are informed that they may choose to skip any questions that they find uncomfortable or withdraw from the study at any time.

For patients who consent to be surveyed, the 30-minute surveys delivered in person by the RA will occur in a private room in the VA clinic setting at each site. Since some patients may not attend the group immediately or at all, patient baseline survey packets with an information sheet will be sent to the patient's mailing address in CPRS/VISTA. Patients who agree to the survey, by completing the survey, will have a VA addressed stamped envelope to return the survey document. For the subset of women selected for the patient interviews, the interviews will be conducted by telephone, but could be done in person (at the medical center) if the patient prefers in-person. Staff interviews will be conducted in person in a private room in the VA clinic setting or by telephone at each site.

Response procedures for adverse events are described in Section 6 Reporting (below).

Potential Benefits of the Research to Subjects and Others

Although individual subjects do not benefit directly, there are potential benefits to human subjects from participation. Participants may be able to impact the development or ongoing modifications of the CV risk toolkit and future dissemination for women at their own or other VA sites. They may also be able to provide feedback on care in the clinic where they receive services or are employed, which may affect their treatment or working environment in the future if this model is widely adopted.

5.2 Recruitment Methods

This study involves both Veteran patients (260 total across 4 sites) and VA Staff participants (60 total across 4 sites).

Patients: Patient subjects will be recruited once they have made contact with the provider in clinic and asked to participate after a clinic visit by the local RA. The RA will check in with the WH PACT members (i.e., providers and RN care manager) to know when the template was used in clinic and if the women Veterans have been referred to

Gateway. Using a visit-based sampling method, patients are eligible during their first visit with the provider during the 15-month implementation period. The patient will be asked if they would like to participate in the research project and if so, the women will be given a packet with the survey and information sheet. A return envelope will be included in the packet for the patient to return the completed survey (either by mail or hand it to the RA). For sites where in-person recruitment is not feasible, the research team will generate a list of all patients seen in the clinic and had a CPRS template activated. Those patients will be contacted by mail about the study. They will receive the same packet described above with the return envelope.

Staff. 15 VA Staff participants will be recruited from 4 sites (total of 60 participants). Staff subjects will be recruited from women's health clinics that are using a WH PACT model of care. To obtain the staff sample, we will work with each site's PBRN Site Lead to develop a list of eligible individuals (and their contact information), who meet the staff categories we would like to include. If needed, the PBRN site leads can work with the Women Veterans Program Manager or Women's Health Medical Director to confirm eligible individuals. The study PI and the Site Lead will present the study to local staff and administrators via email and or phone call. Staff members will be emailed an invitation to participate in an initial interview along with a survey, which will be collected at the time of the baseline interview. This email will also inform the participant that their participation includes three semi-structured interviews, either in person or over the phone, that will take 45 to 60 minutes each, the initial interview in the next few weeks, the second interview 10-12 months later and the final interview about a year later (the expected duration of their participation will be a total of 3 years). The recruitment process will include informing potential staff subjects about the study, who is conducting it, why the individual was selected for recruitment, and how the information gathered will be used. Potential staff subjects will be informed that their participation is entirely voluntary and their decision about participation will not affect their employment, merit, or promotion. After explaining the study, if the staff member is interested, the local research staff will schedule an appointment. We will also inform the participant that in 10-12 months, unless they ask us not to, we will contact them again regarding participating in a similar follow-up interview to document events across time.

5.3 Informed Consent Procedures

Patients. We are requesting a waiver of documented informed consent. For the survey, the informed consent process will include informing potential subjects about the study, who is conducting it, why the individual was selected for recruitment, that their participation in the research will be entered in their medical record, how the information gathered will be used, and about the patient subject payments. This will be included on the information sheet included with the survey. Completion and return of the survey will indicate consent. For surveys that are mailed to participants, we are requesting a waiver of HIPAA authorization. The HIPAA form is not intended for mailing to the respondent and then having the respondent mail it back. The subject does not have an opportunity to ask any questions or voice any concerns if it is done through the mail. Additionally, only when the HIPAA form is completed in person does the sensitive data of name, date of birth, and last four SSN required by the form stay within the VA environment once the form is handed over to the researcher. The risks of mailing this highly sensitive information outweigh the benefits to the respondents. For surveys that are given in person, we will have these participants complete a HIPAA authorization form, which will be securely locked in the RA's filing cabinet. Payments include $20 VA Canteen vouchers for each of two surveys and, for a subset of patients, an additional $10 VA Canteen voucher for the interviews at baseline and six-months post-baseline. Potential subjects will be informed that their participation in the research is entirely voluntary, and that if they choose not to participate, there will be no effect on the care they receive. Methods for how subjects' identity and collected data will be protected will be discussed. For the interviews, verbal consent will be obtained before each interview. For the use of the medical record data, we are requesting a waiver of HIPAA Authorization.

Staff. We are requesting a waiver for documentation of informed consent. Affirmative response to email invitation will constitute informed consent and verbal consent will be recorded at the time of interview. After a response has been received, enrolled staff members will be scheduled for an interview with a member of the research team.

5.4 Inclusion/Exclusion Criteria

Staff

Inclusion Criteria: VA staff affiliated with women's health care and located at PBRN sites. Given the diversity of VA staff, we expect this will include women, men, and members of minority and ethnic groups.

Exclusion criteria: Non-VA staff and not located at a PBRN site.

5.5 Study Evaluations

Qualitative Data Collection:

Non-Human Subjects Research Staff Interviews- To evaluate knowledge, attitudes, beliefs, and perceived acceptability and feasibility of the CV toolkit from key participants (VA staff, including WH primary care providers, nurses, clinical staff and health coaches); we intend to recruit approximately 15 staff per site who will be asked to complete a brief interview and survey. The brief survey, titled the MORE scale, version 1, measures the extent to which the organization our participants work in is willing and able to effective foster patient engagement in their healthcare facility. This survey will be emailed out to staff before their pre-implementation interviews and the data will be collected at the time of their pre-implementation interview. For interviews, participation will consist of three 45-60 minute qualitative interviews (pre-, mid-, and post-implementation) conducted in-person or over the phone by a research staff member. We will focus on knowledge, attitudes, beliefs, and perceived acceptability and feasibility of the toolkit for the pre-implementation interviews (approximately five months into the pre-conditions phase); perceptions of interim implementation processes and outcomes (approximately six months into the implementation phase) and summative perceptions of toolkit implementation and potential for spread (last two months of the maintenance/evolution phase). The mid-implementation assessment will evaluate the progress and implementation barriers and facilitators to CV toolkit implementation and be used to continue to tailor the implementation. Final interviews will re-evaluate baseline domains, and will follow-up on CV toolkit implementation and sustainability.

Ethnographic field notes will be taken by research team members *throughout project* to capture aspects of the context of implementation and otherwise unmeasured aspects of usual care. The two anthropologists on the QUERI Program (Hamilton and Zuchowski) will provide training on writing field notes. Also, minutes will be recorded for all project meetings (including trainings) and conference calls. In addition, substantive emails and other communications regarding implementation will be archived and analyzed.

Information from and about Veterans:

Sources of patient data for this project includes (1) Utilization data on CV services used six months prior to the start of the intervention and over the course of the study program obtained from enrollees' medical records, (2) information provided by patient participants via surveys and interviews, and (3) The implementation facilitator will track participant utilization of the program. Information on goal setting, behavior change intentions and participation in other services will be collected by the facilitator at the group meeting and during follow-up phone calls and entered on a coded tracking sheet. Follow-up surveys will be administered to all women who completed the baseline survey six months after the baseline survey.

After consent, all enrolled participants in each project will complete a 30-minute survey, delivered in-person by a research assistant (RA) at baseline and six-months post-baseline. For sites where it is not feasible to reach all the eligible women in person, the surveys and information sheets will be mailed to the patients address listed in VISTA/CPRS. Patients who do not return surveys within a 2- week window will be sent a reminder post card and then mailed a second informed consent and survey packet by 4 weeks if no survey is received. The surveys focus on patient activation, health-related quality of life, satisfaction with treatment, and project specific measures. In addition, a subset of approximately 45 women Veterans in each study (every third consenting patient) will also be asked to complete an additional 20-minute

qualitative interview with a research staff member at baseline and six-months post-baseline (either in-person or by telephone). The RA will record survey answers directly into a VA computer storing data on a server behind the VA firewall. Patient semi-structured interviews will be coded only with a study ID, digitally audio-recorded, and uploaded to a secure VA server behind the VA firewall. If recording consent is denied, the researchers will take hand written notes, which will be securely transported and stored as described below until they are transcribed into an electronic format. When desired by the patient or the interviewer, or to accommodate the cognitive needs of the subject, the survey or interview can be performed at two or more sessions. At the end of the implementation period we will obtain utilization history through the Data Access Request Tracker (DART) system, conducting chart review in the VA Informatics and Computing Infrastructure (VINCI) environment.

5.6 Data Analysis

Qualitative Analysis: All semi-structured interviews will either be conducted in-person in a private room or be conducted via telephone with the interviewer in a private, closed office (either alone or occupied by other members of the research study team). Interview participants will be instructed not to use their real names or to provide any identifying information during the interviews.

The interview will be recorded via digital recorder and speakerphone. Audio research data will be temporarily stored on a Phillips 9600 digital audio recorder as it is recorded. Data will subsequently be transferred via cable connection (which only works with a security enabled dongle) to a secure server. The Phillips 9600 is a VA approved device and is the most secure recorder on the market. Voice files can be encrypted and password-protected to prevent unauthorized access, making the 9600 the first HIPAA compliant recorder on the market. It allows the user to upload a digital file only once and only via cable with a dongle. Upon completion of uploading the file is erased from the digital recorder; therefore, only one copy of the recording remains, having been saved to a VA server.

The interview content will be transcribed in order to assure that interviewer notes have accurately and fully captured interview content. To do this, the audio-recordings and transcripts will be transmitted via SFTP, PKI, or hand-carry (as set out in the executed DUA with our transcription service contractor, Alpha Transcription) files and recordings may be transferred between the VA and the vendor via: (1) encrypted PKI email, (2) secure File Transfer Protocol (SFTP), or (3) files can be encrypted, copied onto a CD, and hand-carried by Vendor or study team staff, in a VA locked travel bag. The transcriptionist will delete any words that inadvertently identified the research participant, other research participants, or VA providers or leaders. Given that data will be collected by teams remote to Los Angeles, the most likely mechanism for file transfer will be SFTP.

The transcription company will generate an MS Word file transcription of the audio content. Data temporarily stored on Alpha Transcription secure server during the transcription process will be destroyed within 30 days after transcription files have been downloaded and verified by the study or vendor teams. The MS Word transcripts of the interviews will be stored on the VA GLA HSR&D Center of Innovation server, available only to authorized project staff.

Transcripts will be reviewed, edited for accuracy, and summarized by members of the research team. Consistent with our team's approach across multiple projects, matrix analysis methods[41]

will be used for rapid turn-around of the results[42] to share with our Strategic Advisory Group. In-depth analysis of the qualitative data will be conducted using ATLAS.ti, a qualitative data analysis software program that allows for fluid interaction of data across types and sources. Initially, a top-level codebook will be developed for the baseline interviews based on the semi-structured interview guide.[43] Using a constant comparison analytic approach, this codebook will be elaborated upon based on emergent themes, and it will be adjusted as each round of interviews is reviewed. Interviews will be compared within each clinic, across clinics, and over time. Additional sources of qualitative data (i.e. meeting minutes, field notes, and archival information) will also be included in the data set and will be coded separately and in relation to the interview data. These multiple approaches and groupings are easily facilitated within the software program, which has the capacity to group data in multiple ways and which allows the qualitative researchers maximum flexibility in negotiating a complex narrative dataset. Of note, the EMPOWER QUERI qualitative team has been working together for over five years; all described analytic procedures are well established and all members of the team have expertise with qualitative data analysis and dissemination of results.

In the pre-conditions transcripts, we will identify commonly shared knowledge, attitudes, and beliefs related to care model structures, processes, and effectiveness and the potential for effectiveness. In mid-implementation interview data, we will identify factors facilitating and impeding implementation of the care model, and strengths and weaknesses of the model as implemented. We will assess the extent to which components of the model are being implemented, and which components are efficient and easy to incorporate into routine care. We will explore whether particular components appear to be of limited value in improving care and examine clinic and provider characteristics associated with varying levels of care model implementation and effectiveness. In post-implementation interview data, we will take a summative approach to characterizing overall experiences of and perspectives on implementation, with a particular focus on recommendations for scale up and spread.[44]

For providers, we will compare and contrast data from frequent users of the template with infrequent users, and track changes in perceptions about the utility and impact of the toolkit on clinical practice from pre-conditions to maintenance. We will also assess provider attitudes toward ease of referral to the *Gateway to Healthy Living* program, and provider perceptions of changes in patient awareness and activation. For patients, we will compare and contrast data from those who used *Gateway to Healthy Living* with those who did not, and those who used other services. In order to evaluate the patient impact of *Gateway to Healthy Living*, we will assess changes in patient perceptions of CV risk, self-efficacy, and activation.

Quantitative Analysis: We will use descriptive and inferential statistics to understand variations in the measures described above. For patients, we will conduct bivariate analysis to examine variations in outcomes (CV risk factor control, cardiac event or procedure, etc.) by those who participated in the *Gateway to Healthy Living* program, versus those who received a referral to a different program/service, and those who received no referral. For providers, we will examine differences in their patient panel (e.g. those with CV risk factors under control at follow-up) by their engagement in the CV toolkit program. To evaluate the CV toolkit, we will use the nonrandomized stepped wedge design, a generalized mixed model coupled with an allowance for nonrandom effects, to evaluate the implementation across the providers at four sites. The intervention will be defined as “turning on” when a provider first engages in the CV toolkit (first

uses the CV template). We will model the effect of the implementation of the CV toolkit intervention on referral rates, while controlling for organizational level, provider level and patient level covariates.

Impact-focused evaluation: Secondary aims focus on factors that empower Women Veterans to engage in and benefit from care. We will use generalized linear mixed models (GLM) to evaluate a) cross-sectional relationships of patient activation, health-related quality of life, and care experiences at enrollment, with provider and site characteristics, adjusting for patient social and demographic characteristics; and b) prospective changes in patient activation, health-related quality of life, and care experiences from enrollment to 6-month follow-up, adjusting for patient, provider, and site characteristics. We will also construct multi-level mediation and moderation models to explore whether engagement-related factors such as patient activation, strength of treatment preferences, or the communication subscale of the CAHPS are associated with greater benefit from or satisfaction with care.

Power Analysis: Our goal with the power analysis was to ascertain the number of providers who would need to "turn on" the intervention (i.e., the number of PCPs who use the CV template, as well as the minimum number of patients that would need to be exposed to the care model. Consistent with our nonrandomized stepped wedge design, the power analysis presented here is for a 3-level hierarchical linear model where patients are clustered within PCPs within sites. In the final analysis structure, patients are the Level 1 units, the timing of PCP template use/referrals represents Level 2 units, and sites are the Level 3 units. The outcome of interest for CV Toolkit is the number of referrals to services (e.g. *Gateway to Healthy Living* and other services), The outcome is binary (referred/retained vs. not), and measured at the patient level (Level 1). Treatment effect is measured at Level 2, i.e., timing of when the PCPs turn on. Parameters required for calculating power are: alpha (α) = 0.05, sample size of patients clustered within referring PCPs (n) = at least 260 (based on prior work), the number of sites (K) = 4, the Plausible for Retention among those with low utilization (PI) = 5% to 85%, and Effect Size Variability (ESV) = medium or 0.05. Based on the resulting power curve, we need at least 8.78 (rounded to 9) referring PCPs per site to achieve power at 0.80. Our power analyses assume that the treatment effect is linear over time, i.e. patients that are retained longer have proportionally better outcomes. While selected details of the resulting dose response curve may vary, sensitivity analyses demonstrate a reasonable approximation enabling detection of treatment effects.

In addition to project key personnel, the overall EMPOWER QUERI Implementation Core will be involved in data analysis. The Implementation Core is directed by Dr. Hamilton (EMPOWER QUERI PI), an experienced and highly trained implementation scientist. She will be supported by a seasoned team of Co- Investigators, many of whom also have implementation research experience. Drs. Hamilton and Zuchowski will lead the qualitative analysis and Drs. Farmer (Co-PI), Lee and Huynh will lead the team with quantitative analyses including the nonrandomized stepped wedge. The implementation core personnel are supported by several internationally recognized implementation scientists on the Scientific Advisory Group, including Drs. Curran, Mittman, and Yano, who will help with their expertise in guiding the success of this project. The Scientific Advisory Group will not have access to identifiable data.

5.7 Withdrawal of Subjects

The PI may terminate a participant in the study at any time if the study participant does not meet enrollment criteria or does not comply with study requirements, e.g., keeping scheduled appointments with the interview team.

Participants may withdraw at any time with no consequences.

Information obtained up to the time of participant withdrawal or termination may be used in the data analysis.

6.0 Reporting

We do not expect our project to elicit distress among participants, as the subject matter is not of a sensitive nature. However, it is possible that some participants will experience distress at the recall of certain experiences. Interviewers will be trained to respond to indications of distress by redirecting the participant to another area of the interview guide. Should the participant continue to indicate distress, the interviewer will ask the participant if she/he needs to speak to a mental health professional; local contact information of such professionals will be available to all interviewers and will be utilized if necessary.

Under any adverse circumstance, interviewers will notify Dr. Farmer or Dr. Bean-Mayberry of any actions taken in response to the indication of distress (specifically, Dr. Farmer for VA employees and Dr. Bean-Mayberry for VA patients), and regarding any unanticipated serious adverse events. In addition, the IRB will be notified according to guidelines if there is an adverse event.

Response procedures for adverse events

Discomfort with disclosure. Staff who collect survey and interview data will be trained on how to respond to embarrassment or discomfort in an appropriate and compassionate manner. Subjects will be encouraged to contact the study PI Co-PI, or other research staff in the event of a potential adverse reaction that occurs as a consequence of their participation in the interview. They will receive specific written (in the form of a study description and PI/Co-PI's contact information) and verbal instructions during the study consent procedures about how to do so, if needed.

Mandatory reporting. One adversity a subject may encounter is the possibility that staff must report to authorities instances of physical abuse or neglect, or threat of physical harm among subjects to themselves or others. To anticipate these concerns, the study has established procedures and guidelines to respond to risk disclosures and crisis situations. Staff will be trained to recognize risks or crises that require immediate reporting response. We do not expect these events to be common in the CV toolkit study, but will inform all research staff on procedures to follow if any of these events arise. More commonly, we expect that discussion of some of the health issues (cardiovascular related) may possibly result in some emotional or psychological stress for a patient. If that does occur, the RA or interviewer will stop the research process, check on the patient, and inform the patient that she will call the PI or designated local clinical staff contact for assistance.

Each of the possible adverse events is described below, including background, criteria for emergency action, and non-emergency action.

1) Suicidal ideation or intention to harm self

Research staff will not be probing for this information and it is not part of any of the research tasks. However, if a subject spontaneously reports thoughts of self-harm, research staff will follow the procedures below:

a. Emergency: in the rare instance that an individual is in imminent danger and needs emergency medical or mental health services, research staff will adhere to their medical center's policies and procedures for managing and reporting such events including, if appropriate dialing 911 or the local police.

b. Non-emergency: If a subject spontaneously reports that they are thinking of killing themselves or taking their life, for example:

1. "I'm thinking about suicide/killing myself"

2. "I feel like I want to kill myself"

3. "I wish I were dead"

4. "I wish my life were over"

5. "I can't go on" or "I feel I can't go on"

The research staff person will say, "You seem to be having a difficult time. If you think this is an emergency, we can call 911. If you think you need help with this problem, you can talk to your VA clinician or go to the VA emergency room." The research staff person will call either the PI or their delegate within one hour of this incident. They will determine what further action is needed.

2) Intent to harm others

Research staff will not be probing for this information and it is not part of any of the research tasks. Sometimes threats may be voiced spontaneously. If this is a vague statement about intent to harm others and it is not an easily identifiable person, and does not communicate clear intent, capable means or immediate intent to do so, the research staff person will redirect the subject to the task at hand. However, if the subject makes a specific threat to a reasonably identifiable person, then the research staff person will remind the subject about the limits of confidentiality, and follow these procedures:

a. Emergency: In the rare instance that an individual is in imminent danger and needs emergency medical or mental health services, the research staff will adhere to their medical center's policies and procedures for managing and reporting such events including, if appropriate dialing 911 or the local police.

b. Non-emergency: If a subject reports intent to commit harm to others that is a non-emergency in nature but that still communicates a reasonably identifiable person, clear intent, capable means or an immediate intent to do so, the research staff person will contact the PI within one

hour and will complete an incident report the same day. In addition, the research staff person will talk to the subject to express concern and encourage him/her to tell someone. They will determine what further action is needed.

3) Child or dependent abuse/neglect

Research staff will not be probing for this information and it is not part of any of the research tasks. However, if a subject discusses that a child, dependent or elder is being sexually, physically, or verbally abused or there is evidence of neglect (e.g., young child left alone for hours), then we will follow these procedures:

a. Emergency: In the rare instance that a child or dependent is in imminent danger, the research staff will adhere to their medical center's policies and procedures for managing and reporting such events including, if appropriate dialing 911 or the local police.

b. Non-emergency: If there is a report or incident of child or elder abuse that is non-emergency in nature, the research staff person will consult with the PI or delegate by phone within one hour of the incident and will complete a written incident report the same day.

Consulting with the VA Research Service, and VA legal representatives as needed, we will review what is known about each situation and will assess the legal and ethical characteristics of each situation. If it is determined that the study has a legal or ethical obligation to report the incident, we will do so. Reporting procedures of the VA Research Service will be followed for each incident.

7.0 Privacy and Confidentiality

Assurance of Patient Safety

The local site research staff will be in regular communication with the research team at the main site and are responsible for monitoring patient safety at the participating sites. The Project Director will monitor research operations of the project and oversee patient safety. All research staff will be experienced in working with women Veteran patients and will be closely supervised by the study local site PI. Since a Data Safety Monitoring Board (DSMB) is required for multi-site studies, we plan to utilize the central HSR&D DSMB for further oversight. The DSMB provides an ongoing evaluation of the study's progress including patient accrual and retention, monitoring of adverse events, and the adequacy and efficiency of the analysis plan to discern outcomes that might require study modifications, or result in early cessation of the study due its benefits or harms. In terms of patient safety, the DSMB will evaluate all adverse and serious adverse events, by control and intervention site, including all hospitalizations and deaths.

Data Security

VA Research staff use VA computers to collect and analyze study data; either desktop or laptop computers with the VA image installed and managed by the local Information Resource Management department. All laptops are encrypted with VA-approved FIPS 140-2 certified encryption software to ensure that if laptops are ever lost or stolen, no data could be removed. Laptop computers are never removed from VA grounds without supervisory approval and a VA Property Pass approved by the VA research service. Thumb drives are never used as

long-term storage of data with identifiers. If a thumb drive is needed to transfer data from one computer to another, only a VA-approved thumb drive with the proper encryption software would be used after obtaining authorization from the local ISO.

VA staff practice regular and secure data backup procedures. Computer users "lock" their workstations when not actively in use, and office doors are closed and locked when staff members are not present. Hard copies of sensitive data are stored separately from identifiers in locked filing cabinet in a locked office. All research and QI project staff have access to a secure VA server managed by the HSR&D CSHIIP. This server is behind the VA firewall and provides individual storage space for each project, and for each member of the study teams. This server is backed up incrementally on a daily basis with full backup occurring monthly. Backups go to a tape library and the tapes are rotated on a quarterly basis and stored in the safe located in the ISO's office at the Sepulveda campus.

This server also provides a means to transfer data between local and non-local research staff. Project folders can be created where any approved individual on the VA intranet can gain access through their approved VA login to a project server folder. This allows secure data transfers over short and long distances with the smallest risk of accidental data disclosure. Only staff that are listed on delegated authorities for the project through the CIRB, are credentialed by Research, have completed all required data security training, and are approved by the CSHIIP will be given access to the research project folders on the research server. Staff may only access this folder by using their VA login on a VA computer behind the VA firewall. Access to these files is immediately revoked for staff members who leave the project.

All data will be stored on at VA sites behind a VA firewall, and will be shared only among the Principal Investigators, study staff, and transcriptions.

Data Collection Procedures

A series of identification (ID) numbers will be generated for all patient and staff subjects and participants. Data from all subjects will be collected in a private office at each site by a trained member of the project team. A 4 digit study ID code will be generated for each participant and project staff will maintain a link file that contains the following for each participant: : (a) for patients: ID number, subject name, last four of the social security number, gender and date of birth (b) for staff: ID code, gender, name, site, and wave number. This is how the 4 digit study ID codes will be generated for each staff participant: 1st digit=wave #, 2nd digit=site #, Last 2 digits= random # for unique respondent code. This link file will be stored on a secure VA server behind the VA firewall. Patient survey responses will be coded with the study ID and recorded directly into a survey program running on a VA computer and stored in a project-specific folder on the CSHIIP secure server. All information linking subject identifiers to their data will be destroyed in accordance with the VA Records Control Schedule and guidance from the Central IRB.

All staff subjects and a subset of patient subjects will complete a semi-structured interview with a research staff member. With the participants' permission, the interviews will be recorded on VA-approved devices and uploaded to the project-specific folders. Data on patient subjects extracted from VA data systems, will also be stored in project folders. Paper data collected in this project will be limited. Staff subjects will be emailed a survey prior to their baseline interview and this data will be collected at the time of the pre-implementation interview. This

data will be coded with a study ID. These surveys will be keypunched and verified, and securely stored in a locked cabinet in a locked office at the local HSR&D site.

The paper surveys will be stored in a locked file cabinet within a secured room at the local site. A limited number of authorized project staff will have access to these forms. The study master list has the subject ID number, SSN, full name and contact information. This master list is only accessible to the PI, Co-PI, and limited project staff. The master list is stored on a VA computer on a VA server behind the VA firewall.

The HIPAA forms collected from the participants who complete their surveys in person will be stored in a locked file cabinet within a secured room at the local site. A limited number of authorized project staff will have access to these forms.

-Paper surveys collected from participants will have only the subject's ID number and no identifying information. No data will be collected outside the VA. Paper data containing PHI is never left out on unattended desks.

Data Transportation Procedures

If paper data and audio recording devices need to be transported between sites they will be securely carried in VA locked bags. Once on site, they will be secured in a locked file cabinet in a secure room.

Data Transmission Procedures

The qualitative interviews will generate digital voice files, which are considered identifiable. To minimize risk, during recorded interviews subjects will only be identified using their project ID number, and subjects are instructed not to state any names or other identifying information in their interviews. These audio files will be uploaded from recorders to the secure server (See section 5.6 Data Analysis for more details) and then transmitted to Alpha Transcription or some other reputable transcription service using secure FTP where it will be temporarily securely stored according to conditions set out an approved Data Use Agreement. We have used Alpha Transcription in several previous studies, with great success. The transcription company will be informed not to transcribe any identifying information accidentally disclosed in interviews. Any identifying information found in voice files from the qualitative interviews is accidental and rare; no identifying information will be found in transcripts. The study team downloads the transcription files to the project-specific folders on the VA server behind the VA firewall. Once they have been downloaded and verified, the transcription company destroys the copies on their own server.

Access, Storage and Handling of Secondary Data

In addition to surveys and interviews, other outcome data will be extracted from national VA data systems, and patient medical record charts. There are two specific types of data pulls: (1) data abstraction containing information on the women in VA primary care teams by their designated women's health providers at each site (aggregate) and (2) data to link with respondents who consent to have their responses on the survey/ interview linked to their medical files. Data from VA electronic data systems will initially include patients' social security numbers (SSN) along with any other identifiers, since these are used to assure that the data

matches the project participants. We will merge the extracted data with our existing research data. Once the data have been checked to ensure the merge has been successful, within the shortest possible time period, the SSNs will be removed from the analytic data file and stored in a link file kept in a separate, high security folder on secure VA server. For the data pull involving patients who consented to surveys and/or interviews, each subject will already have been assigned a project ID number that does not contain any identifiers. The subject's ID number will replace the SSN in the files.

All information linking subject identifiers to their data will be destroyed in accordance with the VA Records Control Schedule and guidance from the CIRB.

VA records data will be obtained from CPRS, DSS or CDW. In order to obtain data, the project team will work with a list of SSNs of patients consented and enrolled in the study. Project or VA-certified database analysts will be given this list of SSNs and will then run a query to extract the needed data, either working in the VINCI platform or downloading the data to a temporary folder on the CSHIIP secure server. Extracted data will be placed into our secure folder on the local CSHIIP server and coded for analysis. This data will always remain behind the VA firewall. Research staff will be thoroughly trained on the online survey system before enrollment begins to ensure they can accurately gather information from charts. Each subject will already have been assigned a project ID number that does not contain any identifiers. The subject's ID number will replace the SSN in the files.

All the above data are stored and backed up on a secure VA server. Computer users "lock" their workstations when not actively in use and office doors are locked when staff members are not present. Hard copies of sensitive data are stored in a separate locked filing cabinet in a locked office.

Special consideration and precautions will be taken with regard to sharing information provided by individual employees with supervisors and co-workers. While general information derived from employee interviews related to relevant clinical practices, resources, quality improvement activities, and barriers/facilitators will be shared with other site participants in aggregate or synthesized form, detailed information that would allow identification of individual employee responses will not be shared with supervisors of the employees or their co-workers.

8.0 Communication Plan

This study will be led by Dr. Bean-Mayberry (PI), who will be responsible for the implementation of the CV Toolkit and Dr. Farmer (Co-PI), who will be responsible for the evaluation of this project's implementation. Key operation partners include, from WHS, Drs. Patricia Hayes (Co-Chair, Strategic Advisory Group [SAG]) and Sally Haskell (Co-PI on QUERI QI Project); and from NCP, Ms. Hurley and Drs. Dundon, Kinsinger, and Kim (LoS, SAG). Local support stems from GLA WH Medical Director, Dr. Batuman, and WVPM, Ms. Andreassen (LoS, SAG), as well as our ACOS Clinical Redesign and Transformation expert, Dr. Lisa Altman. Drs. Hayes, Haskell, Dundon, Kim, Batuman and Ms. Hurley and Andreassen will provide their expertise to help with success of this project and will not have access to identifiable data. Key input will be culled from our Biostatistician, Dr. Lee and Co-Investigators, Drs. Alison Hamilton (EMPOWER QUERI Director), Lisa Altman, Erin Finley, and Dr. Ramin

Ebrahimi (LoS, SAG member, Cardiologist), Director of the GLA Cardiac Cath Lab, who will help guide the educational training for providers and tailoring the CPRS template locally. Dr. Farmer (Project Co-PI), a nonrandomized stepped wedge expert, will supervise Drs. Jessica Zuchowski, Alexis Huynh and key team members for the implementation evaluation. Mrs. Saifu will serve as Project Director.

The project headquarters will be at the VISN 22 HSR&D CSHIIP offices in Los Angeles. The core team for the CV Toolkit (Drs. Bean-Mayberry, Farmer, Hamilton, Chanfreau, Schweizer, and Mrs. Saifu) will meet weekly to ensure progress and discuss updates for the project.

Dr. Bean-Mayberry will be responsible for informing local sites of protocol changes, reporting compliance issues related to CIRB and VA research service requirements, for reporting progress of research at least annually, and for reporting any injuries or other unanticipated problems involving participants or others.

Local Site leads are responsible for obtaining local approvals, complying with local policies, including notifying local facility directors of research engagement.

Each local site lead will ensure that the study is being conducted according to the IRB-approved protocol. Issues will be discussed with the Corresponding PI. Site leads will be responsible for tracking local events, complying with local reporting requirements, and reporting all events to the Coordinating PI.

On a weekly to biweekly basis, Dr. Bean-Mayberry will meet with Local Site leads. On a monthly basis, calls will be held with all leads to ensure cross-level synergies and consistency in qualitative approaches to data collection and analysis. Enrollment, data collection, and administrative issues will also be discussed. Issues may include IRB, protocol changes, informed consent, and HIPAA.

Any events that may impact the conduct of the study or the safety of participants will be reported by local staff to the Coordinating PI within 1 business day. This includes any SAEs, Unanticipated Problems, concerns about protocol deviations, and any interim results that may impact the conduct of the study.

Although we do not anticipate any SAEs/UAPs if any safety issues (SAEs or UAPs) arise, they will be reported to the Coordinating PI within 1 business day. The PI will follow CIRB reporting guidelines and collect relevant information. Data collection occurs at one point in time; therefore, it is unlikely we will become aware of any SAEs. If we become aware of any SAEs, we will collect the information by phone. Issues or interim results that may impact the conduct of the study will be reported by the Coordinating PI to Local Site PIs on weekly calls.

Sites will be informed when the study is over and they are no longer engaged in research. The coordinating PI will report to CIRB. Local Site PIs are responsible for reporting to local authorities.

We will convene strategic planning calls with the Executive Committee (composed of the PIs, the Program Manager, the Leads, and the Engagement Project Leads) to internally review progress and coordinate efforts at least quarterly.

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